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Effects of a Theta/Sensorimotor Rhythm Neurofeedback Training Protocol on Measures of Impulsivity, Drug Craving, and Substance Abuse in Forensic Psychiatric Patients With Substance Abuse: Randomized Controlled Trial

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Abstract

Background: Forensic psychiatric patients are often diagnosed with psychiatric disorders characterized by high levels of impulsivity as well as comorbid substance use disorders (SUD). The combination of psychiatric disorders and SUD increases the risk of future violence. Chronic substance abuse can lead to a structural state of disinhibition, resulting in more drug taking and eventually loss of control over drug intake. When treating SUD, it is crucial to address high levels of impulsivity and lack of inhibitory control.

Objective: This study set out to investigate the effects of a theta/sensorimotor rhythm (SMR) neurofeedback training protocol on levels of impulsivity, levels of drug craving, and actual drug intake in a population of forensic psychiatric patients with a diagnosis of SUD.

Methods: A total of 21 participants received 20 sessions of theta/SMR neurofeedback training in combination with treatment-as-usual (TAU). Results of the intervention were compared with results from 21 participants who received TAU only.

Results: SMR magnitude showed a significant ($P=.02$) increase post training for patients in the neurofeedback training group, whereas theta magnitude did not change ($P=.71$). Levels of drug craving as well as scores on the motor subscale of the Barratt Impulsivity Scale-11 decreased equally for patients in the neurofeedback training group and the TAU group. Other measures of impulsivity as well as drug intake did not change posttreatment ($P>.05$). Therefore, neurofeedback+TAU was not more effective than TAU only.

Conclusions: This study demonstrated evidence that forensic psychiatric patients are able to increase SMR magnitude over the course of neurofeedback training. However, at the group level, the increase in SMR activity was not related to any of the included impulsivity or drug craving measures. Further research should focus on which patients will be able to benefit from neurofeedback training at an early stage of the employed training sessions.


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KEYWORDS
neurofeedback; impulsivity; substance use disorder; offenders; drug craving
Introduction

Background
Forensic psychiatric patients are often times diagnosed with disorders characterized by high levels of impulsivity. Schizophrenia, attention-deficit hyperactivity disorder (ADHD), and cluster B personality disorders are the most common disorders in forensic psychiatric patients [1,2]. Substance use disorder (SUD) is a common comorbidity, occurring in about 55% to 70% of all patients [2,3]. Individuals abusing alcohol, stimulants, and opioids tend to have higher levels of impulsivity as compared with nonabusing controls [4]. Furthermore, impulsivity is a risk factor for the development and maintenance of SUD [5,6]. Chronic substance abuse can cause a structural state of disinhibition over time, leading to permanent excessive abuse of substances [7-9]. This state is not limited to the acute stages of substance dependency but is also present in patients after stopping regular drug intake [10]. Elevated levels of impulsivity are also associated with more severe symptoms of SUD, which eventually lead to higher levels of drug craving [11]. Once patients receive substance abuse treatment, high levels of impulsivity can increase chances of early relapse and premature termination of treatment [6,10]. For forensic psychiatric patients, substance use is highly associated with the use of violence, regardless of the type of drug used [12-14].

Important in the treatment of forensic patients with SUD is to determine levels of impulsivity and lack of inhibitory control. In accordance with this, common psychotherapeutic approaches for SUD involve the adaptation of strategies that promote conscious decision making, attention to action, and control over behavior [9]. Despite that, relapse rates following remission of treated SUD individuals are as high as 60% [15], stressing the need for additional interventions.

Neurofeedback Treatment for Impulsivity and Substance Use Disorder
In the last two decades, electroencephalographic (EEG) neurofeedback training has shown promising results in reducing high levels of impulsivity in patients suffering from ADHD [16-18]. Neurofeedback training uses real-time EEG measurements and displays this information back to the patient [19]. EEG neurofeedback training works by enhancing or inhibiting brain frequencies that have shown to underlie abnormal psychological states [20]. A frequently used neurofeedback protocol to train impulse control is the so-called theta (3.5-7.5 Hz)/sensorimotor rhythm (SMR, 12-15 Hz) protocol [17,21,22]. In this protocol, the magnitude of the SMR frequency is enhanced, whereas the magnitude of the theta frequency is inhibited.

However, the effectiveness of a theta/SMR neurofeedback protocol on levels of impulsivity and also on symptoms of SUD such as levels of craving and actual drug use in forensic psychiatric patients is unclear. Only a few studies have investigated the effects of neurofeedback training in forensic psychiatric patients [23-26]. Therefore, investigating effectiveness of neurofeedback training can add value to treatment models that are currently used for this group, such as classical psychotherapy and pharmacological treatment.

Objectives
The primary objective of this study was to examine to what extent a theta/SMR neurofeedback training results in the reduction of impulsivity, drug craving, and actual drug use in a population of forensic psychiatric patients with a diagnosis of SUD. Patients were allocated to either a neurofeedback-training group where they received 20 sessions of a theta/SMR neurofeedback training protocol in addition to treatment-as-usual (TAU), or a TAU-only group. For both groups, levels of impulsivity, as measured with the Barratt Impulsivity Scale-11 (BIS-11) [27], and a cued Go/No-Go reaction time task [28] were assessed. Levels of drug craving were measured with a modified version of the Desire for Alcohol Questionnaire (DAQ-SF) [29]. Actual drug intake was assessed with urine or breathalyzer drug testing. Results on primary outcome measures were compared between groups We hypothesized that patients receiving neurofeedback training+TAU would show reduced levels of impulsivity post training as well as reduced levels of drug craving and drug use in comparison with patients receiving TAU only.

Methods

Study Design and Participants
This study reports the results from a randomized controlled trial (RCT) as described in the study by Fielenbach et al [30]. The results of the n-of-1 clinical case series will be reported elsewhere.

The study took place in a maximum security inpatient forensic psychiatric center (FPC) in Groningen, the Netherlands. All patients in this treatment facility are male criminal offenders who were held only partially responsible for the crime they committed due to severe mental illness, according to Dutch jurisdiction [31]. Inclusion criteria were the presence of at least one diagnosis of SUD according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Review (DSM-IV-TR [32]), positive drug testing in the past 24 months before inclusion, and sufficient knowledge of the Dutch language to understand training instructions. All patients had at least one comorbid axis I and/or II diagnosis. Exclusion criteria were a state of acute psychosis, in which patients experienced severe delusions and/or hallucinations and could possibly become a threat to themselves or others (a diagnosis of schizophrenia as well as disorders in the schizophrenia spectrum [eg, schizoaffective disorder] were not considered exclusion criteria). A comorbid diagnosis of epilepsy and visual and/or auditory impairments, which would hamper patients’ ability to follow instructions and adhere to the neurofeedback training, were also exclusion criteria. Medication intake was not restricted. Patients were allowed to continue the use of medication over the course of the study. Treatment supervisors were informed that, during the course of the study, prescribed medication should preferably remain stable and that a change in type as well as dosage of medication should not be made during the course of the study unless absolutely necessary.
Treatment supervisors were asked to inform researchers in case a change in type or dosage of medication did occur.

This study was conducted according to the principles of the Declaration of Helsinki (version 59, Seoul, October 2008) and in accordance with the Medical Research Involving Human Subjects Act. It is ethically approved by the medical ethical council of Brabant, the Netherlands (study number NL46390.008.13).

**Procedure**

In this study, a pre-post test design was used. A power analysis calculation for the RCT, using G*Power 3 based on a 1-tailed alpha value of .05, a power value of 0.80, and an effect size ($f$) of 0.80, yielded a recommended sample size of 21 participants each in the control and intervention conditions.

Out of all participants that met the requirements, a random sample was drawn and randomly assigned to 1 of the 2 study conditions (neurofeedback training+TAU or TAU only). Patients were approached through treatment supervisors for participation and informed about the general outline of the study. If they expressed interest in participating in the study, they were approached by 1 of the researchers to explain the study design and randomization procedure. All patients signed the informed consent. Randomization was done by a random number generator (see Figure 1 for an overview of patient flow through the study).

Participants in both conditions underwent pretreatment measurements (T0), consisting of the measurements described below. Participants in the control group received TAU only. TAU was different for every patient, as treatment modalities are based on individual diagnosis and problematic behavior of the patient as well as the cognitive ability to undergo different treatment modalities. Examples of treatment modalities were nonverbal therapy forms (eg, psychomotor therapy and musical therapy) and cognitive-behavioral group therapy. After 10 weeks, participants in the control group underwent posttreatment measurements (T1), identical to pretreatment measurements.

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**Figure 1.** Consolidated Standards of Reporting Trials (CONSORT) flow diagram for individual randomized controlled trials of nonpharmacologic treatments. Patients who had hair that was unsuitable for conducting electroencephalographic measurements or placement of neurofeedback electrodes, such as dreadlocks, were excluded. For analysis of drug testing, data from 19 patients were used. SUD: substance use disorders; TAU: treatment-as-usual.
Once pretreatment measures were completed, participants in the intervention group started the neurofeedback training. They received 20 neurofeedback training sessions, scheduled 2 times a week for 10 weeks. Neurofeedback training was conducted by a certified neurofeedback therapist. The study was not blinded, as it was clear to patients as well as the neurofeedback therapist which patients received the neurofeedback training.

Participants received a small financial compensation comparable with minimum wage in the treatment facility for participation.

Neurofeedback Training Protocol
For neurofeedback training, electrode Cz was used as the feedback electrode recorded with Ag/AgCl electrodes against a right ear mastoid reference and a FPz ground electrode. Neurofeedback was applied as implemented in the Brainmarker software engine (BrainMarker Device, Brainmarker BV Gulpen). A theta/SMR protocol was used, in which SMR (12-15 Hz) should be enhanced and theta (3.5-7.5 Hz) should be inhibited. If excess high beta (20-32 Hz) or delta (0.5-3.5 Hz) was detected, these frequency bands were inhibited as well, with a maximum of 3 frequency bands being trained in each session. Patients were shown simple video games and instructed to find the most successful strategy to make the main character of the video game move. A movie-based neurofeedback paradigm was given as well, where patients had to stop black curtains from appearing over the computer monitor. The software provided visual positive feedback for increasing SMR magnitude and decreasing theta magnitude. Each round (or trial) of video games lasted 60 seconds, with short breaks in between rounds (trials). Movie-based feedback lasted 90 seconds at a time. The switch between video- and movie-based feedback was done to make neurofeedback more fun and less tiring, as choice of video games provided within the software was limited, as well as very simplistic. For each patient, about 10 rounds of video game-based feedback were employed. As for movie-based feedback, about 10 to 15 rounds were employed. Neurofeedback training lasted for approximately 45 min, including preparation and cleanup.

Feedback thresholds were adjusted manually whenever participants were able to increase or decrease the desired frequency bands for 80% of the time. Participants were verbally encouraged to try to move the main character in the video game as much as possible as well as to keep the monitor free from the curtains during video-based feedback and not just stare at the screen (see Figure 2 for an impression of one of the neurofeedback games). After all training sessions were completed, participants underwent posttreatment measurements (T1).

Measures

Electroencephalography
A 5 min 21-channel EEG resting-state measurement with eyes closed was conducted with Nexus-32 hardware and Biotrace software (MindMedia BV). EEG measurements were collected from 19 standard 10/20 positions [33] and the right and left mastoids with a sampling rate of 512 samples per second. The right mastoid served as the online reference. Flat type electrodes were placed above and below the left eye and at the outer canthi of each eye to correct for vertical and horizontal eye movements. EEG magnitude across delta (0.5-3.5 Hz), theta (3.5-7.5 Hz), alpha (7.5-12 Hz), beta (12-20 Hz), SMR (12-15 Hz), high beta (20-32 Hz), and gamma (32-49 Hz) frequency bands was assessed. Magnitude changes in delta, theta, SMR, and high beta frequency were used for analysis. For analysis, custom-made Matlab scripts (version R2012b) were used. First, data from the resting-state measurements were imported into EEGLAB, bandpass filtered between 1-40 Hz, and inspected for gross movement artifacts that were then manually removed. Subsequently, epochs of 4 seconds length were created. Epochs containing amplitudes exceeding ±100 μV at any scalp electrode and/or epochs containing abnormally distributed data (ie, joint probability or kurtosis >5 SD from expected mean values) were rejected. From the remaining epochs, the first 40 were transformed into FieldTrip format (version 20160620). Power values for electrode Cz were computed using a fast Fourier analysis with a Hanning taper as implemented in FieldTrip.

Figure 2. Impression of one of the games used for neurofeedback training using one frequency band. Participants had to try to exceed the bar above the threshold, after which an encouraging smiley popped up on the screen, giving immediate positive reinforcement.
Mean power values for delta, theta, SMR, and high beta frequency bands were calculated and transferred to SPSS for statistical analysis.

**Barratt Impulsivity Scale-11**

The Dutch version of the BIS-11 [27] is a 30-item self-report questionnaire that assesses common impulsive behaviors and preferences across 3 second-order factors: motor, attentional, and nonplanning. An example of a BIS-11 item is “I do things without thinking;” and items are scored across a 4-point Likert scale ranging from “rarely/never” to “almost always/always.” The BIS-11 is an internally consistent measure of impulsivity among inpatient populations (Cronbach alpha=. 80) [34].

**Cued Go/No-Go Task**

The cued Go/No-Go task is a continuous performance test designed to measure response inhibition [28]. The task was programmed in E-Prime (version 2.0.10.353). Participants are instructed to respond as quickly as possible to a green square appearing on a screen (“Go target”) or to inhibit responses to a blue square (“No-Go target”). The test consists of 250 targets with equal numbers of Go and No-Go targets. Each target is preceded by either a Go or a No-Go cue, indicating the likelihood of a Go or No-Go target to appear. The likelihood of a correct target after a cue is manipulated with a 80/20 ratio, with 80% being a correct cue and 20% being an incorrect cue. Cues are presented with 4 fixed stimulus onset asynchronies (100, 200, 300, and 400 milliseconds). The program displays feedback about the accuracy of the response back to the participant as well as the time (in milliseconds) it took for the patient to respond to the target. Outcome measure is the number of commission errors, reflecting the failure to inhibit a prepotent response to a No-Go square. Number of commission errors in a cued Go/No-Go task is a valid measure of impulse control in a substance abusing population [28].

**Modified Version of the Desire for Alcohol Questionnaire Short Form**

The short form of the DAQ-SF is a self-report questionnaire that measures levels of craving for alcohol among 14 items scored on a 7-point Likert scale (ranging from 1=strongly disagree to 7=strongly agree). The DAQ-SF has been shown to be a reliable measure to assess craving in a substance-dependent population (Cronbach alpha=.70) [35]. For the purpose of this study, items from the Dutch version of the questionnaire [29] were modified to measure desire for drugs in general, as opposed to being restricted to measure desire for alcohol only. An example of a modified item is “All my tension would completely disappear if I drank now” into “All my tension would completely disappear if I used drugs now.” The modification was made due to the fact that alcohol use is very rare in an inpatient setting, whereas use of other drugs (eg, cannabis or cocaine) is more common.

**Drug Use**

Scores on urine or breathalyzer drug testing were collected for each participant. Drug testing was performed regularly for each patient as part of treatment facility policy. Drug use was operationalized as any positive scoring for use of illegal substances. Illegal substances included all known drugs as well as alcohol and nonprescribed medication used as recreational drug consumption (eg, inhaled methylphenidate). According to treatment facility policy, refusal to undergo drug testing was scored as positive drug testing. To score substance abuse, the item “substance abuse” on the risk assessment scale Historische, Klinische, Toekomst-Revised (Historical, Clinical, Future-Revised) was used [36,37]. This item was scored on a 5-point scale, indicating number of positive drug testing as well as willingness to undergo drug testing. Scores ranged from 0 (no drug use whatsoever) to 4 (the patient tested positive at least twice and also refused to undergo drug testing).

**Data and Statistical Analysis**

All participants who completed pre- and posttreatment measures were included in the statistical analysis (n=42). For analysis of drug testing, weekly reports of 2 of the patients from the control group were not available; therefore, the analysis of drug testing consists of data from 40 patients. All data were analyzed with SPSS version 25 (IBM Corp).

Due to violations of statistical assumptions concerning normality and homoscedasticity of almost all dependent variables (BIS motor, BIS attentional, BIS total score, DAQ-SF, delta magnitude, theta magnitude, SMR magnitude, and Cued Go/No-Go commission errors), nonparametric tests were employed. To test for differences between treatment conditions pretreatment, Mann-Whitney U tests were performed for pretreatment scores on BIS-11 total score, BIS-11 subscales “motor,” “nonplanning,” and “attentional” as well as scores on DAQ-SF, number of commission errors, drug testing, and mean theta and SMR magnitude. A Wilcoxon signed-rank test was performed to assess changes within groups between pre- and posttreatment for all dependent variables.

A repeated-measures analysis of variance with time as within-subject variable and treatment condition as a between-subject variable was performed. To assess significance, a within-groups effect size was used (eta squared [η²]). Cutoff scores were used according to Cohen’s rules to assess whether effect size were small (η²=0.02), medium (η²=0.13), or large (η²=0.26) [38]. Pearson correlations were performed to test for relations between changes in delta, SMR, high beta, and theta frequency magnitude pretreatment versus posttreatment and all behavioral measures. Only results significant at the .05 level will be reported.

**Results**

**Patient Flow**

Of those assessed (N=258), 52.71% of patients (136/258) were excluded due to not fitting the inclusion criteria. Moreover, 47.3 % (122/258) of patients were eligible for participation. Those eligible were randomly assigned to either the neurofeedback training+TAU group (n=42) or TAU only group (n=41). Figure 1 summarizes the flow of participants throughout the study. In total, 42 patients completed all posttreatment measurements, of which 21 patients participated in the TAU only group and 21 patients in the neurofeedback training+TAU group. None of...
the patients in the neurofeedback training+TAU group were able to complete training within the scheduled 10 weeks. This was due to holidays and planning issues and also because some patients were mentally unable to complete a training session or caused aggressive incidents, which resulted in temporary separation/placement on a specialized crisis unit. It sometimes also happened that patients were unmotivated to attend a training session. Participation in the study, therefore, lasted for an average of 14.1 (SD 5.32) weeks per patient.

When pretreatment measurements were assessed, mean number of months in treatment was 93.6 months (SD 67.18). The large SD was caused by 5 patients who had already been hospitalized for more than 200 months in the treatment facility. Participants did not differ with regard to mean age between the neurofeedback training+TAU group (mean 38.00, SD 9.18) and TAU only group (mean 38.57, SD 8.41; \( t_{40} = -0.22, P = .63 \)) or mean number of axis I and II DSM-IV-TR diagnoses (neurofeedback training group mean 4.52, SD 1.47; TAU only group mean 4.57, SD 1.63, \( t_{40} = -0.09, P = .38 \)) or month in treatment before inclusion (neurofeedback training group mean 91.90, SD 61.70; TAU only group mean 95.30, SD 73.76, \( t_{40} = -0.16, P = .87 \); see Tables 1-3 for sample characteristics).

**Baseline Differences Between Groups**

A Mann-Whitney \( U \) test indicated that scores on SMR magnitude on pretreatment measurements were significantly higher for patients in the neurofeedback training group (median=1) than for patients in the TAU group (median=.58), \( U=131.00, P = .02, r = .35 \).

**Differences Within Groups**

Only the neurofeedback training group showed significant effects between pre- and posttreatment scores. Within-groups differences on the BIS-11 subscale motor (pretreatment: median=23) showed a significant decrease posttreatment for patients in the neurofeedback training group (median=21, \( Z=2.076, P = .04, r = .45 \)), as well as a significant decrease in craving scores posttreatment (median=34) as measured with the DAQ-SF (\( Z=2.091, P = .04, r = .46 \)). SMR mean amplitude also significantly increased from pretreatment (median=1) to posttreatment (median=2.22; \( Z=2.068, P = .04, r = .45 \)).

**Outcome Measures**

The main outcome measures are presented in Table 4. On the primary outcome measures, results on the motor subscale of the BIS-11 showed a significant effect for Time (\( F_{1,40} = 5.61, P = .02 \)) but not for Time x Group (\( F_{1,40} = 1.28, P = .28 \)). For the drug craving measure DAQ-SF, there was a significant effect for Time (\( F_{1,40} = 6.23, P = .02 \)) but not for Time x Group (\( F_{1,40} = 9.2, P = .34 \)). There was a significant Time x Group effect for mean SMR magnitude (\( F_{1,40} = 5.47, P = .02 \)), indicating an increase for mean SMR magnitude in the neurofeedback training group posttreatment. Results for drug use, mean theta magnitude, and number of commission errors posttreatment were not significant.

Pearson correlations revealed no significant correlations (\( P > .05 \)) between the difference in SMR or theta magnitude by the end of the training and behavioral outcome measures.

### Table 1. Baseline sample characteristics (N=42).

<table>
<thead>
<tr>
<th>Sample characteristics</th>
<th>Neurofeedback training group</th>
<th>Treatment-as-usual only group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (range)</td>
<td>38.00 (21-55)</td>
<td>38.57 (26-55)</td>
</tr>
<tr>
<td>Months in treatment at T0, mean (range)</td>
<td>91.90 (19-248)</td>
<td>95.30 (10-290)</td>
</tr>
<tr>
<td>Axis I and II diagnoses, mean (range)</td>
<td>4.5 (2-8)</td>
<td>4.6 (1-7)</td>
</tr>
<tr>
<td>Psychopathy score (PCL-R(^a)), mean (range)</td>
<td>23.86 (15-32)</td>
<td>23.77 (15-36)</td>
</tr>
</tbody>
</table>

\(^a\)PCL-R: Psychopathy Checklist–Revised.

### Table 2. Type of substance use diagnosis for the neurofeedback training group and the treatment-as-usual only group (N=42).

<table>
<thead>
<tr>
<th>Type of substance use diagnosis</th>
<th>Neurofeedback training group, n (%)</th>
<th>Treatment-as-usual only group, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>9 (42.86)</td>
<td>13 (61.90)</td>
</tr>
<tr>
<td>Cannabis</td>
<td>12 (61.90)</td>
<td>19 (90.48)</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>4 (19.05)</td>
<td>8 (38.10)</td>
</tr>
<tr>
<td>Opioids</td>
<td>1 (4.76)</td>
<td>4 (19.05)</td>
</tr>
<tr>
<td>Cocaine</td>
<td>5 (23.81)</td>
<td>9 (42.86)</td>
</tr>
<tr>
<td>Sedative</td>
<td>2 (9.52)</td>
<td>1 (4.76)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (14.29)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
### Table 3. Comorbid axis I and II diagnosis and index offense for the neurofeedback training group and the treatment-as-usual (TAU) only group (N=42).

<table>
<thead>
<tr>
<th>Comorbid axis I and II diagnosis and index offense</th>
<th>Neurofeedback training group, n (%)</th>
<th>Treatment-as-usual group, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pervasive developmental disorder&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2 (9.52)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>ADHD&lt;sup&gt;b&lt;/sup&gt;</td>
<td>6 (28.57)</td>
<td>3 (14.29)</td>
</tr>
<tr>
<td>Disorders in the schizophrenia spectrum</td>
<td>12 (57.14)</td>
<td>10 (47.62)</td>
</tr>
<tr>
<td>Mood and anxiety disorder</td>
<td>2 (9.52)</td>
<td>2 (9.52)</td>
</tr>
<tr>
<td>Pedophilia</td>
<td>1 (4.76)</td>
<td>1 (4.76)</td>
</tr>
<tr>
<td>PTSD&lt;sup&gt;c&lt;/sup&gt;</td>
<td>2 (9.52)</td>
<td>3 (14.29)</td>
</tr>
</tbody>
</table>

### Comorbid axis II disorder

<table>
<thead>
<tr>
<th>Comorbid axis II disorder</th>
<th>Neurofeedback training group, n (%)</th>
<th>Treatment-as-usual group, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antisocial personality disorder</td>
<td>8 (38.10)</td>
<td>7 (33.33)</td>
</tr>
<tr>
<td>Borderline personality disorder</td>
<td>2 (9.52)</td>
<td>4 (19.05)</td>
</tr>
<tr>
<td>Personality disorder not otherwise specified</td>
<td>7 (33.33)</td>
<td>7 (33.33)</td>
</tr>
<tr>
<td>Avoidant personality disorder</td>
<td>1 (4.76)</td>
<td>1 (4.76)</td>
</tr>
</tbody>
</table>

### Index offense<sup>d</sup>

<table>
<thead>
<tr>
<th>Index offense</th>
<th>Neurofeedback training group, n (%)</th>
<th>Treatment-as-usual group, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homicide</td>
<td>9 (42.86)</td>
<td>7 (33.33)</td>
</tr>
<tr>
<td>Sexual offense</td>
<td>2 (9.52)</td>
<td>4 (19.05)</td>
</tr>
<tr>
<td>Arson</td>
<td>1 (4.76)</td>
<td>2 (9.52)</td>
</tr>
<tr>
<td>Violence</td>
<td>3 (14.29)</td>
<td>3 (14.29)</td>
</tr>
<tr>
<td>Threat against life</td>
<td>4 (19.05)</td>
<td>3 (14.29)</td>
</tr>
<tr>
<td>Theft</td>
<td>2 (9.52)</td>
<td>2 (9.52)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Pervasive developmental disorder: Autism spectrum disorder, Asperger disorder, developmental disorder not otherwise specified.

<sup>b</sup>ADHD: all types of attention-deficit disorder.

<sup>c</sup>PTSD: posttraumatic stress disorder.

<sup>d</sup>Index offense: in case of more than one index offense, the most serious one is reported, based on the classification given in the study by Nieuwenhuizen et al [3].

### Table 4. Main outcome measures of repeated measures analysis. Sample sizes were N=42, except for scores on drug use which was n=40. Significant results are in italics.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Neurofeedback training, mean (SD)</th>
<th>Treatment-as-usual, mean (SD)</th>
<th>Post- or premeasurement</th>
<th>F</th>
<th>P value</th>
<th>F</th>
<th>P value</th>
<th>F</th>
<th>P value</th>
<th>Time x Group</th>
<th>η²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 (SD)</td>
<td>T1 (SD)</td>
<td>T0 (SD)</td>
<td>T1 (SD)</td>
<td></td>
<td></td>
<td>Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIS-11&lt;sup&gt;a&lt;/sup&gt;</td>
<td>67.05 (11.05)</td>
<td>63.10 (10.88)</td>
<td>63.33 (12.23)</td>
<td>62.62 (11.5)</td>
<td>3.02</td>
<td>.09</td>
<td>.41</td>
<td>.52</td>
<td>1.45</td>
<td>.24</td>
<td>.03</td>
</tr>
<tr>
<td>BIS-11 motor</td>
<td>24.10 (6.24)</td>
<td>21.67 (3.97)</td>
<td>21.81 (4.49)</td>
<td>20.95 (4.42)</td>
<td>5.61</td>
<td>.02</td>
<td>1.27</td>
<td>.27</td>
<td>1.28</td>
<td>.26</td>
<td>.03</td>
</tr>
<tr>
<td>BIS-11 nonplanning</td>
<td>25.86 (4.21)</td>
<td>25.05 (.5.82)</td>
<td>25.3 (6.18)</td>
<td>25.6 (6.03)</td>
<td>.14</td>
<td>.71</td>
<td>.00</td>
<td>.99</td>
<td>.60</td>
<td>.44</td>
<td>.02</td>
</tr>
<tr>
<td>BIS-11 attentional</td>
<td>17.10 (3.36)</td>
<td>16.38 (3.2)</td>
<td>16.19 (4.06)</td>
<td>16.05 (3.79)</td>
<td>.96</td>
<td>.33</td>
<td>.36</td>
<td>.55</td>
<td>.43</td>
<td>.52</td>
<td>.01</td>
</tr>
<tr>
<td>DAQ-SF&lt;sup&gt;b&lt;/sup&gt;</td>
<td>44.19 (17.77)</td>
<td>36.38 (20.45)</td>
<td>42.72 (17.48)</td>
<td>39.24 (16.49)</td>
<td>6.23</td>
<td>.02</td>
<td>.02</td>
<td>.89</td>
<td>.92</td>
<td>.34</td>
<td>.02</td>
</tr>
<tr>
<td>Commission errors</td>
<td>2.05 (3.44)</td>
<td>1.52 (1.91)</td>
<td>1.00 (1.00)</td>
<td>1.14 (1.42)</td>
<td>.30</td>
<td>.59</td>
<td>1.59</td>
<td>.21</td>
<td>.92</td>
<td>.34</td>
<td>.02</td>
</tr>
<tr>
<td>Drug use</td>
<td>.53 (.64)</td>
<td>.38 (.50)</td>
<td>.23 (.31)</td>
<td>.22 (.35)</td>
<td>1.67</td>
<td>.20</td>
<td>2.91</td>
<td>.10</td>
<td>1.27</td>
<td>.27</td>
<td>.03</td>
</tr>
<tr>
<td>Theta</td>
<td>3.94 (3.67)</td>
<td>4.31 (3.53)</td>
<td>2.54 (1.64)</td>
<td>2.75 (1.72)</td>
<td>1.81</td>
<td>.19</td>
<td>3.12</td>
<td>.09</td>
<td>.14</td>
<td>.71</td>
<td>.00</td>
</tr>
<tr>
<td>SMR&lt;sup&gt;c&lt;/sup&gt;</td>
<td>1.01 (.52)</td>
<td>1.23 (.66)</td>
<td>.65 (.39)</td>
<td>.64 (.35)</td>
<td>5.00</td>
<td>.03</td>
<td>10.56</td>
<td>.00</td>
<td>5.47</td>
<td>.02</td>
<td>.12</td>
</tr>
</tbody>
</table>

<sup>a</sup>BIS-11: Barratt Impulsivity Scale-11.

<sup>b</sup>DAQ-SF: Desire for Alcohol Questionnaire.

<sup>c</sup>SMR: sensorimotor rhythm.
Discussion

Principal Findings

This RCT was conducted to investigate to what extent a theta/SMR neurofeedback training protocol in combination with TAU is able to reduce impulsivity and symptoms of SUD in a population of male forensic psychiatric patients residing in an FPC. The RCT compared a neurofeedback training group of 21 patients who received neurofeedback training in addition to TAU with a control group of 21 patients receiving TAU only. Changes in targeted frequency bands and changes in levels of impulsivity, drug craving, and drug intake posttreatment were examined in patients in the neurofeedback training group and compared with patients in the TAU only group. Results indicate that SMR magnitude showed a significant increase posttreatment in the neurofeedback training group, whereas theta magnitude did not show any changes. Surprisingly, patients in the neurofeedback training group had significantly higher SMR magnitude pretreatment than patients in the TAU only group.

Levels of drug craving and motor impulsivity as assessed with the BIS-11 decreased equally for patients in the neurofeedback training group and the TAU only group. Therefore, the combination of TAU and neurofeedback training was not more effective than TAU only. Other measures of impulsivity and number of drug use did not change posttreatment.

To the best of our knowledge, this is the first RCT study investigating the effects of neurofeedback training in a population of forensic psychiatric patients. Studies on investigating neurofeedback training have steadily increased in the past two decades, but neurofeedback training is rarely used as a treatment option for forensic psychiatric patients. This could partially be due to the fact that these patients usually present with a variety of disorders, and research on the effects of neurofeedback usually exclude patients with comorbid disorders [39-42]. Furthermore, practitioners might be hesitant to employ a treatment modality for which the efficacy in such a complex patient population is yet to be demonstrated.

The fact that effects of neurofeedback training were not superior to TAU only has also been observed in other studies that applied neurofeedback in an attempt to reduce levels of impulsivity. Bink et al [43] employed a theta/SMR protocol in children with ADHD but found the combination of TAU and neurofeedback as effective as TAU only. Schönenberg et al [44] also found no superiority of a theta/beta neurofeedback training over a meta-cognitive therapy or even a sham neurofeedback condition. Both Bink et al [43] and Schönenberg et al [44] applied the training in subjects with a single, well-defined disorder without any comorbidities. Hence, it can be argued that for patients with multiple disorders and characterized by high levels of impulsivity, finding behavioral improvements due to neurofeedback training may be even more difficult.

The results of this study also raise the question as to how participants’ failure to decrease theta activity over the course of the training is associated with the lack of behavioral improvements posttreatment. To date, there are no clear guidelines about how many neurofeedback training sessions are actually needed to achieve significant treatment effects; it is possible that improvements in the theta frequency band could have been achieved with more sessions. Bink et al [43] found that adolescents with ADHD were better able to suppress theta frequency by the end of the training sessions than at the beginning of neurofeedback training. In the study by Bink et al [43], 37 sessions were employed, but they still did not observe an effect of the neurofeedback training in the reduction of impulsivity. It may be the case that the 20 sessions of neurofeedback provided in this study simply were not enough for this patient group to learn to regulate the theta frequency band. However, patients’ inability to adhere to the training schedule of 2 neurofeedback sessions a week might be indicative of the feasibility of a neurofeedback protocol that employs even more sessions. Throughout this study, it was difficult to keep patients engaged in the study. Although the specific patient population at hand is difficult to engage in treatment no matter which treatment is applied, the fact that none of the patients in the neurofeedback training group were able to attend 2 sessions a week is concerning. This was partially due the fact that neurofeedback software is still in its infancy and options concerning the employed training methods are limited. In most cases, the implemented video games are quite simplistic. A lot of patients reported that they found the intervention dull, which most likely was of negative influence on treatment motivation. An abbreviated protocol might be better suited for this patient population in terms of keeping patients engaged in the training. In addition, as results of this study showed no significant relation between patient’s reduction in theta magnitude and behavioral outcome measures, it remains unclear as to whether (more) improvements in theta activity regulation can lead to (better) clinical improvements at the behavioral level. However, patients did manage to increase SMR magnitude posttreatment. It is possible that the SMR frequency band is easier to regulate with neurofeedback training. In a recent study by Fielenbach et al [45], which focused on whether forensic psychiatric patients are actually able to learn to regulate cortical activity through neurofeedback training, more patients were able to systematically increase SMR activity as opposed to reducing theta activity. In a study by Doppelmayr and Weber [46], healthy participants were better able to regulate SMR activity than to change the theta/beta ratio, and a recent study by Janssen et al [39] showed that adolescents were not able to inhibit their theta frequency but did manage to increase beta activity.

It is unclear why patients in the neurofeedback training group showed higher pretreatment SMR magnitude than patients in the TAU only group, as patients’ distribution over groups was random. However, previous studies with healthy participants have suggested that pretreatment SMR magnitude is a predictor of participants ability to increase of SMR magnitude over the course of neurofeedback training [47-50]. Possibly, the higher pretreatment levels of SMR magnitude contributed to the finding that patients did manage to increase SMR magnitude over the course of training.

Recently, quantitative electroencephalography (QEEG)-guided neurofeedback protocols are increasingly implemented in clinical practice. With these protocols, pretreatment EEG deviations are first assessed and the applied neurofeedback...
protocol then focuses on treating these EEG deviations, as opposed to applying a standard neurofeedback protocol to all participants. Although there is also discussion in the literature about the use of QEEG approach of neurofeedback treatment (eg, Johnson and Bodenhamer-Davis [51]), this approach fits with the rise of personalized medicine in the past decade, where a treatment approach tailored to the individual is applied rather than a one-size-fits-all approach. Especially for forensic psychiatric patients, usually presenting with a wide range of comorbidities, manifesting through various deviations in EEG-frequencies, this might be a more suitable approach than applying standardized neurofeedback protocols.

**Limitations and Recommendations for Future Studies**

Patients taking prescription medication were allowed to keep taking these medications during the course of the study. Given the special setting where this study was conducted, limiting medication intake would have severely hampered patient recruitment. However, almost all types of medication commonly prescribed for forensic psychiatric patients tend to have effects on EEG frequencies. Several studies have shown that stimulant medication such as methylphenidate normalizes EEG frequencies and may lead to a reduction of theta band magnitude and an increase in low beta bands magnitude [49,50]. Medication for disorders in the schizophrenia spectrum, such as clozapine, have been shown to increase theta activity (Hyun et al [52]). It is very well possible that the results of this study were, to some extent, influenced by the type and/or dosage of patients’ medication. A theta/SMR neurofeedback protocol might not lead to significant changes in EEG-frequencies when these frequency bands are already normalized due to use of medication, although this remains speculative. In this study, changes in medication were insufficiently tracked during the course of the study. Future studies should investigate the effects of medication on the EEG spectrum more closely before applying neurofeedback or should at least control for medication intake during the analysis to achieve more conclusive results. Another limitation concerning medication is the fact that some medication, such as aripiprazole, is known to have positive effects on levels of craving (Beresford et al [53]), which could have influenced the results on the craving questionnaire DAQ-SF.

Moreover, with the patient sample of this study, there was heterogeneity concerning substances used by study participants. This is quite common in patients with SUD, as many patients are polydrug abusers. This may have altered the results and potentially influenced the effects of neurofeedback in these patients. In addition, we followed treatment facility policy, where a refusal to undergo drug testing is scored as having a positive drug testing. There is no way to be certain that patients who refused to undergo drug testing did, in fact, use illicit substances. However, given our clinical experience, patients refusal to undergo drug testing usually lies in the fact that they have relapsed in drug use, as patients have no reason to refuse to undergo drug testing other than fear of having drug use exposed. Refusal to undergo drug testing will result in the loss of privileges, so that refusing to undergo drug testing comes at a reasonable cost to patients.

In addition, the fact that none of the patients in the neurofeedback training group were able to complete the training in the scheduled amount of time could have influenced the results. Possibly, results achieved in terms of enhancing or inhibiting EEG frequencies were lost in between sessions because patients were not able to follow the scheduled training sessions. To date, there is no conclusive research indicating the ideal number of neurofeedback training sessions or the most beneficial interval time in between training sessions. For this study, adhering to a very strict training schedule, where patients would have been excluded from further participation whenever they missed a session, would have resulted in a very high number of dropouts and consequently in lower power of the results found. Nonetheless, the failure of patients’ adherence to the schedule could have been of influence on the study results. Another limitation of this study is that a sham-neurofeedback control group was not added to the study. Although some authors challenge the use of a sham neurofeedback condition [54], as even a sham-based neurofeedback training can lead to treatment outcomes, it could have been useful to add a waiting list group as an untreated control condition.

Future studies should also investigate whether results in terms of patients’ ability to increase or decrease their frequency magnitude vary when manually adjusted thresholds are applied versus when automatically adjusted thresholds are applied. Manually adjusted thresholds are subject to the expertise of the neurofeedback trainer; therefore, they are also subject to, for example, inattention of the trainer. Automatically adjusted thresholds provide a more objective way of adjusting thresholds, which might be better suitable for scientific purposes.

**Conclusions**

This study highlights that more research is needed to assess the efficacy of a theta/SMR neurofeedback protocol for the reduction of impulsivity, drug craving, and drug intake in forensic psychiatric patients with substance abuse problems. Results showed that patients were unable to learn the whole neurofeedback protocol as they did not succeed in reducing theta activity. Future research should focus on assessing which patients will be able to benefit from neurofeedback training at an early stage of the employed training sessions. Given that neurofeedback training is often times applied in vulnerable patient populations such as children, adolescents, and patients with severe mental illness or addiction, it can be considered unethical to enroll these patients in any treatment with the knowledge that it will most likely not lead to beneficial outcomes in terms of reduction of clinical symptoms. Weber et al [55] have made an important start with their research on predicting successful learning of SMR neurofeedback in healthy participants. This research needs to be extended to clinical populations.
References


51. Fielenbach et al JMIR MENTAL HEALTH 2018 | vol. 5 | iss. 4 | e10845 | p.16 http://mental.jmir.org/2018/4/e10845/ (page number not for citation purposes)
Supported Internet-Delivered Cognitive Behavior Treatment for Adults with Severe Depressive Symptoms: A Secondary Analysis

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Abstract

Background: Depression is a highly prevalent mental health issue that exacts significant economic, societal, personal, and interpersonal costs. Innovative internet-delivered interventions have been designed to increase accessibility to and cost-effectiveness of treatments. These treatments have mainly targeted mild to moderate levels of depression. The increased risk associated with severe depression, particularly of suicidal ideation often results in this population being excluded from research studies. As a result, the effectiveness of internet-delivered cognitive behavioral therapy (iCBT) in more severely depressed cohorts is less researched.

Objective: The aim of this study is to examine the effect of iCBT on symptoms of severe depression, comorbid symptoms of anxiety, and levels of work and social functioning.

Methods: Retrospective consent was provided by participants with elevated scores (>28 severe depression symptoms) on the Beck Depression Inventory (BDI-II) who accessed an iCBT intervention (Space from Depression) with support for up to 8 weeks. Data were collected at baseline, posttreatment, and 3-month follow-up on the primary outcome (BDI-II), and secondary outcomes (the Generalized Anxiety Disorder-7 and the Work and Social Adjustment Scale).

Results: A significant change was observed on all measures between pre- and postmeasurement and maintained at 3-month follow-up. Clinical improvement was observed for participants on the BDI-II from pre- to postmeasurement, and suicidal ideation also reduced from pre- to postmeasurement.

Conclusions: Users of Space from Depression with symptoms of severe depression were found to have decreased symptoms of depression and anxiety and increased levels of work and social functioning. The intervention also demonstrated its potential to decrease suicidal ideation. Further investigation is required to determine why some individuals improve, and others do not. iCBT may have the potential to be used as an adjunct treatment for severe depression symptoms, but participants may require further treatment if they receive iCBT as a standalone intervention. Although promising, further research incorporating control groups is needed to support the utility of Space from Depression for use in or as an adjunct to treatment for severe depression.

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KEYWORDS
severe depression; internet-delivered interventions; iCBT
**Introduction**

**Background**

Depression is a serious public health concern and is predicted to be the leading cause of disability in the world by 2030 [1]. Depression exacts significant economic, societal, personal, and interpersonal costs [2]. Consequently, numerous interventions, both psychological [3] and pharmacological [4], have been implemented to reduce its prevalence.

**Treatment for Depression**

Evidence-based treatments for depression can comprise of pharmacological and psychological interventions [5]. Historically, pharmacological interventions have been given precedence, but psychological interventions have demonstrated their efficacy [6]. Research also suggests that two-thirds of clients with depression hold a preference for psychological interventions over pharmacological solutions [7]. However, accessing evidence-based psychological interventions can be difficult because of the many barriers [8,9], including not having access to treatment due to a lack of health service resources [8]. These barriers can be more pronounced for severe depression [10], and most individuals with severe levels of depression do not receive adequate treatment [11].

A typical diagnosis of depression as per the *International Classification of Diseases, Tenth Revision* involves an individual having at least one of 3 key symptoms of depression (depressed mood, loss of interest in daily activities, reduction in energy) for 2 weeks. Depression severity can be mediated by the presence of several other symptoms, including low self-confidence, disturbed sleep, poor concentration or suicidal thoughts [12]. The differentiation between severe depression and a mild/moderate episode is that symptoms are more pronounced and numerous, while also impairing functioning to a greater extent [13].

**Internet-Delivered Interventions**

Innovative attempts to overcome these barriers have led to the development of internet-delivered psychological interventions, primarily based on cognitive behavioral principles for the treatment of depression and other mental health disorders [14]. Internet-delivered interventions can overcome some of the barriers associated with traditional treatment methods [15]. Meta-analyses have demonstrated positive results with internet-delivered cognitive behavioral therapy (iCBT) for depression [16,17], with The National Institute for Health and Care Excellence (NICE) guidelines recommending iCBT as a treatment option in the management of mild to moderate depression [13]. A legacy issue within the field of internet interventions has been that most studies have focused on participants who present within this mild to moderate symptom range, meaning the evidence base for the use of internet-delivered interventions with severe presentations is less established [18].

Nevertheless, this is changing, and some studies have demonstrated the effectiveness of iCBT in reducing symptoms of severe depression [14,19-22], with some illustrating maintenance of improvements at 6-month follow-up [19]. However, the complexities associated with delivering a successful internet-delivered intervention for this population are naturally more challenging, with some studies suggesting that severely depressed individuals participate less in iCBT [23] and sometimes demonstrate less improvement than the mild to moderately depressed group [24]. Despite this, iCBT programs tailored to each individual have been found to produce similar effects for those with severe depression, as those with mild to moderate levels [25]. Such findings have also been demonstrated in a younger cohort [23]. Progressing implementation of internet-delivered interventions with severely depressed cohorts has been much slower than in mild to moderately depressed groups, particularly because of the increased risk of suicide associated with this population [26]. Research evaluating internet-delivered interventions often exclude suicidal ideation as an ethical consideration. As such, their effects on reducing suicidal ideation and ultimately the risk of suicide are not well documented [27,28]. However, it stands that the literature in this field is slowly growing and has illustrated the benefit of iCBT for individuals with greater severity of depressive symptoms.

Where some health systems have been efficient in their adoption of iCBT and other internet-delivered interventions (the improving access to psychological therapies program in the United Kingdom), the use of iCBT in natural settings is not well documented, where iCBT may be classified as an inappropriate treatment option for severe cases. For example, the NICE guidelines for depression [13] identify iCBT and computerized therapies as appropriate treatments for mild-moderate depression, but not necessarily for more severe presentations. Despite this caution, a meta-analysis by Bower et al [14] regarding the impact of initial severity of depression on the effectiveness of low-intensity psychological interventions (both written/physical and online), concluded that those with severe presentations of depression benefit equally to those in lower severity categories. Furthermore, the ongoing monitoring of symptoms, that is facilitated seamlessly through technology, ensures accurate care delivery and informs clinical decisions on the care being delivered. These statements are further supported by the work of Watts et al [29], whose analysis of patients prescribed iCBT for depression with comorbid suicidal ideation illustrated significant decreases from pre- to posttreatment. Thus, despite the limited evidence so far, it seems appropriate, providing the intervention is safely delivered, to explore the potential of iCBT as a treatment for more severe depressive symptomatology.

iCBT can be of benefit to services as a frontline treatment for depression. As a low-intensity intervention, it consumes less clinical resource in its administration. Within a stepped care model, an individual can receive and benefit from an iCBT intervention while they wait for higher intensity treatment resources to become available. However, technology has since progressed, allowing for the delivery of treatments on more robust systems. One such intervention is SilverCloud, but the current utility of this low-intensity treatment for those with severe depression is unknown.

This study aims to explore the effect of the SilverCloud iCBT intervention on those with severe depression. It analyzes a cohort...
that did not meet the criteria for inclusion in a randomized controlled trial (RCT) investigating the impact of iCBT on mild to moderate depression. The authors hypothesized the following:

- The intervention could impact positively on self-reported symptoms of depression, anxiety and work, and social functioning within a cohort with severe depression symptoms.
- The results of this study offer a unique opportunity to assess the effects on suicidal ideation in the cohort, and the authors hypothesized that suicidal ideation would be lower post intervention.
- Clinically meaningful change in depressive symptoms will be observed for the group.

Methods

Design

Participants in this secondary analysis consisted of a subsample from a larger RCT [27,28]. The larger RCT recruited participants who were within the mild to moderate symptom severity as determined by a score of between 14 and 28 on the Beck Depression Inventory (BDI-II). Those scoring above these criteria on the BDI-II (ie, within the “severely” depressed range) were excluded from the main RCT study but were offered access to treatment with support and invited to complete posttreatment and follow-up questionnaires. Individuals scoring in this range also received a referral to the general practitioner as per risk protocols. No case-control group was recruited for this cohort as it extended beyond the scope of the main research study.

Participants and Recruitment

Table 1 describes the sociodemographic characteristics of the sample. Participants of the present study scored within the “severe” range for depression (>28 on the BDI-II) [30]. As part of the original RCT protocol, participants were recruited via outreach work and information on the website of Aware, a national depression charity in Ireland. Two-hundred and eleven (N=211) participants were excluded from the main RCT due to symptom severity. An ethical amendment was submitted and approved at a later date to contact these individuals via email to request permission for their data to be analyzed as part of the current secondary analysis. Of the 211, 67 (32%) participants replied and consented for their data to be used in the secondary analysis of outcomes. In total, 67 participants provided data at baseline on all measures, with responses on measures from 33 (49%) participants on the BDI-II and Work and Social Adjustment Scale (WSAS), 34 (51%) on the Generalized Anxiety Disorder-7 item inventory (GAD-7) at post treatment, and from 22 (33%) on all measures at 3-month follow-up.

Measures

Participants were assessed at baseline and posttreatment (after 8 weeks of service provision) and again at 3-month follow-up. At baseline, the BDI-II, Sociodemographic and History Questionnaire, GAD-7, and the WSAS were completed for screening purposes. After that, the BDI-II, GAD-7, and WSAS were completed at the end of treatment, week 8, and at 3-month follow-up. The 21-item BDI-II [30] is a widely used questionnaire measuring symptoms and severity of depression based on the criteria for depressive disorder diagnosis as outlined in The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) [31].

Table 1. Participant demographics (N=67).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD); range</td>
<td>36.3 (10.4); 18-58</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Female</td>
<td>59 (88)</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>13 (19)</td>
</tr>
<tr>
<td>Undergraduate</td>
<td>30 (45)</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>7 (10)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (21)</td>
</tr>
<tr>
<td>None</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Part-time/student</td>
<td>14 (21)</td>
</tr>
<tr>
<td>Full-time</td>
<td>25 (38)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>15 (22)</td>
</tr>
<tr>
<td>Retired</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Disabled</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Stay-at-home parent</td>
<td>10 (15)</td>
</tr>
</tbody>
</table>
The scale designates levels of severity: minimal (0-13), mild (14-19), moderate (20-28), and severe (29-63). The BDI-II has been found to have excellent internal consistency and test-retest reliability with a diverse range of samples [30,32,33]. It has also demonstrated good convergent validity with other measures of depression among clinical and nonclinical adult samples [34]. Reliability analysis of this measure for the current sample indicated appropriate levels of internal consistency (alpha=.71).

The GAD-7 [35] comprises 7 items measuring symptoms and severity of anxiety based on the DSM-IV diagnostic criteria. The GAD-7 has good internal consistency (alpha=0.89) and good convergent validity with other anxiety scales [36]. The GAD-7 is increasingly used in large-scale studies as a generic measure of changes in anxiety symptomatology, using a cutoff score of 8 [37,38]. Reliability analysis of this measure for the current sample indicated appropriate levels of internal consistency (alpha=.84).

The Work and Social Adjustment Scale (WSAS) [39] is a simple, reliable, and valid measure of impaired daily functioning across five dimensions: work, social life, home life, private life, and close relationships. Reliability analysis of this measure for the current sample indicated appropriate levels of internal consistency (alpha=.72).

The Intervention

The SilverCloud Space from Depression program is a 7-module, internet-delivered cognitive behavioral program, with an option to unlock further content as the user progresses. Program content is delivered on a web 2.0 platform and features several forms of rich media (videos, animations, and audio) to facilitate the delivery of the intervention. Treatment content consists of cognitive and behavioral strategies common to CBT protocols: behavioral activation, cognitive restructuring, and activity scheduling [28]. For the current trial, the program was delivered in a supported format and participants received brief asynchronous feedback based on their progress each week for a period of up to 8 weeks. A detailed description of the modules is provided in Table 2.

Trained volunteers from a national depression charity in Ireland provided support for the intervention. The role of the supporter in this trial was to provide motivational support and encouragement to their assigned patient. The cohort undertook several face-to-face training sessions hosted by the charity before commencing in their role, with the content of the training designed to educate on CBT, the program, the role of the supporter, and how best to respond to patients in distress. An assistant psychologist was employed by the depression charity to assist the supporters, as well as to monitor all correspondence between supporters and their patients. This individual reported directly to the Education and Online Services coordinator, who regularly consulted with the clinical director of the charity. Further risk protocols were incorporated at review points, where a client was escalated along service protocols if they shared information with their supporter that indicated a risk to themselves or others. Where patients indicated a response greater than zero on item 9 of the BDI-II, the supporter was sent an email alert, and clients were presented with “get help now” links and local crisis numbers. This protocol was standard for all patients of the charity, and not just those in the severe group. The supporter would then contact the patient at their earliest convenience, and they would discuss the options available to them.

Table 2. Contents of Space from Depression and brief descriptions of modules.

<table>
<thead>
<tr>
<th>Module name</th>
<th>Brief description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting started</td>
<td>• Outlines basic premise of CBT, provides information about depression, and introduces some of the key ideas of Space from Depression</td>
</tr>
<tr>
<td></td>
<td>• Users are encouraged to begin to chart their current difficulties with depression</td>
</tr>
<tr>
<td>Tune In I: getting to grips with mood</td>
<td>• Focus is on mood monitoring and emotional literacy</td>
</tr>
<tr>
<td></td>
<td>• Users can explore different aspects of emotions, physical reactions, action and inaction, and how they are related</td>
</tr>
<tr>
<td>Tune In II: spotting thoughts</td>
<td>• Module focuses on noting and tracking thoughts</td>
</tr>
<tr>
<td></td>
<td>• Users can explore the connection between their cognitions and their mood, and record them graphically</td>
</tr>
<tr>
<td>Change It I: boosting behavior</td>
<td>• Module focuses on behavioral change as a way to improve mood</td>
</tr>
<tr>
<td></td>
<td>• Ideas about behavioral activation are included, and users can plan and record activities, and chart their relationship with their mood</td>
</tr>
<tr>
<td>Change It II: challenge your thoughts</td>
<td>• Module supports users to challenge distorted or overly negative thinking patterns, with thought records, as well as helpful coping thoughts</td>
</tr>
<tr>
<td>Change It III: core beliefs</td>
<td>• Module outlines the role that deeply held core beliefs could play in mood and depression</td>
</tr>
<tr>
<td></td>
<td>• A range of interactive activities available to identify, challenge, and balance any unhelpful core beliefs</td>
</tr>
<tr>
<td>Bringing it all together</td>
<td>• Module encourages bringing together all skills and ideas they have gathered so far, note their warning signs, and plan for staying well</td>
</tr>
</tbody>
</table>
**Ethical Approval**

Original ethics approval was received for the study on November 25, 2013. Posthoc ethical approval was granted on November 16, 2015, to contact those scoring in the severe ranges of the BDI-II. The subsample was provided with information on the secondary analysis and participants were requested to provide informed consent should they wish to participate.

**Data Analysis**

Baseline comparisons across the variables of age, gender, education level, and employment status were conducted, along with baseline comparisons across the measures of BDI-II, GAD-7, and WSAS between data gathered from all clients with “severe” depression (N=211) as per the BDI-II, and those who consented for their data to be used in the follow-up analysis (n=67).

Multivariate imputation by chained equations was applied to impute missing question scores using the R MICE v2.0 package [40]. Variables were then imputed with 100 imputations for 30 iterations using predictive mean matching. Following imputation, linear mixed models were fitted for each of the three measures (BDI-II, GAD-7, and WSAS) using the R package lme4 v1.1-17 [41], pooling results over the 100 individual datasets. This method was chosen due to its robustness in the handling of missing data, as this study recorded 49% (33/67) missing data at posttreatment and 68% (46/67) missing data at 3-month follow-up. F tests for fixed effects were carried out with the ANOVA (analysis of variance) function of the R package ImeTest [42], using Satterthwaite’s method for denominator degrees-of-freedom approximation. Effect sizes (Cohen d), averaged over all imputed datasets, were calculated using the mean change and standard deviation of change scores which is a recommended method for repeated measures designs [43-45]. Clinically significant change and deterioration were calculated based on a movement of 9 or more points on the BDI-II from pre- to posttreatment measurement [46]. Reliable recovery was calculated based on a movement of 9 more points, as well as having a posttreatment score of less than 10 on the BDI-II [30]. As per this methodology, 4 categories were established: reliable improvement, reliable deterioration, reliable recovery, and no change.

**Results**

**Baseline Characteristics**

No significant differences were observed between the BDI-II, GAD-7, and WSAS using t tests between the overall cohort with severe depression (N=211) and those who consented (n=67) to having their posttreatment and follow-up data included in the analysis. Across demographic variables, no significant differences in gender, employment status or age were observed at baseline. However, a significant difference was observed on the level of education between the 2 groups ($\chi^2_4=10.0, P=.04$), with the consenting participants having a higher level of education overall.

**Treatment Response**

Participants engagement with the treatment was positive. To begin with, the participants completed a mean of 17.4 sessions (SD 17.3) over the duration of the treatment period. The mean session time per participant was 0.49 hours (SD 0.41), which amounts to a total mean exposure to the active treatment of 9.22 hours (SD 10.57). However, examining the standard deviation of this total time on the platform would suggest a large variance (i.e., 10.57 hours). To illustrate this data further, quartiles have been reported in Table 3.

**Multiple Imputation**

The Little MCAR test revealed a nonsignificant result ($\chi^2_{16}=10.8, P=.82$), indicating that the data were missing completely at random and not contingent on any measured variables within the data set. Further exploration of the data indicated that no other variables (education level, gender, employment, BDI-II baseline score, GAD-7 baseline score, WSAS baseline score) were significantly different between participants who completed exit measures and participants who did not complete exit measures ($\chi^2$ and t tests). Similarly, these were not significantly different between participants who completed 3-month measures and participants who did not complete 3-month measures.

**Posttreatment and Follow-Up Effects**

Linear mixed-model ANOVAs were conducted separately on the participant data (N=67) using time as the within-subjects variable for the BDI-II, GAD-7, and WSAS. For the BDI-II, a significant time effect on depression was found. The BDI-II scores significantly decreased from baseline with a mean of 35.94 (SD 6.91), to posttreatment with a mean of 23.76 (SD 9.68), to 3-month follow-up with a mean 14.52 (SD 7.45) measurement points, ($F_{2,132}=174.9, P<.001$). Suicidality, as per question 9 on the BDI-II, was also found to significantly decrease across the measurement time points ($F_{2,132}=18.5, P<.001$). Similar trends were observed in regards to the analyses of secondary measures, where significant decreases in scores were also observed for the GAD-7 ($F_{2,132}=98.3, P<.001$), and significant increases for WSAS ($F_{2,132}=33.0, P<.001$). Descriptive statistics are presented in Table 4.

**Reliable Change**

Reliable change for the imputed data of the “severely” depressed group was explored using participants that had BDI-II data at both pre- and posttime points. At posttreatment, 43/67 (64%) participants were classified as reliably improved. Of those who were classified as reliably improved, 6 of the 67 (9%) participants met the criteria for recovery. The remaining 18/67 (36%) individuals were classified as unchanged, where scores did not exceed a movement of 9 points in either direction.
Table 3. Treatment response data (N=67).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Percentiles</th>
<th>Descriptive statistics</th>
<th>Percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean (SD)</td>
<td>Median</td>
</tr>
<tr>
<td>Number of sessions</td>
<td></td>
<td>17.4 (17.3)</td>
<td>13</td>
</tr>
<tr>
<td>Total time on platform (hours)</td>
<td></td>
<td>9.22 (10.57)</td>
<td>4.8</td>
</tr>
<tr>
<td>Time per session (hours)</td>
<td></td>
<td>0.49 (0.41)</td>
<td>0.4</td>
</tr>
<tr>
<td>Number of activities completed</td>
<td></td>
<td>33.4 (41.6)</td>
<td>16</td>
</tr>
<tr>
<td>Activities per session</td>
<td></td>
<td>1.79 (1.23)</td>
<td>1.5</td>
</tr>
<tr>
<td>Percentage of program viewed</td>
<td></td>
<td>0.46 (0.36)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Table 4. Descriptive statistics of the sample (n=67).

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline, mean (SD)</th>
<th>Posttreatment</th>
<th>3-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>95% CI (lower-upper)</td>
<td>Effect size d (95% CI)</td>
</tr>
<tr>
<td>BDI-IIa</td>
<td>35.9 (6.9)</td>
<td>23.7 (9.7)</td>
<td>21.40-26.12</td>
</tr>
<tr>
<td>BDI-II Q9b</td>
<td>0.8 (0.6)</td>
<td>0.5 (0.6)</td>
<td>0.39-0.66</td>
</tr>
<tr>
<td>GAD-7c</td>
<td>13.6 (4.9)</td>
<td>8.0 (4.4)</td>
<td>6.91-9.09</td>
</tr>
<tr>
<td>WSASd</td>
<td>20.4 (8.1)</td>
<td>15.2 (7.0)</td>
<td>13.49-16.93</td>
</tr>
</tbody>
</table>

aBDI-II: Beck Depression Inventory-II.
bBDI-II Question 9: Beck Depression Inventory Question 9 measuring suicidality.
cGAD-7: Generalized Anxiety Disorder-7 item inventory.
dWSAS: Work and Social Adjustment Scale.

Discussion

Principal Findings

The current paper sought to investigate the impact of an internet-delivered CBT intervention for the treatment of depression, Space from Depression, on symptoms of severe depression. The BDI-II was observed to have significant decreases with large effect sizes from pre- to post and 3-month follow-up timepoints. The results are encouraging, with participants demonstrating solid changes from pre-post assessment, and the changes beyond that time are suggestive of a continued positive change in symptom reduction. Baseline differences between the overall sample (N=211) and those who consented (n=67) found that those who consented had higher education levels, but did not vary across other clinical or sociodemographic variables. This difference in education is indicative of the wider literature; individuals with higher levels of education are more likely to participate in research [47], potentially stemming from increased levels of volunteerism [48] and belief in science [49] in this population. Treatment response rates for the study were also good, with 50/67 (75%) of participants completing 5 or more sessions.

The results demonstrate comparative effect sizes of improvement in severe depressive symptoms to those experienced in a mild to moderately depressed group, supporting the use of iCBT for severe depression [14,19]. Over half of the participants, 43/67 (64%) who provided pre- and posttreatment data experienced reliable improvement by participating in the intervention, supporting the potential for iCBT as an effective measure in this population. However, mean scores on the BDI-II remained within the moderately depressed range at posttreatment indicating that the majority of participants would still require further psychological treatment, despite improvement in their depressive symptomatology. These results are consistent with the conclusions of Bower et al [14], where although clinically reliable change was observed in the sample, the majority of those improved were still within clinical ranges (37/67, 55%) and would require further treatment. Further, despite no control group being recruited, limiting the statements that can be made in regards to effectiveness, this severe sample was found to have actively used the intervention over their course of treatment. This provides some support for the relationship between the intervention and the outcomes being reported. Outcomes on secondary measures of the GAD-7 and WSAS significantly decreased from pre- to post timepoints, with significant differences and large effect sizes observed. These scores did not significantly differ at follow-up points, implying a maintenance of gains across the sample from post-treatment to 3-month follow-up, similar to what was observed by Meyer et al [19]. The decrease in anxiety scores as a result of iCBT treatment for depression was mirrored in the larger RCT this sample was derived from [28]. Reduction of comorbid symptoms in severe depression may be of particular importance to this population given the association that has been found between the severity of depressive symptoms and greater instances of comorbid conditions [50].
Increasingly in depression research, the need to include data points relevant to quality of life and functional impairment has been recognized [51,52]. The current study utilized the WSAS, and administering measures such as this can provide researchers and practitioners with deeper insight into current levels of experienced impairment and the recovery process. As a multi-domain scale encompassing areas such as work, leisure activities and home life, the improvements observed in the WSAS illustrate the positive consequences of a low-intensity iCBT intervention outside of decreasing depression symptoms. Other studies utilizing iCBT have recorded similar improvements in their samples [53-55], yet qualitative investigations may be necessary to understand the impact of iCBT on improvements in functioning further. Although preliminary, these results provide support for the helpfulness of iCBT, where an effective intervention should demonstrate its ability to produce outcomes not just on disorder symptomatology, but also in the areas of life typically affected by the disorder.

Clinically significant change is an important concept due to its potential to provide a complete picture of the impact of interventions, which goes beyond the averages of the group and outlines change at an individual level [56]. Conducting reliable change analyses also allows for researchers to be confident that changes in the score are more than fluctuations around a data point and, to an extent, regression to the mean. The approach adopted in this study was conservative and robust, and the reliable change analysis in research completers illustrated that 43/67 (64%) individuals reliably improved, with the remainder being unchanged. Six of the 67 (9%) individuals recovered using the criteria of <10 and a 9-point change on the BDI-II. The results further show potential for the use of internet-delivered interventions for severe populations, where a large proportion of individuals in a cohort with severe presentations achieved meaningful reductions in symptoms, and in some cases transitioning to mild-moderate categories from severe.

Suicidal ideation was significantly reduced from pre- to postintervention. The authors acknowledge that despite mean scores being less than 1 on this item of the BDI-II (where a score of 1 on the measure indicates the presence of suicidal thoughts without intentions), the results nonetheless lend support to previous trials investigating this area [57]. The results provide preliminary evidence for the feasibility of online interventions as effective means to tackle the increased risk of suicide in depressed populations.

The current study demonstrated the potential for a supported internet-delivered intervention to alleviate symptoms in individuals with severe presentations. Implementing supported iCBT interventions allows for sufficient monitoring of patients and the capability to intervene and offer further support in the case where risk escalates [19]. It is relatively unknown whether individuals with severe depression benefit more, or less from support than those in the mild to moderate range, though recent analyses have suggested that there is no difference in how populations of severity benefit from low-intensity interventions [14,58]. Further research would be helpful to delineate mechanisms associated with internet-delivered interventions and how they fluctuate depending on the population and severity.

**Limitations**

While the initial results from this study are promising, the original protocol meant that no control group was recruited and therefore caution is advised as we are unable to conclude that the treatment delivered is responsible for the observed effects. We received a response rate of 37.1% (67/211) of the sample, which can be considered a limitation and represents a potential for self-selection bias. At baseline, we found no significant differences between responders and non-responders on all clinical and socio-demographic variables apart from education. Higher levels of education were found for participants who consented for their follow-up data to be used for this secondary analysis. The authors acknowledge that this may bias the data. However, it has been highlighted that differences in education do not impact on treatment response and outcome in CBT-therapies [59]. The result highlights the need for further investigation to discern the mediating and moderating effects of education and other variables on outcome from iCBT treatment for severe depression.

Further investigations implementing RCT or feasibility designs are warranted to discern the utility of *Space from Depression* in more severe cohorts, where our findings must also be understood within the context of the relatively small sample which gave consent for their data to be reported. Research regarding the long-term effects of an online intervention on severe depression would also be an important consideration. Participants’ depression and anxiety symptoms were indexed by self-report rather than clinical diagnosis. However, the authors employed standardized self-report measures that are well-established and have previously been used in numerous research studies relating to depression and internet-delivered interventions. Another potential limitation lies in the fact that the intervention was designed for a mild to moderately depressed group, and so, there may be some aspects that are less relevant for those with severe depression. A final limitation of the study is the large amount of missing data that was observed at posttreatment and 3-month follow-up for these individuals, and the authors, therefore, acknowledge that the results and their generalizability should be interpreted with caution.

**Conclusion**

The current study demonstrated the potential for an internet-delivered intervention to reduce symptoms of severe depression. The participants demonstrated reliable decreases in anxiety symptoms and improvements in work and social functioning. Furthermore, reliable improvement in depression symptomology was observed. Suicidal ideation was reduced as a result of engaging in the intervention, and these results suggest that internet-delivered interventions may have the potential to provide a robust method of risk assessment and monitoring. Current treatment guidelines, such as NICE [13], recommend iCBT as a low-intensity treatment option for mild to moderate presentations of depression and advise high-intensity treatments for severe forms of depression. The present findings provide preliminary evidence to justify further research into the utilization of iCBT and the SilverCloud intervention as part of...
a treatment plan for severe depression that could prove beneficial for some individuals.

Acknowledgments

The authors greatly acknowledge SilverCloud Health for funding this study. DR and LT conceptualized the original trial from which this secondary analysis was derived. DD and JB wrote the initial draft of the paper, with reviews from DR, LT, and MA contributing to the final draft. SC was the data manager and statistician. DD and SC developed and actioned the data analytic protocol.

Conflicts of Interest

DR, DD, JB, MA, and SC are employees of SilverCloud Health, developers of computerized psychological interventions for depression and anxiety, stress and comorbid long-term conditions. LT is a research consultant for SilverCloud Health who is based in Trinity College, Dublin.

References


Abbreviations

ANOVA: analysis of variance
BDI-II: Beck Depression Inventory
CBT: cognitive behavioral therapy
DSM-IV: The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition)
GAD-7: Generalized Anxiety Disorder-7 item inventory
iCBT: internet-delivered cognitive behavioral therapy
NICE: The National Institute for Health and Care Excellence
RCT: randomized controlled trial
WSAS: Work and Social Adjustment Scale
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Identifying the Underlying Factors Associated With Patients’ Attitudes Toward Antidepressants: Qualitative and Quantitative Analysis of Patient Drug Reviews

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Abstract

Background: Nonadherence to antidepressants is a major obstacle to deriving antidepressants’ therapeutic benefits, resulting in significant burdens on the individuals and the health care system. Several studies have shown that nonadherence is weakly associated with personal and clinical variables but strongly associated with patients’ beliefs and attitudes toward medications. Patients’ drug review posts in online health care communities might provide a significant insight into patients’ attitude toward antidepressants and could be used to address the challenges of self-report methods such as patients’ recruitment.

Objective: The aim of this study was to use patient-generated data to identify factors affecting the patient’s attitude toward 4 antidepressants drugs (sertraline [Zoloft], escitalopram [Lexapro], duloxetine [Cymbalta], and venlafaxine [Effexor XR]), which in turn, is a strong determinant of treatment nonadherence. We hypothesized that clinical variables (drug effectiveness; adverse drug reactions, ADRs; perceived distress from ADRs, ADR-PD; and duration of treatment) and personal variables (age, gender, and patients’ knowledge about medications) are associated with patients’ attitude toward antidepressants, and experience of ADRs and drug ineffectiveness are strongly associated with negative attitude.

Methods: We used both qualitative and quantitative methods to analyze the dataset. Patients’ drug reviews were randomly selected from a health care forum called askapatient. The Framework method was used to build the analytical framework containing the themes for developing structured data from the qualitative drug reviews. Then, 4 annotators coded the drug reviews at the sentence level using the analytical framework. After managing missing values, we used chi-square and ordinal logistic regression to test and model the association between variables and attitude.

Results: A total of 892 reviews posted between February 2001 and September 2016 were analyzed. Most of the patients were females (680/892, 76.2%) and aged less than 40 years (540/892, 60.5%). Patient attitude was significantly (P<.001) associated with experience of ADRs, ADR-PD, drug effectiveness, perceived lack of knowledge, experience of withdrawal, and duration.
of usage, whereas age (F_{9,574}=0.72, P=.58) and gender (χ^2=2.7, P=.21) were not found to be associated with patient attitudes. Moreover, modeling the relationship between variables and attitudes showed that drug effectiveness and perceived distress from adverse drug reactions were the 2 most significant factors affecting patients’ attitude toward antidepressants.

Conclusions: Patients’ self-report experiences of medications in online health care communities can provide a direct insight into the underlying factors associated with patients’ perceptions and attitudes toward antidepressants. However, it cannot be used as a replacement for self-report methods because of the lack of information for some of the variables, colloquial language, and the unstructured format of the reports.

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KEYWORDS
medication adherence; attitude; perception; antidepressive agents; patient-centered care; chronic disease; depression; community networks; internet; social media; data mining; framework method

Introduction

Background

The prevalence of use of antidepressants among Americans increased from 7.7% in the years 1999 to 2002 to 12.7% in 2011 to 2014 [1], with the global market estimated at US $11.6 billion in 2017 [2]. The therapeutic benefits of antidepressants depend on adherence to prescribed regimen; however, between 30% and 68% of patients are nonadherent [3], leading to increased risks of depression relapse, emergency visits, low quality of life, and significant burdens on the individual and health care system [4].

Several studies indicate that nonadherence is weakly associated with personal attributes and clinical variables, but it is strongly associated with patients’ beliefs and attitudes toward medication [3,5,6]. Identifying the key dimensions of patients’ attitudes toward antidepressants is a challenging task [7]. Although self-report scales for measuring patients’ attitude toward antidepressants are well validated, they are associated with some methodological difficulties (eg, missing factors influencing attitude, sampling bias, and patients’ reluctance to reveal personal information). On the other hand, generic scales such as the Beliefs about Medicines Questionnaire [8] and Drug Attitude Inventory [9] that are widely used in many patient groups are not specifically designed to evaluate patients’ attitudes toward antidepressants.

Online health care communities have provided patients with a unique platform to report their experiences freely and express their main concerns and perceptions about their treatments. This information may not be collected by traditional self-report methods such as questionnaires, interviews, or physician assessments [10-12]. A public opinion survey found that 30% of Americans actively participate in creating health-related knowledge in online health care forums [13]. This rate is higher among patients with mental disorders, possibly due to stigma against them [14]. With the growing emphasis on patient-centered care, the ability to directly measure individuals’ attitudes toward medications from their reviews in social media may increase early detection of factors that contribute to nonadherence and negative outcomes [15]. To the extent of our knowledge, no study has focused on identifying factors influencing attitude toward antidepressant treatment as reported by patients in online health care forums.

Contributions

The premise of this study is that patients’ self-reports of their experiences with antidepressants therapy on drug review forums may constitute a reliable source to uncover various dimensions of attitude toward these medications.

In this study, we utilized the online health care forum called askapatient to identify underlying factors associated with attitudes toward antidepressants. We used a novel mixed-method approach to generate structured data from unstructured text, evaluate the association between attitude and both personal and clinical variables, and model the relationship between the variables and patients’ attitudes toward antidepressants. To achieve the latter, we identified clinical and personal factors from literature that have shown to affect attitude toward psychiatric medications and then used these factors for designing an initial framework of analysis for patients’ drug reviews.

We hypothesize that clinical variables including drug effectiveness, experience of adverse drug reactions (ADRs), perceived distress from ADRs (ADR-PD), and duration of treatment are associated with patients’ attitudes toward antidepressants. We also hypothesize that drug effectiveness and presence of adverse effects are the most important factors affecting patients’ attitudes toward medications. Furthermore, we hypothesize that personal variables including age, gender, and patients’ lack of knowledge about medications are associated with the patients’ attitudes toward antidepressants.

Methods

Summary of the Method

The methodology of this study is composed of multiple phases. We first generated structured data from unstructured patients’ review using the analytical framework method. Then, we used the structured data to test the hypotheses and model the relationship between variables and attitude. Figure 1 shows the summary of the methodology for this study.

Drug Sources and Data Source

The data source of this study is a health care forum called askapatient. This health care forum collects patients’ experiences for a wide-range of medications, along with the patients’ age, gender, reason for drug prescription, and duration of usage. Patients can also rate their satisfactions with the drugs.
through a Likert scale from 1 (not satisfied) to 5 (very satisfied). For the purpose of this study, we considered the patients’ satisfaction with the drugs as their overall attitudes toward the medications.

Patient satisfaction in several studies has been characterized by patients’ beliefs and attitudes [16,17]. In addition, the Likert scale is equivalent to the scales used by attitude studies to present outcome of self-report scales such as Drug Attitude Inventory and Antidepressant Compliance Questionnaire.

The drug sources for this study are sertraline and escitalopram from the selective serotonin reuptake inhibitor (SSRI) class, and venlafaxine and duloxetine from the serotonin-norepinephrine reuptake inhibitor (SNRI) class. We chose these drugs because they are associated with a wide range of ADRs and withdrawal symptoms (WDs) that might affect the patients’ attitudes toward the drugs and because they are among the most commonly prescribed antidepressants [18].

**Data Collection**

We randomly collected 892 drug reviews for the 4 antidepressants that were posted between February 2001 and September 2016. The sample size was calculated using the formula introduced by Barlett et al [19] for categorical data. We applied stratified sampling procedure so that the proportion of patients in each attitude group (1-5) was an approximate of the full population.

As this health care forum does not have an application programming interface, we developed a Web crawler system to collect all the drug reviews from the forum. University of Wisconsin-Milwaukee’s institutional review board exempted this study as the study data are publicly available and no patient consent was required.

**Figure 1.** A summary of the research methodology of the study. IAA: interannotator agreement; ANOVA: analysis of variance; API: application programming interface; IRB: institutional review board.
Developing the Analytical Framework

We used the Framework Method to summarize patients’ experience with medications. The Framework Method is a flexible tool that uses inductive, deductive, or hybrid approaches (combination of inductive and deductive approaches) to generate themes for developing highly structured data from qualitative data [20]. In the deductive approach, themes are generated using literature, whereas in the inductive approach, themes are generated using open coding. In this study, we adopted a hybrid method that combines both inductive and deductive approaches for generating themes to analyze patients’ reviews in online healthcare communities.

Generating Themes Using Deductive Approach

We conducted a comprehensive review of the literature to identify pertinent factors affecting patients’ attitude toward antidepressants. The identified factors were categorized into 5 categories: pharmaceutical treatment, health care system, psychosocial, patient-related, and depression-related factors. These factors were used as the themes to construct a preliminary analytical framework for data analysis. Table 1 shows the categories of the themes and the themes in each category. The details of the themes are available in [21].

Generating Themes Using Inductive Approach (Open Coding)

A total of 310 drug reviews were randomly selected for analysis using the preliminary analytical framework. Passages of drug reviews that could not be covered by the preliminary analytical framework were discussed in our regular team meeting for generating new themes. The identified themes reflected patients’ experiences with the medications. Using this approach, 8 new themes were generated: WDs, perceived distress from WDs, intentional withdrawal (discontinuation), unintentional withdrawal (missing dose, running out of medication), patient recommendations to others, overall attitude toward medications, problem with financial support, and problem with social support.

Developing the Final Analytical Framework

To reduce the complexity of the data analysis, themes that covered less than 5% of the drug reviews were eliminated or merged with other themes. For example, affordability and partner support were excluded, and general concern and necessity were merged with overall attitude toward drug. Themes that were conceptually related to other themes but difficult to distinguish were merged in the final analytical framework. For example, perceived necessity and perceived effectiveness were merged. We also removed patients’ general attitudes toward medications because they were strongly correlated with patients’ rating (satisfactions) for the drugs. Table 2 includes definitions of the themes and subthemes used in the final analytical framework with examples of patients’ reviews for the drugs.

Analysis of Dataset Using the Analytical Framework

This phase consisted of the following 2 main steps: (1) data preprocessing and (2) annotating the dataset using the themes in the analytical framework.

Data Preprocessing

The majority of drug review posts were composed of multiple sentences, each of which covers various aspects of patients’ experiences with drugs. To improve accuracy of data analysis and reduce the observational error, we set the unit of analysis at the sentence level. To split the reviews into sentences, we first addressed the grammatical and punctuation errors in colloquial language using regular expression, and then we applied the Natural Language Toolkit [22] to split reviews into separate sentences.

Table 1. Factors affecting patients’ attitudes toward antidepressants (identified by a comprehensive review of the literature).

<table>
<thead>
<tr>
<th>Category</th>
<th>Factors in each category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacological treatment factors</td>
<td>• Perceived effectiveness</td>
</tr>
<tr>
<td></td>
<td>• Perceived necessity</td>
</tr>
<tr>
<td></td>
<td>• Perceived concern</td>
</tr>
<tr>
<td></td>
<td>• Adverse drug reaction</td>
</tr>
<tr>
<td></td>
<td>• Perceived distress from the adverse effect</td>
</tr>
<tr>
<td>Health care system factors</td>
<td>• Patient-provider relationship</td>
</tr>
<tr>
<td></td>
<td>• Health care setting</td>
</tr>
<tr>
<td></td>
<td>• Affordability of the treatment</td>
</tr>
<tr>
<td>Social-cognitive and psychological factors</td>
<td>• Stigma and cultural related factors</td>
</tr>
<tr>
<td></td>
<td>• Partners’ support</td>
</tr>
<tr>
<td>Patient-related factors</td>
<td>• General concern and necessity</td>
</tr>
<tr>
<td></td>
<td>• Knowledge about pharmacological aspects of medication</td>
</tr>
<tr>
<td></td>
<td>• Sociodemographic factors</td>
</tr>
<tr>
<td></td>
<td>• Educational level</td>
</tr>
<tr>
<td>Depression factors</td>
<td>• Depression severity, type, and duration</td>
</tr>
<tr>
<td></td>
<td>• Patient insight about depression</td>
</tr>
</tbody>
</table>
Annotating Sentences Using the Themes in the Analytical Framework

All drug reviews in the sample were annotated using the analytical framework at sentence level. Four annotators with health background participated in the data annotation process. All sentences were double coded. The defined items in the framework were not mutually exclusive. In other words, a sentence may be annotated as more than 1 individual theme. For example, this sentence “It really helped me, however I suffered from side effects.” was annotated as both as “effectiveness” and “perceived distress from adverse drug reaction.”

Calculating Interannotator Agreement

We used Cohen kappa to calculate interannotator agreement (IAA) [23]. The overall kappa score for the entire dataset was .75 with the highest value for perceived distress from ADR-low (.89) and the lowest for patient-physician interaction-positive (.50). To resolve the disagreement, instances of disagreement were reviewed and discussed by the same annotators who annotated the respective document earlier. For a specific item, annotation was added or removed if they were marked by any of the annotators, given that they both agreed on the decision. Otherwise, the sentences were labeled as “others.”

Table 2. Themes and subthemes used in the final analytical framework with examples.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse drug reactions-presence or absence</td>
<td>If the patient explicitly reported experiencing ADRs(^a) associated with the drug consumption.</td>
<td>“Effexor XR gave me horrible nightmares and I kept waking up.”</td>
</tr>
<tr>
<td>Perceived distress from ADRs-high</td>
<td>If the patient explicitly mentioned that they suffered from ADRs, used any qualifiers indicating severe ADRs, or indicated functional problems such as limitation in daily functioning because of ADRs.</td>
<td>“The side effects are intolerable.”</td>
</tr>
<tr>
<td>Perceived distress from ADRs-low</td>
<td>If the patient explicitly mentioned that the ADRs were tolerable and/or used qualifiers indicating mildness/transience persistency of ADRs.</td>
<td>“Any side effects were, for me, tolerable compared to the benefits.”</td>
</tr>
<tr>
<td>Perceived distress from ADRs-medium</td>
<td>If the perceived distress form ADR cannot be labeled as high or low, then it is medium.</td>
<td>“I suffered from headache.”</td>
</tr>
<tr>
<td>Withdrawal symptoms-presence or absence</td>
<td>If the patient explicitly reported experiencing any sign/symptoms associated with the process of dosage reduction or drug discontinuation.</td>
<td>“I weaned slowly and I feel nauseous a lot.”</td>
</tr>
<tr>
<td>WD(^b)-perceived distress-high</td>
<td>If the patients explicitly mentioned they suffered from withdrawal symptoms, functional problems associated with the WDs, or they used qualifiers indicating the severity of a specific WD.</td>
<td>“The withdrawal symptoms are horrible.”</td>
</tr>
<tr>
<td>WD-perceived distress-low</td>
<td>If the patient explicitly mentioned that the WDs were tolerable or used qualifiers indicting mildness/transience of WDs.</td>
<td>“Withdrawal was fine; When I stopped the drug, I had mild dizziness.”</td>
</tr>
<tr>
<td>Perceived distress from WDs-medium</td>
<td>If the perceived distress form WD cannot be labeled as high or low, then it is medium.</td>
<td>“When I tried to stop the drug, I had some dizziness.”</td>
</tr>
<tr>
<td>Drug effectiveness-effectiveness</td>
<td>A drug is effective if the patient reported that depression symptoms improved or resolved after drug consumption.</td>
<td>“For the first few weeks it helped me feel better.”</td>
</tr>
<tr>
<td>Drug effectiveness-ineffectiveness</td>
<td>A drug is ineffective if the patient reported that depression symptoms became worse or stayed the same.</td>
<td>“It did not help me at all.”</td>
</tr>
<tr>
<td>Patient-physician interaction-positive</td>
<td>A patient-physician interaction is positive, if the patient expressed their satisfaction from communications with clinicians.</td>
<td>“Success with these meds truly depends on staying in touch with your physician.”</td>
</tr>
<tr>
<td>Patient-physician interaction-negative</td>
<td>A patient-physician interaction is negative, if the patient expressed their dissatisfaction from communications with clinicians.</td>
<td>“Doctors do not understand the crazy side effects of starting this class of drugs.”</td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td>If the patient complained that they did not receive sufficient information about ADRs or WDs of the drugs and the mechanism of its management.</td>
<td>“No one informed me of the withdrawal nightmare.”</td>
</tr>
<tr>
<td>Experience of WD-unintentional</td>
<td>If the patient explicitly mentioned that they forgot to take medication (missing dosages) or ran out of medication, the discontinuation is unintentional.</td>
<td>“When I miss a day I feel very spaced out, thick, groggy, sad.”</td>
</tr>
<tr>
<td>Experience of WD-intentional</td>
<td>If the patient explicitly mentioned that they stopped (discontinue) the medication or they are in the process of discontinuation (weaning off or tapering off).</td>
<td>“I had to stop taking it.”</td>
</tr>
</tbody>
</table>

\(^a\)ADRs: adverse drug reactions.  
\(^b\)WD: withdrawal symptoms.
Preparing the Dataset for Analysis

Summarizing the Dataset
As data analysis was conducted at sentence level, an individual patient’s review may be annotated several times for availability of a theme. To summarize annotation for each patient’s review, multiple expressions of a theme for a single review were reduced to 1. If for a single review, perceived distress from ADRs or WDs was annotated as both high and low, we considered perceived distress-high as the representative of that single review. If a single review was annotated for both effectiveness and ineffectiveness, we retained both expressions of themes.

Strategy for Handling Missing Values
Strategies for handling missing values are composed of the following steps:

Elimination of the Missing Values
To handle the missing values, we first eliminated all the drug reviews with no text. Any review that did not provide information for the themes (variables) in the analytical framework was also removed from the dataset. The variable “patient-physician interaction” was also removed because of low IAA (50%) and high number of missing values.

Imputation of the Missing Values
To handle the rest of the missing values, we adopted different imputation methods depending on the nature of the missing values for each variable. For the variables “age,” “gender,” and “duration of usage,” missing values were imputed under the assumption of “missing completely at random”; that is, the missing values are a random sample of the complete data. The variable “age” was imputed by mean, “gender” by mode, and “duration of usage” by median. For “drug effectiveness,” the missing data were imputed under the “missing at random assumption.” Under this assumption, the missing values were modeled as a function of other variables in the dataset. The k-nearest neighborhood was used for estimating the missing values for this variable. For the rest of the variables, an individual drug review was annotated for the availability of the expression of that value (themes); otherwise, it was labeled as absent. Therefore, the variables did not include any missing values.

Data Analysis Methods
All analysis was conducted using R version 3.4.3. Descriptive statistics of central tendency and distribution were used to describe the key variables for the sample. Chi-square statistics were used to assess categorical associations. Analysis of variance was applied to study a mix of continuous and categorical variables. Ordinal logistic regression was used to model the relationship between the independent variables and attitude (dependent variable). Alpha value was set at .05 (two-tailed) for assessing statistical significance.

Results

Data Source Characteristics
Table 3 summarizes the characteristics of the data sample. The drug reviews were posted between February 2001 and February 2016. A total of 5 of the drug reviews did not have any text and were removed from the dataset. Approximately half of the patients were satisfied with the drugs specified in this study, indicating that unsatisfied patients are not dominant in the sample. The majority of the patients were female (680/892, 76.2%), which is in accordance with the report published by the Centers for Disease Control and Prevention showing that 2 times as many women use antidepressants as men [1]. Approximately two-thirds of the patients were aged less than 40 years, implying that younger patients are more willing to report their experiences with medications in online health care forums. Duration of medication usage ranged from 1 day to 20 years. Patients reporting an experience after 1 day might indicate concerns about drug mechanisms. Assessing duration of usage revealed that 37% of the reviews were made by patients in acute phase of depression treatment, 28% were reported by patients in the continuation phase of treatment, and 34% were reported by patients in the maintenance phase of treatment. This information indicates that drug reviews were almost evenly distributed between 3 phases of antidepressant treatment.

Frequency of the Variables
Table 4 shows the frequency of the variables in the sample. More than 90% of the patients reported that they experienced ADRs associated with antidepressants, whereas more than half reported they were distressed by the ADRs. Almost two-thirds of the patients reported that the antidepressants were effective in treating depression symptoms and improving functional abilities. Almost 30% of the patients reported intentional drug discontinuation, whereas only 5% reported unintentional drug discontinuation. Less than 10% of the patients provided any information on their perceived experience of communication with health care providers; therefore, we removed the variable patient-physician interaction from the data analysis.

Association Between Attitude and Variables
Analyses of associations were conducted to determine whether patients’ attitudes are associated with any of personal and clinical variables specified in the dataset. The variables “experience of ADRs” (χ²=31.1, P<.001), “ADR-PD” (χ²=231.6, P<.001), “drug effectiveness” (χ²=548.5, P<.001), “complaint about the lack of knowledge” (χ²=59.4, P<.001), “experience of withdrawal” (intentional and/or unintentional; χ²=55.6, P<.001), and “duration of usage” (F₄,₄874=43.66, P<.001) were strongly associated with patients’ attitude toward medications. However, age (F₄,₄874=0.72, P=.58) and gender (χ²=2.7, P=.21) were not associated with the patient attitude toward the drugs. In summary, the results support the hypotheses that clinical variables (experience of ADRs, perceived distress of ADRs, and drug effectiveness) and personal variable (complaint about the lack of knowledge about medications) were related to patients’ attitude toward antidepressants. However, the results did not support the hypotheses that age and gender were associated with patients’ attitude toward antidepressants.
Table 3. Sample statistics for reviews posted between February 2001 and September 2016 (N=892).

<table>
<thead>
<tr>
<th>Sample statistics</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reviews with text, n (%)</td>
<td>887 (99.4)</td>
</tr>
<tr>
<td>Number of reviews provided information for the variables of this study, n (%)</td>
<td>879 (98.5)</td>
</tr>
<tr>
<td><strong>Attitude</strong>&lt;sup&gt;a&lt;/sup&gt;, n (%)</td>
<td></td>
</tr>
<tr>
<td>Rated as 1</td>
<td>195 (22.2)</td>
</tr>
<tr>
<td>Rated as 2</td>
<td>104 (11.8)</td>
</tr>
<tr>
<td>Rated as 3</td>
<td>152 (17.3)</td>
</tr>
<tr>
<td>Rated as 4</td>
<td>209 (23.8)</td>
</tr>
<tr>
<td>Rated as 5</td>
<td>219 (24.9)</td>
</tr>
<tr>
<td><strong>Gender</strong>, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>680 (76.2)</td>
</tr>
<tr>
<td>Male</td>
<td>212 (23.8)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>37 (12.03)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>35 (14-83)</td>
</tr>
<tr>
<td><strong>Age categories (years), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>49 (5.6)</td>
</tr>
<tr>
<td>20-29</td>
<td>242 (27.5)</td>
</tr>
<tr>
<td>30-39</td>
<td>249 (28.3)</td>
</tr>
<tr>
<td>40-49</td>
<td>200 (22.7)</td>
</tr>
<tr>
<td>50-59</td>
<td>106 (12.1)</td>
</tr>
<tr>
<td>≤60</td>
<td>33 (3.8)</td>
</tr>
<tr>
<td><strong>Duration of usage (months)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>18 (31.7)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (1 day-240 months [20 years])</td>
</tr>
<tr>
<td><strong>Duration of usage categories, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;1 month</td>
<td>215 (24.5)</td>
</tr>
<tr>
<td>1 to &lt;3 months</td>
<td>116 (13.2)</td>
</tr>
<tr>
<td>3 to &lt;6 months</td>
<td>120 (13.6)</td>
</tr>
<tr>
<td>6 months to &lt;1 year</td>
<td>125 (14.2)</td>
</tr>
<tr>
<td>1 to &lt;2 years</td>
<td>82 (9.3)</td>
</tr>
<tr>
<td>2 to &lt;5 years</td>
<td>128 (14.6)</td>
</tr>
<tr>
<td>5 to &lt;10 years</td>
<td>66 (7.5)</td>
</tr>
<tr>
<td>≥10 years</td>
<td>27 (3.1)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Average of rating: 3.16.
Table 4. Frequency of variables in the dataset.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Frequency, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse drug reactions (ADR)</strong></td>
<td></td>
</tr>
<tr>
<td>Presence</td>
<td>823 (93.6)</td>
</tr>
<tr>
<td>Absence</td>
<td>56 (6.4)</td>
</tr>
<tr>
<td><strong>ADR-perceived distress</strong></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>483 (54.9)</td>
</tr>
<tr>
<td>Medium</td>
<td>230 (26.2)</td>
</tr>
<tr>
<td>Low</td>
<td>166 (18.9)</td>
</tr>
<tr>
<td><strong>Drug effectiveness</strong></td>
<td></td>
</tr>
<tr>
<td>Effectiveness</td>
<td>524 (59.6)</td>
</tr>
<tr>
<td>Effectiveness-ineffectiveness</td>
<td>120 (13.6)</td>
</tr>
<tr>
<td>Ineffectiveness</td>
<td>235 (26.8)</td>
</tr>
<tr>
<td><strong>Patient-physician interaction</strong></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>47 (5.3)</td>
</tr>
<tr>
<td>Positive</td>
<td>62 (7.1)</td>
</tr>
<tr>
<td>Negative-positive</td>
<td>4 (0.5)</td>
</tr>
<tr>
<td>Missing value</td>
<td>766 (87.1)</td>
</tr>
<tr>
<td><strong>Complain of the lack of knowledge</strong></td>
<td></td>
</tr>
<tr>
<td>Presence</td>
<td>60 (6.8)</td>
</tr>
<tr>
<td>Absence</td>
<td>819 (93.2)</td>
</tr>
<tr>
<td><strong>Experience of withdrawal (intentional and/or unintentional)</strong></td>
<td></td>
</tr>
<tr>
<td>No experience</td>
<td>508 (57.8)</td>
</tr>
<tr>
<td>Experience</td>
<td>371 (42.2)</td>
</tr>
<tr>
<td><strong>Unintentional withdrawal</strong></td>
<td></td>
</tr>
<tr>
<td>No report</td>
<td>831 (94.5)</td>
</tr>
<tr>
<td>Reported</td>
<td>48 (5.5)</td>
</tr>
<tr>
<td><strong>Intentional withdrawal</strong></td>
<td></td>
</tr>
<tr>
<td>No report</td>
<td>639 (72.7)</td>
</tr>
<tr>
<td>Reported</td>
<td>240 (27.3)</td>
</tr>
</tbody>
</table>

Modeling the Relationship Between Variables and Attitude

The relationship between attitude and the variables “experience of ADR,” “perceived distress of ADRs (ADR-PD),” “drug effectiveness,” “experience of WD,” “duration of usage,” and “complaint about the lack of knowledge” were modeled using ordinal logistic regression. The equation for the model is as follows:

\[
\text{Attitude} \sim \text{Experience of ADR} + \text{ADR Perceived Distress} + \text{Effectiveness} + \text{Experience of WD} + \text{Duration of Usage} + \text{Lack of Knowledge}
\]

The variables “age” and “gender” were excluded from this model because they were not significantly associated with the patients’ attitudes toward antidepressants. Table 5 shows the coefficient, the SE, and the P value for the outcome variables for this model. The coefficient for the variables in the predictive model shows that perceived ineffectiveness decreases the log odds of patients’ attitude toward antidepressants by 3.97 compared with perceived effectiveness. For ADR-PD, having ADR-PD low versus high changes the log odds by 1.93. For duration of treatment, for every additional day of treatment, the log odd of attitude increases by 0.0002. For the variables “experience of withdrawal,” “complaint of the lack of knowledge,” and “experience of ADR,” for every unit change in this variable (absence vs presence), the log odds of attitude changes by −0.7, −0.4, and −0.5, respectively. The results support the hypothesis that drug effectiveness is the most important factor affecting attitude toward antidepressants. Experience of ADRs compared with perceived distress of ADRs is a less important factor. A patient’s attitude toward antidepressants is influenced more by perceived distress received from ADRs than experience of ADRs.
Table 5. Coefficients of the variables in the predictive model.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SE</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience of ADR&lt;sup&gt;a&lt;/sup&gt;</td>
<td>−0.51</td>
<td>1.17e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ADR-PD&lt;sup&gt;b&lt;/sup&gt;-low</td>
<td>1.94</td>
<td>1.87e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ADR-PD-medium</td>
<td>0.81</td>
<td>1.58e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Base (ADR-PD-high)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effectiveness-ineffectiveness</td>
<td>−0.87</td>
<td>1.94e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Ineffectiveness</td>
<td>−3.98</td>
<td>2.12e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Base (effectiveness)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience of withdrawal</td>
<td>−0.7</td>
<td>1.38e-01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Complaint of the lack of knowledge</td>
<td>−0.43</td>
<td>3.22e-01</td>
<td>.17</td>
</tr>
<tr>
<td>Duration</td>
<td>0.00025</td>
<td>8.44e-05</td>
<td>.002</td>
</tr>
</tbody>
</table>

<sup>a</sup>ADR: adverse drug reactions.
<sup>b</sup>ADR-PD: perceived distress from ADRs.

Discussion

Principal Findings

In this study, we explored usability of the patients’ self-report experience in an online health care forum to generate hypotheses concerning the association between personal and clinical variables with attitude. We used a mixed-method approach to generate structured data from unstructured text, evaluate the hypotheses, and model the relationship between attitude and the identified variables. Our findings showed that in line with the literature, drug ineffectiveness [24,25], experience of ADR [26-28], lack of knowledge [29,30], and duration of usage were associated with negative attitude toward antidepressants. Association between variables “patient-physician interaction” and attitude was not tested in this study because of low IAA and high rate of missing values.

The demographic variables “age” and “gender” are not associated with levels of attitude. Our findings for age and gender are in agreement with the findings of the studies conducted by Jacob et al [31], Murata et al [27], and Ng at al [28]. However, these findings are in contrary to the findings of the study conducted by Prins et al [32].

Data analysis of this study showed that drug review posts in social media provide significant insight into patients’ perceptions and attitudes toward antidepressants as well as the pharmacological factors. However, they may not provide significant insights into patients’ intentional nonadherence because the key factor in defining adherence is the patient’s agreement with the health care provider’s treatment plan. Thus, further inquiry may be needed to determine whether the antidepressant discontinuation was in consultation with clinicians.

Implications of the Study

The findings of this study have significant implications for developing clinical interventions aiming to improve patient attitude and adherence toward medications. One major finding is that patients’ lack of knowledge about drug mechanism and potential adverse effects may negatively influence patient attitude toward antidepressants. Prescribers are therefore well advised to inform patients about the potential risks of antidepressants and assist them in achieving realistic expectation of the treatment. Another major implication of this study is that perceived distress received from ADRs and WDs are significant predictors for patients’ attitude and in turn, medication adherence. Clinicians could encourage patients to record adverse effects and their impacts on daily functioning to identify the patients’ actual experience with the drugs. This information may help clinicians tailor interventions to improve patients’ perception of medication and consequently adherence to the antidepressant treatment. Moreover, because patient attitude toward antidepressants are shaped by perceived drug effectiveness, and antidepressants’ full effects are not seen for typically 4 to 6 weeks, clinicians should track patients’ response and encourage them to complete an adequate trial. Several studies have shown that physician support can significantly improve patient attitude and adherence toward medications.

The dataset generated using the analytical framework can be used for designing a patient-driven self-report scale for measuring patient attitude toward antidepressants. This dataset shows how patients express their concerns, complaints, and feelings about pharmacological effects of antidepressants. Ultimately, using this colloquial language in designing self-report scale may reduce the risk of patient misinterpreting the questions.

The methodology of data analysis and the analytical framework developed in this study have significant implications for data analysis of patient experiences with pharmacologic agents collected in other health care forums or reported through patient portals.

Limitations

Several study limitations are worth noting:

1. Although patients’ self-report experience of the medications provides a significant insight into underlying factors affecting attitudes toward medications, self-reported
information is not a rich source of patients’ perceptions toward health care providers, general perceived need and concerns for medications, and perceived social support. In contrast, the Antidepressant Compliance Questionnaire and the Beliefs about Medicines Questionnaire scales measure these factors using a self-reporting method. Overall, drug reviews in online health care forums cannot be used as a replacement for self-report scales measuring patients’ attitudes toward antidepressants. However, they can serve as a supplementary source for measuring patients’ attitude toward antidepressants.

2. This dataset spans from 2001 to 2016. Although this dataset provides a general picture of the underlying factors affecting patients’ attitudes toward antidepressants, it does not reflect the changes in prescribing guidelines for antidepressants during the 15 years. Changes in the antidepressants’ dosages can affect patients’ experiences with ADRs and perceived effectiveness of the drugs. Future studies can compare the trend of patients’ attitudes toward antidepressants and changes in prescribing guidelines.

3. The sample of this study includes a combination of patients’ experience in acute, continuous, and maintenance phases of antidepressants treatment, ranging from 1 day to 20 years.

Although combining and analyzing patients’ experiences in different phases of treatment can provide an overall insight into the factors affecting patients’ attitude to antidepressants, it does not provide precise information about the underlying factors affecting each specific phase. Future studies may focus on a specific phase of antidepressant treatment to identify the underlying factors and compare the findings between the phases.

4. There is the concern that findings of the study may mostly reflect patients’ experiences at the maintenance phase of the antidepressant treatment. However, the statistics on the sample show that 37% of patients reported duration of treatment of less than 3 months, 28% reported between 3 months and less than 1 year, and 33% of the patients reported less than 1 year. This statistic indicates that the sample is a good representation of patients in different phases of treatment and long-time users are not dominant. Although the patients’ experiences with the medications are different and patients with longer experience may provide more information about the antidepressant, the majority of the patients provided information for the variables (themes) used for data analysis of this study.

5. Although the result of this study may be generalized to other antidepressants from the SSRI and SNRI class, it may not be generalized to other classes, such as the tricyclic antidepressants or the norepinephrine and dopamine reuptake inhibitors, as the ADRs and WDs may be different.

Since we collected the data from a single health care forum, there is a risk that the findings are not representative of patients in other online health care communities. The review posts in an online health care forum may also not be a representative source for all demographic groups. Some minorities, poor, or elderly patients may lack the literacy, access, or skill to report their experiences in an English-speaking online health care forum.

6. Although online health care forums provide a platform for patients to report their perceptions and attitudes toward medication freely, the risk of inaccurate reporting and false information cannot be eliminated.

7. Even though the dataset is double coded, there is the possibility that annotators did not interpret a sentence correctly and therefore assigned it to a wrong theme.

8. Although patients in the health care forum reported their major concerns about medications, the forum does not prompt patients to report their experience with withdrawal or drug effectiveness. Therefore, some patients may not report their experiences for the variables, causing bias in data analysis.

9. Finally, there is a concern for negative response bias as the patients voluntarily choose to share their experience online. However, almost 50% of patients in this study were satisfied or highly satisfied with their antidepressant medications, compared with only 35% of patients who were dissatisfied or highly dissatisfied. In addition, nearly half of the reviewers used the antidepressants for more than a year. Both findings suggest that the reviewers were not the most dissatisfied patients using antidepressants in this health care forum.

Future Work

Several future research directions are suggested by the results. First, the analytical framework developed in this study may be applied for analysis of patient self-reported experiences for other types of medications. Analyzing data using this framework can assist researchers in identifying underlying factors associated with patients’ attitudes and perceptions as well as medication discontinuation. Another area for inquiry is to identify and normalize patients’ expressions of ADRs and WDs of the antidepressants, then measure their associations with patients’ attitude. Current studies measuring adverse effects associated with antidepressants use the Antidepressants Side-Effect Checklist, which does not include a comprehensive list of the ADRs. Exacting the ADRs from patients’ experiences may address the limitation of the self-report scales. Finally, the dataset generated in this study can be used for training text mining algorithm and machine learning systems to automatically extract from patients’ expressions, the wide range of information related to adverse effects of drugs.

Conclusions

In this study, we showed that self-report experiences of a drug by patients in an online health care forum could provide a unique insight into identifying underlying factors associated with patients’ perceptions and attitudes to antidepressants. However, it cannot be used as an alternative for self-report scales and interview methods due to its lack of information for some of the variables, colloquial language, and the unstructured format of the data. The data analysis also showed that drug reviews might not be a reliable source for predicting patients’ intentional nonadherence behavior. Further inquiry may be needed to determine whether the medication discontinuation was in consultation with clinicians or not.
Acknowledgments
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Conflicts of Interest
None declared.

References


**Abbreviations**

ADR: adverse drug reaction  
ADR-PD: perceived distress from ADRs  
IAA: interannotator agreement  
SSRI: selective serotonin reuptake inhibitor  
SNRI: serotonin-norepinephrine reuptake inhibitor  
WD: withdrawal symptom
Identifying the Underlying Factors Associated With Patients' Attitudes Toward Antidepressants: Qualitative and Quantitative Analysis of Patient Drug Reviews

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doi:10.2196/10726
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Individualized Web-Based Exercise for the Treatment of Depression: Randomized Controlled Trial

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Abstract

**Background:** Due to the high prevalence of depressive disorders, it is mandatory to develop therapeutic strategies that provide universal access and require limited financial and human resources. Web-based therapeutic approaches fulfill these conditions.

**Objective:** The objective of our study was to assess the feasibility, acceptability, and efficacy of a supervised, individualized 8-week Web-based exercise intervention conducted for patients with moderate to severe depression.

**Methods:** We recruited 20 patients with unipolar depression and randomly assigned them into 2 groups (intervention, exercise program group, n=14, and control, treatment-as-usual group, n=6). At baseline, depressive symptoms were rated via the Quick Inventory of Depressive Symptomatology (QIDS) by patients themselves (QIDS–self-report, QIDS-SR) and by a blinded psychiatrist (QIDS–clinician rating, QIDS-C). In addition, performance diagnostics (lactate analysis, spiroergometry during a treadmill walking test) were conducted. Quality of life was assessed via the Short Form-36 questionnaire (SF-36) and self-efficacy via the General Self-Efficacy scale (GSE). In addition, habitual physical activity (HPA) was determined via the Baecke questionnaire. Participants of the intervention group received exercise schedules once weekly with endurance and strength training instructions. Rating of depressive symptoms was repeated after 6-12 days and 8 weeks; performance diagnostics and the completion of all the questionnaires were repeated after 8 weeks only.

**Results:** The severity of depression subsided significantly in the intervention group after 8 weeks (median change in QIDS-SR: −5; interquartile range, IQR: −2 to −10), although it was already evident within the first 6-12 days (median change in QIDS-SR: −6; IQR: −2 to −8). During the intervention, participants undertook a median of 75 (IQR: 63 to 98) minutes of endurance training per week or 84% (16 [IQR: 9 to 19] of 19 [IQR: 15 to 21]) recommended endurance units in total. In addition, 9 (IQR: 4 to 12) of 10 (IQR: 8 to 13) recommended strength training exercise units were conducted during the 8 weeks. Performance diagnostics revealed a substantial increase in the maximum output in Watt for the intervention group after 8 weeks. Moreover, the intervention showed a favorable effect on SF-36 items “emotional well-being” and “social functioning” as well as on GSE and HPA scores.

**Conclusions:** Our individualized Web-based exercise intervention for moderate to severe depression was highly accepted by the patients and led to a significant and clinically relevant improvement of depressive symptoms.

**Trial Registration:** ClinicalTrials.gov NCT02874833; https://clinicaltrials.gov/ct2/show/NCT02874833 (Archived by WebCite at http://www.webcitation.org/72ZUUR4tE)

**KEYWORDS**

depression; exercise; Web-based intervention; eHealth


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(page number not for citation purposes)
Introduction

Unipolar depression or major depressive disorder (MDD) is the worldwide leading cause of disability [1] with a life time prevalence of around 17% [2]. MDD is commonly treated with either antidepressive medication or psychotherapy or both [3]. However, side effects of and an often skeptical attitude toward pharmacotherapy lead to poor compliance [4]. In addition, about 30%-50% of patients do not respond adequately to antidepressants [5,6]. On the other hand, personalized psychotherapy requires high personal effort, especially for highly prevalent diseases such as MDD. However, such high personnel expenses cannot be implemented, especially in rural areas. The resulting imbalance of supply and demand leads to waiting periods of several months [7]. Thus, the development of easily accessible, cost-saving, ubiquitous, and effective treatment strategies, well accepted by patients, is of great importance in health politics. In this study, we exploited such an innovative form of therapy in terms of an individualized, supervised, Web-based exercise therapy in patients with MDD and moderate to severe depressive symptoms. We chose this approach because physical activity is currently recommended as a safe and effective adjunctive therapy in the treatment of MDD in numerous national guidelines [8-10].

To the best of our knowledge, this is the first Web-based exercise approach in the treatment of MDD. Previous Web-based trials on depression have focused on self-help and cognitive behavioral therapy (CBT) [11-13]. Meta-analyses assessing the effectiveness of these interventions on depression severity have reported variable results [14,15]. However, moderate effects on depressive symptoms were reported when Web-based CBT was offered in an individually tailored form [16]. Accordingly, our Web-based exercise program was monitored and individually adapted for each patient.

So far, Web-based exercise therapy has been applied to a variety of patient groups such as type 2 diabetes patients [17,18], breast cancer survivors [19], or osteoarthritis patients [20]. The outcomes in the respective studies were promising in terms of improved blood sugar parameters [18], reduced fatigue [19], or an enhanced activity level [18-20]. Thus, Web-based exercise interventions have a remarkable potential for improving health-related outcomes.

In the last years, exercise has garnered growing interest as a component in the treatment of depression. Evidence suggests that exercise may lead to a marked reduction in depressive symptoms, comparable with pharmacotherapy, after 16 weeks [5,21]. The latest Cochrane Review [22] reported a moderate clinical effect of exercise on depressive symptoms. However, if only studies with high methodological quality were considered, the effects of exercise were shown to be only small to moderate, in line with the meta-analysis of randomized controlled trials by Krogh et al [23] and Joseffson et al [3]. In contrast, a more recent meta-analysis supported the assumption of an underestimation of exercise effects on depressive symptoms due to publication bias [24]. In sum, further standardized studies are needed to give a robust estimate about the therapeutic effect size of exercise.

It has not yet been clarified which type, duration, and intensity of exercise is most effective in depression [22] and whether there are exercise-specific physiological changes that mediate antidepressive effects [25]. The specific psychological or biological mechanisms through which physical activity may lead to positive effects on depressive symptoms remain a matter of current research. However, exercise seems to be a promising adjunctive therapy option for depression, given that there exists no specific monomodal therapy that is effective in every patient [21].

In contrast to previous exercise studies on depression [5,26,27], we developed an individualized Web-based approach that did not schedule attendance exercise sessions. The purpose of this study is to evaluate (1) the feasibility and (2) the antidepressive effects of our Web-based exercise program.

Methods

General Information and Ethics

The multidisciplinary single-center trial was a collaboration between the Department of Psychiatry and Psychotherapy and the Institute of Sports Medicine of the University of Mainz. The study was designed as a feasibility study, which would be continued with higher sample sizes and under participation of multiple centers if the study provided promising outcomes. All procedures were approved by the regional Ethical Board Mainz, Germany. Previous and ongoing treatment was not affected by study participation.

Inclusion Criteria

Patients who fulfilled the following criteria were included in the study:

1. Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use confidential health information in accordance with national and local subject privacy regulations
2. Sufficient computer or internet literacy to get along with our internet platform
3. Aged 20-65 years, inclusive, at the time of informed consent
4. Montreal Cognitive Assessment [28] >18 to exclude moderate to severe cognitive impairment
5. Apart from a clinical diagnosis of major depression or bipolar affective disorder, the subject must be in good health as determined by the investigator based on medical history and physical examination.
6. Quick Inventory of Depressive Symptomatology (QIDS) scores >5
7. No changes in antidepressive therapy in the 4 weeks before study entry

For detailed exclusion criteria, please refer to ClinicalTrials.gov (NCT02874833).

Participants and Randomization

Participants were recruited offline between July 2016 and October 2017 through local outpatient psychiatrists. Two patients disclaimed our offer to participate in the study. A total of 20 participants with depressive symptoms were enrolled after...
2 of 22 patients were excluded due to myocardial inflammation and pregnancy. Patients did not receive any compensation for participating in the study.

For randomization, numbers between 0 and 1 were randomly computer generated and used for assignment to either the control group (values ≤.3) or intervention group (IG; values of >.3). At baseline (T0), depressive symptoms were rated by patients themselves and by a blinded psychiatrist (SL or CK). Thereafter, patients were subjected to performance diagnostics (lactate diagnostics, spiroergometry), which was followed by either an 8-week supervised, individualized Web-based exercise program (IG) or treatment as usual (control group). Within 6-12 (median: 9) days after T0, the rating was repeated (T1). The final examination, including clinical rating and performance diagnostics, took place after 8 weeks (T2). Controls underwent all examinations, while any other form of existing therapy (eg, antidepressive medication) was not affected (Figure 1).

**Intervention and Internet Platform**

IG patients gained access to our home page (Figure 2) and were provided with a heart rate monitor (Polar FT1; Polar Electro, Büttelborn, Germany) and 4 different types of resistance bands (Thera-Band, Akron, OH, United States). The platform was designed to be user friendly [29]. Message function was used to send exercise schedules to the patients once weekly. After each week, motivational feedback was given to improve adherence [30,31].

Schedules included the recommended extent of exercise with a maximum of 3 endurance and 2 strength training units per week. An additional group training session was offered biweekly by a sports therapist. At the end of each week, patients were expected to upload a protocol of their weekly activity on our platform, making the protocol available to the supervisor. Based on this response, training goals were individually adapted in the duration and intensity for the following week to keep motivation high and prevent patients from overload and frustration.

**Structure of Weekly Exercise**

Endurance exercise recommendations were based on heart rate (baseline +1.5 mmol model [32]) with a duration of 30-60 minutes per unit; this has been proven to be effective in the reduction of depressive symptoms [5,27,30]. However, as suggested by Craft and Landers [33] and in line with guidelines [34], it was necessary for some untrained or unexperienced subjects to start with a more moderate duration of 20 minutes per session and 2 units per week. Patients with a poor exercise capacity were recommended to start with walking instead of jogging. By taking these personal preferences and individual conditions into account, we aimed at achieving high adherence [27,30]. Furthermore, adjustment and weekly progression of the endurance training were assessed via Borg scale [35] (Figure 3) to keep the intensity in a moderate to vigorous range according to common guidelines and recommendations [8,9,30].

If patients reported Borg values to be <4, training intensity was moderately increased [36] in terms of an expanded duration of approximately 10 minutes per week or by recommending a higher average heart rate, leading to a higher intensity. In case of fatigue or injury or if exercise was too hard (Borg>7), intensity and duration were reduced according to patients’ request. In this case, alternative units such as relaxing were recommended. Furthermore, strength training exercises for major muscle groups were performed at home following the detailed instructions provided on our home page. Progression was ensured with increased sets and repetitions or by changing the type of resistance band.
Figure 1. Flowchart of the study.
**Figure 2.** Design of our home page with chat and message function, training videos, and upload area for training schedules.

**Figure 3.** Activity protocol of one participant; patients responded after each week by uploading their filled protocol either as a scan or a Word document. In this example, intensity and duration of the endurance training was recommended to be increased, whereas the intensity of the strength training was advised to be decreased.

<table>
<thead>
<tr>
<th>Training Units Conducted</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endurance training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>duration (in minutes)</td>
<td>32</td>
<td></td>
<td>30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>subjective intensity (6-10)</td>
<td>2</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>average heart rate (bpm)</td>
<td>125</td>
<td></td>
<td>121</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>highest heart rate (bpm)</td>
<td>158</td>
<td></td>
<td>157</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>complaints (pain, problems,…)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>other (particularities)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Strength training</strong></td>
<td></td>
<td>3 Sets, 12 Reps</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>subjective intensity (6-10)</td>
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<td>0</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>complaints (pain, problems,…)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>other (particularities)</td>
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</tbody>
</table>

**Evaluation of Primary Outcomes**

**Adherence**

Adherence has been defined as attendance, lack of dropout, participation rate, or the fulfillment of predefined goals [37]. IG patients dropped out if no protocol was uploaded for >2 weeks. Controls, however, dropped out if they failed to attend the final examination at T2 [38]. The participation rate in our exercise program was defined as (1) training units conducted and (2) the ratio of training units conducted and training units recommended [21,38]. Data were extracted from the weekly protocols of participants (Figure 2). All units that did not count to regular, prescribed strength or endurance exercise, such as hiking or relaxing, were counted as alternative units. In addition, after T2, using a self-developed questionnaire among patients, we evaluated satisfaction with our program and reasons for not meeting our exercise recommendations.

**Depression Scales**

The severity of depressive symptoms was determined using QIDS (clinician rating, QIDS-C, and self-report, QIDS-SR) [39]. Rating was conducted at baseline, at T1 within 6-12 days, and after 8 weeks. QIDS scores can range from 0 to a maximum of 36. QIDS showed good internal consistency (Cronbach alpha=.86), and QIDS-SR16 total scores highly correlated with IDS-SR30 (r=.96) and HAM-D24 (r=.86; [39]).
Evaluation of Secondary Outcomes

Self-Efficacy, Quality of Life, and Habitual Physical Activity

The Short Form-36 (SF-36) Quality of Life questionnaire [40] was filled out by every patient at baseline and after 8 weeks. SF-36 items show high reliability (Cronbach alpha >.85, reliability coefficient >.75) and construct validity [41]. In addition, the General Self-Efficacy scale (GSE) [42] and habitual physical activity (HPA) [43] were assessed at T0 and T2.

Physiological Parameters

After clinical rating and answering questionnaires, all patients performed a treadmill walking test until exhaustion to determine peak oxygen uptake (VO2 peak) and lactate threshold. Slope and velocity were increased stepwise after 3 minutes of walking at a time, as described elsewhere [36]. Lactate samples were drawn after every step to determine lactate threshold using the baseline +1.5 mmol model [32]. Maximum output in Watt was determined using the formula: 9.81 × weight (kg) × velocity (m/s) × sin α.

Statistical Methods

For statistical analysis, we used JMP13 (SAS, Cary, NC, USA), SPSS 23 (IBM, Chicago, IL, USA), and the software package R, version 3.4.2 (2017-09-28, R Foundation for Statistical Computing, Vienna, Austria). Differences in baseline characteristics were examined using Mann-Whitney U test. The correlation between QIDS-SR and QIDS-C was calculated using Spearman’s rank correlation coefficient. In addition, comparisons at different time-points were determined using Wilcoxon signed-rank test and Bonferroni correction for multiple testing. To evaluate the influence of the intervention compared with that of the control condition, analysis of covariance (ANCOVA) was performed for each outcome. The outcomes at T2 served as dependent variables and the ones at T0 as covariates. To exclude a violation of ANCOVA preconditions, we tested for normal distribution in the residuals of the dependent variable and for homogeneity of regression slopes by analyzing the interaction term of independent variable × covariate. Furthermore, P < .05 was considered as statistically significant.

For the explorative analysis of the trajectories of the QIDS-SR and QIDS-C measures, we fit multilevel linear models. Hereby, the number of training units in the actual number of days in the program after T0 was used as covariates, and the observations for individuals were nested in the respective groups, that is, intervention or control. Furthermore, the log-linear transformation of the response variables QIDS-SR and QIDS-C showed better model fit, hinting at an exponential decay over time. For the covariate analysis, missing data were dealt with by using the last observation carried forward method. In the explorative multilevel analysis, missing data were omitted from the dataset.

Results

Patients’ Characteristics

All patients included were diagnosed with major depression, none with bipolar affective disorder. Of all, 14 patients were assigned to the IG, while 6 patients served as controls. Table 1 outlines the clinical characteristics of the patients at baseline. Of note, 15% (3/20) patients dropped out after T1 and before T2, while all 6 IG patients, while all 20 controls completed the study. Dropouts were because of missing responses for >2 weeks after T1 (Figure 1). Medication did not change over the course of the study, except for 1 IG subject for whom a dosage reduction of an antidepressive drug was prescribed by the treating physician.

At baseline, patients rated their depressive symptoms with a mean QIDS-SR score of 16, that is, severe depressive symptoms, whereas QIDS-C was rated slightly lower at 14, representing moderate depressive symptoms [39]. QIDS-SR and QIDS-C scores were correlated with each other (r=.64, P < .001). The mean physical fitness in terms of VO2 peak was determined at 26 mL/min/kg, which matches the predicted values of healthy subjects, adjusted for sex, age, and weight [44].

Adherence

The dropout rate for IG was 21% (3/14), while all controls completed the study. In the IG, a median of 75 (interquartile range, IQR: 63 to 98) minutes of endurance exercise was performed per week. Overall, 84% (16 [IQR: 9 to 19] of 19 [IQR: 15 to 21]) recommended endurance units were completed. In addition, patients undertook 90% (9 [IQR: 4 to 12] of 10 [IQR 8 to 13]) recommended strength training units during the intervention. Four (IQR: 2 to 28) optional, alternative training units, such as relaxing, hiking, or yoga, were furthermore executed during 8 weeks. The offer to join group training with a sports therapist was accepted by 1 patient only.

Self-reported reasons for missing the prescribed training were as follows: orthopedic problems (n=4), depressive symptoms (n=4), illness (n=3), or work (n=2). Moreover, our questionnaire revealed that 9 of 11 patients did not fear any injury, all of the 11 patients saw no risk during exercise, 9 of 11 patients revealed that 9 of 11 patients did not fear any injury, all of the 11 patients saw no risk during exercise, 9 of 11 patients perceived communication through our platform as “personal,” and 10 of 11 patients assessed the number of weekly training sessions as adequate.

Effects on Depressive Symptoms After 8 Weeks

Figure 4 outlines scores of the depression scales QIDS-SR und QIDS-C at T0 and T2 in both groups. Depressive symptoms significantly decreased in IG during the 8-week intervention, as reflected in both QIDS-SR (median change: −5; IQR: −2 to −10; P = .001) and QIDS-C (median change: −5; IQR: −2 to −7; P = .02) scores. However, symptom relief was not different to controls. A reduction in depressive symptoms of ≥50% was shown via QIDS-SR in 36% (5/14) IG patients and via QIDS-C in 21% (3/14) IG patients. ANCOVA revealed no statistically significant difference between the IG and control group. However, 1 patient in the control group showed a striking improvement in depressive symptoms from a QIDS-SR score of 22 at baseline to 2 at T2.
Table 1. Patients' characteristics at baseline.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Exercise group</th>
<th>Controls</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 (29)</td>
<td>3 (50)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Female</td>
<td>10 (71)</td>
<td>3 (50)</td>
<td>13 (65)</td>
</tr>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>43 (14)</td>
<td>51 (12)</td>
<td>45 (14)</td>
</tr>
<tr>
<td><strong>Height (cm), mean (SD)</strong></td>
<td>171 (8)</td>
<td>168 (7)</td>
<td>170 (8)</td>
</tr>
<tr>
<td><strong>Weight (kg), mean (SD)</strong></td>
<td>77 (17)</td>
<td>88 (11)</td>
<td>80 (16)</td>
</tr>
<tr>
<td><strong>Body mass index (kg/m^2), mean (SD)</strong></td>
<td>26.5 (5.6)</td>
<td>31.3 (4.3)</td>
<td>27.0 (5.6)</td>
</tr>
<tr>
<td><strong>Depression scores, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QIDS-SR^a</td>
<td>16 (3)</td>
<td>17 (4)</td>
<td>16 (3)</td>
</tr>
<tr>
<td>QIDS-C^b</td>
<td>14 (3)</td>
<td>15 (1)</td>
<td>14 (3)</td>
</tr>
<tr>
<td>Montreal Cognitive Assessment, mean (SD)</td>
<td>26 (2)</td>
<td>26 (3)</td>
<td>26 (2)</td>
</tr>
<tr>
<td><strong>Spiroergometry, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VO\textsubscript{2} peak\textsuperscript{c} (mL/min/kg)</td>
<td>27.0 (7.6)</td>
<td>23.8 (5.9)</td>
<td>26.0 (7.1)</td>
</tr>
<tr>
<td>Maximum output (Watt)</td>
<td>112 (37)</td>
<td>110 (55)</td>
<td>112 (42)</td>
</tr>
<tr>
<td><strong>Treatment at study entry, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychotherapy alone</td>
<td>2 (14)</td>
<td>0 (0)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Psychopharmacotherapy alone</td>
<td>7 (50)</td>
<td>3 (50)</td>
<td>10 (50)</td>
</tr>
<tr>
<td>Psychotherapy and psychopharmacotherapy</td>
<td>3 (21)</td>
<td>3 (50)</td>
<td>6 (30)</td>
</tr>
</tbody>
</table>

^aQIDS-SR: Quick Inventory of Depressive Symptomatology-self-reported.  
^bQIDS-C: Quick Inventory of Depressive Symptomatology-clinician-rating.  
^cVO\textsubscript{2} peak: peak oxygen uptake.

Figure 4. Depression scores of the controls and intervention group (IG) on the Quick Inventory of Depressive Symptomatology-self-reported (QIDS-SR; left) and QIDS-clinician rating (QIDS-C; right) at baseline (T0) and after 8 weeks (T2).
Early Antidepressive Response

Figure 5 shows depression scores of T1 after 6-12 days compared with the baseline. Depressive symptoms in IG were significantly reduced, as reflected in both QIDS-SR (median change: −6; IQR: −2 to −8; \( P=0.003 \)) and QIDS-C (median change: −3; IQR: −2 to −6; \( P=0.04 \)) scores. ANCOVA showed an estimated advantage for IG at T1 in the QIDS-SR score of −3.1 points (coefficient B). However, this effect was not statistically significant (\( P=0.06; \text{Eta}^2=0.2 \)). An early response of >50% reduction was observed for 36% (5/14) patients in QIDS-SR scores and for 21% (3/14) patients in QIDS-C scores. A depressive symptom reduction of ≥20% [45] was observed for 71% (10/14) patients in QIDS-SR scores and for 50% (7/14) patients in QIDS-C scores, while only 33% (2/6) controls showed an early response of ≥20% in both the QIDS-SR and QIDS-C scores.

Self-Efficacy, Quality of Life, and Habitual Physical Activity

Figure 6 shows the effect of the intervention and treatment as usual on GSE. ANCOVA revealed a positive influence of the intervention on SF-36 quality-of-life items “emotional well-being” (\( P=0.02, \text{Eta}^2=0.29 \)) and “social functioning” (\( P=0.04, \text{Eta}^2=0.23 \)), while the total quality-of-life score (\( P=0.07 \)) and the item “mental health” (\( P=0.08 \)) showed an estimated advantage. As expected, IG showed a higher level of physical activity than controls, reflected in total HPA (\( P=0.007, \text{Eta}^2=0.36 \)) and HPA items “leisure time” (\( P=0.02, \text{Eta}^2=0.27 \)) and “sport” (\( P=0.001, \text{Eta}^2=0.51 \)).

Effects on Physiological Performance Parameters

Figure 7 illustrates the physiological parameters in terms of VO\(_2\) peak and maximum output in Watt. IG patients showed an improvement in VO\(_2\) peak of 0.7 mL/min/kg while VO\(_2\) peak of controls declined by 1.6 mL/min/kg. The maximum output in Watt was improved by 4% in the IG, while that in controls declined by 9% after 8 weeks. Compared with controls, ANCOVA revealed no statistically significant influence on the IG regarding VO\(_2\) peak (\( P=0.07 \)) and lactate threshold (\( P=0.09 \)), but showed a significant influence on the maximum output in Watt (\( P=0.006; \text{Eta}^2=0.37; B=14.1 \)).

Explorative Multilevel Analysis

With respect to QIDS-SR, the multilevel analysis showed a statistically significant effect of day of the measure (estimate: −0.01 on the log-linear scale, \( P<0.01 \)) and number of training units (estimate: −0.07 on the log-linear scale, \( P=0.05 \)) as well as their interaction term (estimate: 0.001 on the log-linear scale, \( P=0.04 \)). Similar effects could be determined for QIDS-C with respect to the day of measure (estimate: −0.01 on the log-linear scale, \( P<0.01 \)) and its interaction term with training units (estimate: 0.001 on the log-linear scale, \( P=0.05 \)). The number of training units did not show a statistically significant effect on QIDS-C (\( P=0.07 \)).

Side Effects of the Intervention

Beside minor orthopedic problems in 4 cases, no side effects of regular exercise were reported by the patients.
Figure 6. General self-efficacy scores at T0 (baseline) and T2 (after 8 weeks). Analysis of covariance revealed a favorable effect on the General Self-Efficacy scale for the intervention group (IG) compared with the controls ($P=.02$, $\eta^2=0.28$).

Figure 7. Peak oxygen uptake (VO2 peak; left) and maximum output in Watt (right) at baseline (T0) and after 8 weeks (T2) for the intervention group (IG) and the controls.

Discussion

Principal Findings

Due to the high prevalence, high personnel expenses, and therapeutic costs of MDD, it is desirable to have therapeutic strategies at hand that are effective and provide universal access with limited financial and human resource requirements. Web-based and computerized therapeutic approaches have been found to be promising to fulfill these claims [46]. To date, the focus has been on CBT [11,47] or self-help [12] internet therapy. Exercise has been suggested as an augmentation or alternative therapy for depressed patients [9,22]. Here we show for the first time that an 8-week Web-based exercise intervention with individualized weekly training schedules is feasible and effective in patients with moderate to severe depressive symptoms.

Adherence

During the 8-week intervention, patients conducted 84% (16/19) of recommended endurance units and 90% (9/10) strength training units, which exceeds [48] or is comparable to the adherence reported in previous studies regarding attendance [5,27] or home-based exercise, that is, exercising at home with regular contact to the supervisor [21].

The depression severity in this study was moderate to severe, that is, higher than that in previous trials that investigated the effects of exercise on depressive symptoms [21,26,27]. Christensen et al [38] reported that the probability of adherence in Web-based therapeutic trials decreases with the severity of
depression. It is, thus, somewhat surprising that adherence in this study was comparable to that in previous ones [5,21,27]. The dropout rate in our study was 21% in the IG, comparable to personalized psychotherapy [49] but probably lower than that for psychotropic drugs. Up to 50% do not adhere to their antidepressants [50].

The high therapeutic adherence in our study might partially be attributed to the preferential recruitment of patients with a relatively high interest in sports. Our patient sample reached the predicted VO₂ peak values [44], in contrast to the expected lower physical fitness values in depression [51]. This suggests that the physical fitness of our participants was higher-than-average for patients with depression. The Web-based exercise might, therefore, be a preferred therapeutic option for patients with depression who were physically active before the manifestation of the depressive disorder.

**Efficacy in Major Depressive Disorder**

IG patients showed a significant decline in depressive symptoms after 8 weeks in both self- and clinician rating. Moreover, the intervention led to a significant improvement in self-efficacy and quality-of-life items “emotional well-being” and “social functioning.”

Interestingly, we had already observed a significant IG response within 6-12 days of the commencement of the study. Both QIDS-SR and QIDS-C scores were reduced by ≥50% in 36% (5/14) and 21% (3/14) patients, respectively. An early reduction of ≥20% in depressive symptoms was assessed in 71% (10/14) patients in QIDS-SR scores and in 50% (7/14) patients in QIDS-C scores, which is comparable to the response rate to selective serotonin reuptake inhibitors (78%) within the first 14 days of treatment reported in a previous study [45]. However, the early response rate to selective serotonin reuptake inhibitors, as described by Tadic et al [45], is likely to be overestimated as it was evaluated under conditions of inpatient treatment that entails multimodal therapy with several putative antidepressive factors.

Because it is unlikely that exercise results in physiological adaptations within 2 weeks, an early improvement in depressive symptoms may rather be attributed to the increased self-efficacy and/or further factors such as personal contact, care, motivation, ongoing monitoring, and patient expectations toward a positive effect [21,30], that is, factors that are suggested to contribute to placebo effects. Early antidepressive effects of exercise may be mediated by these placebo effects [52], but they may also be explained by the following: (1) disengaged higher-order functions of the prefrontal cortex to keep unhelpful emotional processes from compromising optimal motor execution (transient hypofrontality hypothesis [53]); (2) the dual-mode theory of affective responses to exercise [54]; or (3) the opponent-process theory of emotion [55]. However, even if placebo effects were mainly responsible for the early positive effects of exercise, this would not devalue exercise as a therapeutic option because placebo effects are likely to constitute a large proportion of the response to antidepressants as well [56].

In contrast to the initial antidepressive effects, the sustained reduction in depressive symptoms after 8 weeks could be attributed to physiological adaptations triggered by exercise. Regular physical activity over several weeks might have provoked a complex interaction of psychological (eg, increased self-efficacy) and neurobiological (eg, increased serotonin synthesis in the brain) adaptations [31]. As the explorative multilevel analysis revealed, an exponential decay model can be expected for the treatment. Thus, both a time-function and the number of training units per time should be included in future analyses to model the trajectories of the QIDS-SR and QIDS-C variables.

**Comparison to Web-Based Cognitive Behavioral Therapy**

Computerized CBT (cCBT) is highly accepted [57] and has garnered increasing attention due to its capability to deliver a potentially effective and efficient therapeutic method to large numbers of people with depression. However, independent evaluations of cCBT have failed to prove relevant clinical benefits in depression [15] unless offered in an individually tailored form [16]. In this study, depressive symptoms declined with individualized Web-based exercise therapy. This therapeutic approach has, thus, a similar potential as individually tailored cCBT. However, in contrast to cCBT, it has the advantage of being cognitively little demanding. In this study, 40% of depressive participants showed a Montreal Cognitive Assessment score of <26, indicating mild cognitive impairment. In depression, attentional and executive functions are often affected, which limits the patients’ capability to follow the cognitive demanding instructions of cCBT. Another advantage of exercise is its positive influence on cardiovascular risk factors, the immune system, bone metabolism, and others [58], which helps prevent somatic disorders such as cardiovascular and cerebrovascular diseases and type 2 diabetes mellitus [26], to which patients with chronic depression are more vulnerable than others. However, a Web-based exercise program has the disadvantage that people must be motivated and physically able to perform exercise therapy. This is a particular challenge in depression because people with depression are, on average, physically little active [59,60]. Thus, it is likely that individualized Web-based exercise will be accepted by a subgroup of depressive patients only. However, patients’ acceptability can be enhanced by starting with a lesser number of exercise units (2 instead of 3) with individually adapted moderate intensity and by providing regular motivational feedback.

**Study Limitations**

One objective of this study was to evaluate the acceptability of individualized Web-based exercise therapy and its effects on depressive symptoms. The study was, thus, designed as it is appropriate for a feasibility study. Hence, the sample size was rather small, especially for the control group (n=6). Furthermore, 1 participant in the control group showed full remission at T2 from severe depressive symptoms at study entry, entailing a probable overestimation of antidepressive effects in the control group. Thus, comparisons between the intervention and control groups should be considered as little valid.

Another limitation of this study is its duration of 8 weeks. The exercise duration of 8 weeks with constant 3 endurance units per week usually results in an improvement of all physiological performance parameters (VO$_2$ peak, lactate threshold, and maximum output in Watt) [61] On the basis of the results reported by Blumenthal et al [21], we expected that patients with MDD would be able to perform constantly 3 endurance exercises per week. However, most of our patients with MDD were only capable of starting with 2 endurance units per week. Thus, our 8-week exercise intervention led merely to a significant increase in the maximum output in Watt but not in VO$_2$ peak and lactate threshold. We, hence, recommend performing regular endurance exercise for, at least, 10 weeks to achieve an improvement in all physiological performance parameters in future MDD studies. This is in line with a previous recommendation for the prescription of exercise in MDD [30]. IG participants performed, on average, 75 minutes of weekly endurance exercise over the 8 weeks. This only meets the minimum level of required exercise for both healthy and depressed subjects [9,34,62], which in combination with the short intervention may have led to a nonsignificant improvement of physiological performance parameters. Nonetheless, patients also benefit from a small amount of physical activity [63]. Follow-up data were not obtained in this feasibility study. Hence, data on the long-term effects of our exercise intervention are missing. Follow-up data on the long-term effects of exercise in MDD are limited in literature, but they indicate a sustained benefit on depressive symptoms [64,65], with a significant number of patients continuing exercise on their own [66]. Babyak et al [65] showed that the antidepressive effects of aerobic exercise were sustained over a follow-up period of 6 months; interestingly, patients in the exercise group had also significantly lower relapse rates than those in the medication group during the follow-up. No study has hitherto examined the effects of a Web-based exercise intervention. Web-based apps show a trend toward computerization.

Conclusions and Implications for Further Research

We showed for the first time that an individualized, Web-based exercise program is feasible and effective in patients with moderate to severe depression. Our program could be an option for (1) patients who do not respond to or do not want to apply pharmaceuticals or psychotherapy and (2) patients who are motivated and physically able [33] to complete a structured exercise program over several weeks. In addition, the study gives important implications for future randomized, fully computerized, and individually tailored exercise trials in MDD.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

References


Abbreviations

ANCOVA: analysis of covariance
CBT: cognitive behavioral therapy
GSE: General Self-Efficacy scale
HPA: habitual physical activity
IG: intervention group
MDD: major depressive disorder
QIDS-C: Quick Inventory of Depressive Symptomatology-clinician rating
QIDS-SR: Quick Inventory of Depressive Symptomatology-self-reported
Identifying and Understanding Communities Using Twitter to Connect About Depression: Cross-Sectional Study

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Abstract

Background: Depression is the leading cause of diseases globally and is often characterized by a lack of social connection. With the rise of social media, it is seen that Twitter users are seeking Web-based connections for depression.

Objective: This study aimed to identify communities where Twitter users tweeted using the hashtag #MyDepressionLooksLike to connect about depression. Once identified, we wanted to understand which community characteristics correlated to Twitter users turning to a Web-based community to connect about depression.

Methods: Tweets were collected using NCapture software from May 25 to June 1, 2016 during the Mental Health Month (n=104) in the northeastern United States and Washington DC. After mapping tweets, we used a Poisson multilevel regression model to predict tweets per community (county) offset by the population and adjusted for percent female, percent population aged 15-44 years, percent white, percent below poverty, and percent single-person households. We then compared predicted versus observed counts and calculated tweeting index values (TIVs) to represent undertweeting and overtweeting. Last, we examined trends in community characteristics by TIV using Pearson correlation.

Results: We found significant associations between tweet counts and area-level proportions of females, single-person households, and population aged 15-44 years. TIVs were lower than expected (TIV 1) in eastern, seaboard areas of the study region. There were communities tweeting as expected in the western, inland areas (TIV 2). Counties tweeting more than expected were generally scattered throughout the study region with a small cluster at the base of Maine. When examining community characteristics and overtweeting and undertweeting by county, we observed a clear upward gradient in several types of nonprofits and TIV values. However, we also observed U-shaped relationships for many community factors, suggesting that the same characteristics were correlated with both overtweeting and undertweeting.

Conclusions: Our findings suggest that Web-based communities, rather than replacing physical connection, may complement or serve as proxies for offline social communities, as seen through the consistent correlations between higher levels of tweeting and abundant nonprofits. Future research could expand the spatiotemporal scope to confirm these findings.

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KEYWORDS

depression; Web-based; social connection; Twitter; tweet; online communities
Introducing

Each day, 313 million global users share 500 million messages or tweets on the popular social networking site Twitter [1]. Within a 280 character limit, users can type a hashtag followed by a word or phrase to discuss a specific topic, link content about the same topic, or initiate dialogue on a topic. Twitter content is publicly available worldwide, providing valuable data for research, including the topic of mental health [2].

Each year in the United States, about 7% of adults suffer from depression, but only half seek professional help [3,4]. In many communities, mental disorders such as depression carry a social stigma, resulting in further isolation and lack of treatment [5]. Increasingly, individuals with depression are turning to Web-based communities for support [6]. Because Twitter is a popular networking platform, people often turn to it to connect about mental health issues such as depression [2]. In one study, researchers examined depressive symptoms based on the Diagnostic and Statistical Manual of Mental Disorders in tweets and found them characterized by low mood, fatigue, or loss of energy and problems with the social environment [7,8]. In another study examining the same hashtag as this study, #MyDepressionLooksLike, researchers found that the content of tweets included themes such as dysfunctional thinking, lifestyle challenges, social struggles, apathy and sadness, suicidal thoughts and behaviors, and seeking relief from depression [2].

Other research has focused on why users communicate about mental health through Web-based communities like Twitter. For example, the study #WhyWeTweetMH resulted in several themes for tweeting about mental health, including a sense of community, raising awareness, combating stigma, a space for expression, and coping and empowerment [9]. In a study by Park et al (2012) of about 20,000 tweets from approximately 15,000 users regarding depression, results revealed higher levels of tweets about users’ own depressive feelings or symptoms as opposed to comments on treatments or others’ symptoms [10]. A study from South Korea found that Twitter users who are not depressed view Twitter as a place to share information, whereas depressed Twitter users view it as a site meant for social awareness and emotional interaction [11]. Twitter users with depression “followed,” or subscribed to, other users who posted about emotional and everyday life activities; they found it uplifting to read other peoples’ positive tweets and reading about others’ depression caused them to feel less isolated [11]. However, other research reveals that use of social media can exacerbate mental health symptoms such as depression because of constant social comparison, bullying, suicide contagion, and other aspects [12-15]. While prior research has provided insight into individual-level predictors of seeking connection about depression on social media, less is known about community-level factors.

Possibly, lack of neighborhood amenities, such as parks and museums, may indicate fewer destinations for social interaction between residents. In this way, social bonds may be influenced by a neighborhood’s structural and functional characteristics [16]. Lack of amenities may also increase stress among residents who must exert extra effort to gain access to these resources [16]. Poorer neighborhoods may have lower levels of trust between neighbors and lower social support, in part because of blighted conditions in the built environment [16]. In fact, evidence suggests that signs of physical disorder (eg, vacant homes) can lead to feelings of hopelessness and diminish social relationships [17]. Weich et al found that depression was higher among people living in neighborhoods with an abundance of vacant lots and fewer amenities such as gardens and local shops [18].

Lack of neighborhood amenities and thus limited social interactions may be factors that influence use of Twitter for seeking connection about depression. To explore community characteristics that may lead to higher numbers of Twitter users seeking Web-based support, this study employed spatial data to understand how built and demographic features of communities relate to use of Twitter for depression support. Our findings may inform community efforts to increase social interaction and provide support for residents’ mental health. This study provides unique information that has not yet been analyzed by examining geographical location and community amenities in the context of tweets about depression.

Methods

Ethical Approval

Our research was determined to be Nonhuman Subjects research by the Michigan State University Institutional Review Board. All researchers involved received ethical training by the same institutional review board.

Twitter Data

Tweets were downloaded through Twitter’s public streaming data [19]. Using NCapture, tweets were identified by the hashtag #MyDepressionLooksLike (QSR International, Burlington, MA, USA). This hashtag encouraged Twitter users with depression to share their experiences and connect with one another, making it useful in answering our research question.

Twitter restricted data capture to a random sample of 10% of total tweets from public content, and we compiled it into a database [2]. The temporal window for tweet-capture lasted from May 25 to June 1, 2016 (one week of the Mental Health Month), and tweets were pulled at 10:00 am Eastern Standard Time each weekday. Tweets meeting the following criteria were included: (1) each tweet was an original, not a retweet; (2) only one tweet per user; and (3) tweets with geolocations located within a designated 12-state northeastern study area. Thus, 104 tweets were included for analysis at the county level.

County Demographic Data

To predict expected tweets by county, we compiled demographic data commonly associated with depression diagnoses. We collected demographic data from the 2010 Census and the American Community Survey 2015 5-year estimates [20,21], including age, gender, race, household status, and percent living in poverty. Depression has been found to be the highest among women, unmarried people, low-income persons, ethnic minorities, and people aged 15-44 years [18,22-28]. Thus, we
compiled county percentages of single-person households, females, those aged 15–44 years, white population, and those living below the poverty line (see Table 1 for data sources).

**Community Characteristics Data**

To understand the relationship between community characteristics and levels of tweeting, we compiled data for characteristics that could provide support, in-person treatment, opportunities for social interaction, or indicators of active community residents. These characteristics included parks or protected open spaces, places of worship, museums, active voter rates, mental health care providers, nonprofit organizations (organized by National Taxonomy of Exempt Entities code), K12 schools, and owner-occupied housing units. Likewise, we compiled data on characteristics that might hinder community support, including vacant housing units. Community characteristic data came from several sources (see Table 1). Rates were generated for most variables per 100,000 total population. K12 school rates were generated per 100,000 school-aged population. Percent of active voters was calculated as the percentage of the adult population actively voting in 2016.

Nonprofit organizations were sorted into groups by purpose using Stata v11.1 (StataCorp, College Station, TX, USA): health, human services, public and societal benefit, religion, and education. Counts of nonprofit organizations by group, places of worship, mental health care providers, and vacant and owner-occupied housing units were summed by county. A rate per 100,000 population was then calculated. The spatial locations of museums, K12 schools, parks, and county boundaries were mapped using ArcGIS v10.5 (Esri, Redlands, CA, USA) [29]. Counts per county were summed, and then a rate per 100,000 total population was calculated. Park areas (in miles²) were also calculated in ArcGIS, as a percentage of the county’s total land area.

Active voter totals were all from the fourth quarter of 2016. We aggregated active voter counts by county and then divided these counts by the active voter population. We then calculated the percent of active voters. For states that do not report active voter totals, we used that state’s voter turnout rate for the 2016 presidential election.

**Calculating a Tweeting Index Value**

We assumed that, in theory, community levels of support seeking through Twitter should be predicted by demographic characteristics associated with depression and poor mental health [23,25-28]. Thus, we fitted a regression model to predict county-level tweet counts using those variables. Specifically, our multilevel Poisson regression model with robust SEs included independent predictors commonly associated with depression diagnoses including percent female, percent population aged 15-44 years, percent white, percent single-person households, and percent below poverty line, offset by the county population. The model also accounted for the clustering of counties within states.

Our focal interest was on understanding areas that have higher or lower tweeting than expected. So, after fitting the model, we calculated the difference between observed and expected counts and categorized these residuals into tweeting index value (TIV) tertiles, whereby 1=undertweeting, mean −0.37 (SD 0.53); 2=tweeting as expected, mean −0.02 (SD 0.01); and 3=overtweeting, mean 1.36 (SD 1.55). These TIVs were then used to examine community characteristic trends.

**Table 1.** Demographic and community characteristic data sources.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Data source</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent aged 15-44 years</td>
<td>US Census Bureau</td>
<td>2010</td>
</tr>
<tr>
<td>Percent female</td>
<td>US Census Bureau</td>
<td>2010</td>
</tr>
<tr>
<td>Percent white</td>
<td>US Census Bureau</td>
<td>2010</td>
</tr>
<tr>
<td>Percent single-person household</td>
<td>US Census Bureau</td>
<td>2010</td>
</tr>
<tr>
<td>Percent below the poverty line</td>
<td>US Census Bureau (American Community Survey 5-year estimates)</td>
<td>2015</td>
</tr>
<tr>
<td>Owner-occupied housing unit rate</td>
<td>US Census Bureau (American Community Survey 5-year estimates)</td>
<td>2015</td>
</tr>
<tr>
<td>Vacant housing unit rate</td>
<td>US Census Bureau (American Community Survey 5-year estimates)</td>
<td>2015</td>
</tr>
<tr>
<td>Places of worship rate</td>
<td>Association of Religion Data Archives</td>
<td>2010</td>
</tr>
<tr>
<td>Mental health care providers rate</td>
<td>County Health Rankings &amp; Roadmaps</td>
<td>2015</td>
</tr>
<tr>
<td>Museum rate</td>
<td>Institute of Museum and Library Services</td>
<td>2017</td>
</tr>
<tr>
<td>K12 schools per 100,000 children</td>
<td>United States Geological Survey</td>
<td>2016</td>
</tr>
<tr>
<td>Percent active voter</td>
<td>State Board of Electors</td>
<td>2016</td>
</tr>
<tr>
<td>Percent area occupied by park</td>
<td>State Geographic Information Systems Data Portals</td>
<td>Various</td>
</tr>
<tr>
<td>Nonprofit organizations rates</td>
<td>Urban Institute National Center for Charitable Statistics Data Archives</td>
<td>2005</td>
</tr>
<tr>
<td>School-aged population</td>
<td>US Census Bureau</td>
<td>2010</td>
</tr>
<tr>
<td>County boundaries</td>
<td>United States Geological Survey</td>
<td>2016</td>
</tr>
</tbody>
</table>

*aTweet counts were collected by the research team and are not included here. Nonprofits were broken down into National Taxonomy of Exempt Entities classes for analysis, but these classes are not shown here. Rates per 100,000 total population unless otherwise noted.*
During analysis, we decided to test whether our results might be driven by inclusion of one county—Washington, DC—because this county appeared to be an outlier for several reasons. For example, while its museums and other community amenities are very high, the population tends to be younger, and tweet counts were the highest. For this reason, we conducted a sensitivity analysis whereby the above model was also fitted without DC included. However, our incident rate ratios (IRRs) changed <1% for all independent variables (see Multimedia Appendix 1); therefore, these results are not included here. All subsequent analyses included all 245 counties. All analyses were conducted using Stata v11 (StataCorp, College Station, TX, USA).

### Evaluation of Community Characteristics by Tweeting Index Values

The suite of community characteristics outlined previously was selected due to each factor’s potential role in promoting or hindering support, in-person treatment, opportunities for social interaction, or indicators of active community residents. We calculated means of each characteristic by TIV. We then calculated a ratio of TIV5:1 and a Pearson correlation coefficient ($r$) and $P$ value.

### Results

Mapping captured #MyDepressionLooksLike tweets revealed that most counties in the study region were not using the hashtag during the observation period (Figure 1). Most tweets were in urban environments (eg, New York City and Washington, DC). Many counties near the eastern seaboard had higher numbers of tweets than counties farther inland. Delaware and Vermont each had only one county with a captured tweet. Maryland, New York, and Pennsylvania had the highest tweet counts in our study region. However, their statewide means showed they were similar to other states. Washington, DC was an outlier in descriptive statistics of counties by state (Multimedia Appendix 2), having higher percentages of single-person households, people living below the poverty line, females, and population aged 15-44 years. New Hampshire had the lowest average percentage of single-person households (mean 15), while Connecticut had the lowest average percentage living below the poverty line (mean 9). Average county percentages of female population were similar across all states. Maine had the lowest average percentage population aged 15-44 years (mean 35). Washington, DC had the lowest percentage of white population (241,892/601,723, 40%), and Maine and Vermont had the highest average percentages of white population (mean 96).

We found a positive, statistically significant correlation between several independent variables and tweet count (Table 2). These variables included percent population aged 15-44 years (IRR=1.11, $P=.02$), female (IRR=1.70, $P<.001$), and single-person households (IRR=0.90, $P=.03$). Percentages white and below poverty level were not statistically significant (Table 2). Regression model residuals were then used to create TIVs, which showed lower than expected tweets (TIV 1) in eastern seaboard areas and expected values (TIV 2) in western inland areas (Figure 2). Communities tweeting more than expected were generally scattered across our study region, with the exception of a cluster in the northern seaboard area.

Seeking to understand the relationship between the built environment and the levels of tweeting to connect about depression, we assembled a suite of community characteristics and related them to TIVs. We observed a U-shaped relationship between our TIVs and many of our community factors (see Table 3): rates of K12 schools, vacant housing, museums, places of worship, vacant housing rates, and health nonprofits. Almost all factors exhibiting $U$ patterns also exhibited statistically significant correlations with TIV. In other words, areas with both undertweeting and overtweeting correlated with lower rates of these community characteristics. One exception was percent active voters, whereby lower values for TIV (undertweeting) correlated with higher rates of active voters. We also observed an upward gradient between TIV and rates of many types of nonprofits including all, human services, public benefit, religion, and education. Specifically, lower rates of nonprofits correlated with undertweeting and higher rates correlated with overtweeting.
Figure 1. #MyDepressionLooksLike tweets by county for 11 states and the District of Columbia (2016).

Table 2. Regression results used to calculate tweeting index values (n=245) for counties in the study region.

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Incident rate ratio</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent aged 15-44 years</td>
<td>1.11</td>
<td>.02</td>
<td>1.02-1.21</td>
</tr>
<tr>
<td>Percent female</td>
<td>1.70</td>
<td>&lt;.001</td>
<td>1.25-2.29</td>
</tr>
<tr>
<td>Percent white population</td>
<td>0.99</td>
<td>.37</td>
<td>0.96-1.02</td>
</tr>
<tr>
<td>Percent single-person household</td>
<td>0.90</td>
<td>.03</td>
<td>0.82-0.99</td>
</tr>
<tr>
<td>Percent below poverty level</td>
<td>1.05</td>
<td>.31</td>
<td>0.95-1.16</td>
</tr>
</tbody>
</table>
Figure 2. Tweeting index values by county for 11 states and the District of Columbia. TIV: Tweeting index values.
Table 3. Community characteristics by tweeting index values.

<table>
<thead>
<tr>
<th>Community characteristics</th>
<th>TIV1&lt;sup&gt;a&lt;/sup&gt;</th>
<th>TIV2&lt;sup&gt;b&lt;/sup&gt;</th>
<th>TIV3&lt;sup&gt;c&lt;/sup&gt;</th>
<th>TIV3:TIV1</th>
<th>r</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>K12 schools per 100,000 children, mean</td>
<td>199</td>
<td>289</td>
<td>212</td>
<td>1.07</td>
<td>0.19</td>
<td>.004</td>
</tr>
<tr>
<td>Museums rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>17</td>
<td>33</td>
<td>20</td>
<td>1.18</td>
<td>0.20</td>
<td>.002</td>
</tr>
<tr>
<td>Percent area occupied by park, mean</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>1.11</td>
<td>0.04</td>
<td>.49</td>
</tr>
<tr>
<td>Places of worship, mean&lt;sup&gt;d,e&lt;/sup&gt;</td>
<td>104</td>
<td>177</td>
<td>93</td>
<td>0.89</td>
<td>0.16</td>
<td>.01</td>
</tr>
<tr>
<td>Vacant housing rate, mean&lt;sup&gt;d,e&lt;/sup&gt;</td>
<td>6</td>
<td>17</td>
<td>7</td>
<td>1.17</td>
<td>0.16</td>
<td>.01</td>
</tr>
<tr>
<td>Owner-occupied housing rate, mean&lt;sup&gt;d,e&lt;/sup&gt;</td>
<td>26</td>
<td>29</td>
<td>25</td>
<td>0.96</td>
<td>0.08</td>
<td>.21</td>
</tr>
<tr>
<td>Percent active voter, mean</td>
<td>76</td>
<td>72</td>
<td>74</td>
<td>0.97</td>
<td>-0.15</td>
<td>.02</td>
</tr>
<tr>
<td>Mental health care providers rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>209</td>
<td>157</td>
<td>293</td>
<td>1.40</td>
<td>0.09</td>
<td>.18</td>
</tr>
<tr>
<td>Nonprofits (all) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>412</td>
<td>527</td>
<td>579</td>
<td>1.41</td>
<td>0.23</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nonprofits (health) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>70</td>
<td>91</td>
<td>84</td>
<td>1.20</td>
<td>0.15</td>
<td>.017</td>
</tr>
<tr>
<td>Nonprofits (human services) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>147</td>
<td>184</td>
<td>195</td>
<td>1.33</td>
<td>0.23</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nonprofits (public or societal benefit) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>41</td>
<td>50</td>
<td>80</td>
<td>1.95</td>
<td>0.24</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nonprofits (religious) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>12</td>
<td>14</td>
<td>17</td>
<td>1.42</td>
<td>0.13</td>
<td>.04</td>
</tr>
<tr>
<td>Nonprofits (education) rate, mean&lt;sup&gt;d&lt;/sup&gt;</td>
<td>76</td>
<td>85</td>
<td>97</td>
<td>1.28</td>
<td>0.13</td>
<td>.04</td>
</tr>
</tbody>
</table>

<sup>a</sup>TIV: tweeting index values.
<sup>b</sup>Undertweeting.
<sup>c</sup>Overtweeting.
<sup>d</sup>Rate per 100,000 people.
<sup>e</sup>Values in thousands.

**Discussion**

**Principal Findings**

Most prior research on use of Twitter to connect about depression focused on interpersonal variables. This research focusing on community factors uniquely contributes to the literature. In this study, three positive, statistically significant associations were found to predict the count of tweets from people connecting about depression, including percent female, percent population aged 15-44 years, and percent single-person households. These findings correspond with other studies showing higher rates of depression among women and single-person households [18]. The percent female correlation further suggests that women experiencing depression are turning to Twitter at higher rates than men although previous research has shown no difference in general Twitter use between men and women [30].

While we found several significant associations, some anticipated predictors of tweet counts were not confirmed. Percent below poverty level and percent white were not significantly associated with tweet counts. Our insignificant findings for area-level poverty contrast with some published data showing an association between poverty and depression [31]. On the other hand, our findings echo those from Cutrona et al, whereby other neighborhood factors, such as social disorder, were more influential than poverty [16]. Prior results on depression and race have been inconsistent, with some studies indicating that the built environment may be more relevant to depression than race composition [32]. Other studies indicate that perceived discrimination, social support, and coping may play a role in the relationship between race and depression [33].

In examining community characteristics related to overtweeting or undertweeting, rates of K12 schools, museums, places of worship, vacant housing rates, and health nonprofits exhibited a U-shaped gradient across TIVs. Although Kaplan and Yen claim it difficult to illustrate a relationship between depression and lack of amenities, fewer amenities have been associated with higher depression rates within a neighborhood in prior research [34]. Our study reflected these difficulties because several community characteristics had a U-shaped relationship with TIVs. However, the rates of several types of nonprofits showed a clear, upward trend with TIVs, similar to other studies [17]. Lack of neighborhood amenities, such as community-building nonprofits, may not only be associated with higher rates of depression, but may also lead to lower levels of connecting about depression in Web-based communities. This suggests that Web-based communities, rather than replacing physical connection, act as complements and proxies for nonvirtual social communities. In other words, if communities have abundant nonprofit organizations serving the public, thereby improving community participation, residents experiencing depression may be more likely to connect about depression on the Web [35]. Conversely, if a community is lacking these amenities, the isolation that residents feel may transfer to their Web-based presence [16].
This paper expanded the literature about depression in relation to Twitter by exploring and providing information about community characteristics that correlate with people turning to a Web-based community to connect about depression. Before this study, literature about depression relating to Twitter mainly consisted of how to interpret depression based on tweets and why people tweet about their mental health issues, such as depression. This included findings underlying the positive impact of Web-based platforms such as Twitter in discussing mental health issues, but also pointed to social media use and adverse consequences, including increased depressive symptoms. While often overlooked, people’s environment strongly impacts the state of their mental health [36,37]. This study provided insight into aspects of a person’s environment, for instance, living in an area with many nonprofits, which may have encouraged Twitter use to bolster social connections.

Limitations
Our study has several limitations. First, future research could expand the study area beyond the northeastern United States. As seen from Park et al’s 2013 study in South Korea, people from all over the world use Twitter to seek connections, so understanding their physical communities may also lend insight into the research question. Future studies could also expand the time frame from which tweets were gathered. Increasing the time frame for capturing data would allow this paper to have greater population validity and allow for inferences about how neighborhood changes relate to depression. Because of our limited spatiotemporal scope and use of NCapture, our sample size was smaller than originally anticipated, thus presenting generalizability concerns. Additionally, we used the geotagged location to characterize the community of Twitter users; this partially limited our sample and may have introduced error. Geotags may not be representative of the Twitter user’s community; rather, they could indicate places users were traveling to temporarily. Additionally, we used counties as a proxy for “community” since existing community-level data is often reported at the county level. In the future, we suggest a smaller geographic scale such as a city or town because these units are usually more representative of a person’s community.

Conclusion
Our study is one of the first to explore built and social environmental contributions to the use of Twitter to connect about depression. Communities that overtweet and undertweet were more likely to have lower rates of K12 schools, museums, places of worship, vacant housing rates, and health nonprofits. These communities were also likely to have higher rates of active voters. Especially evident in our study is that communities with higher rates of nonprofits exhibited higher than expected levels of tweeting—suggesting that lack of community investment may influence Web-based connection seeking. Urban planning efforts may usefully promote amenities to bolster social interactions and lessen isolation, thus ultimately offering opportunities for social support for depression.

Acknowledgments
This study was funded by Michigan State University’s Provost Undergraduate Research Initiative. We would like to thank Josh Vertalka, Katherine Bogen, Heather McCauley, and Amanda Rzotkiewicz for their contributions to the research process.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Tables used for sensitivity analysis.

Multimedia Appendix 2
Descriptive statistics for counties in study region by state.

References


27. Pratt LA, Brody DJ. Depression in the United States household population, 2005-2006. NCHS Data Brief 2008 Sep 7;1-6 [FREE Full text] [Medline: 19389321]


Abbreviations

IRR: incident rate ratio
TIV: tweeting index value

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The Mediating Role of Perceived Social Support Between Physical Activity Habit Strength and Depressive Symptoms in People Seeking to Decrease Their Cardiovascular Risk: Cross-Sectional Study

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Abstract

Background: Regular physical activity treatment has been advocated for the prevention and rehabilitation of patients at risk of cardiovascular diseases and depressive symptoms. How physical activity is related to depressive symptoms is widely discussed.

Objective: The aim of this internet-based study was to investigate the role of perceived social support in the relationship between physical activity habit strength and depressive symptoms.

Methods: In total, 790 participants (mean 50.9 years, SD 12.2, range 20-84 years) who were interested in reducing their cardiovascular risk were recruited in Germany and the Netherlands. Data collection was conducted via an internet-based questionnaire addressing physical activity habit strength, depressive symptoms, and perceived social support. Cross-sectional data analysis was done with SPSS version 24 using the Macro PROCESS version 2.16.3 by Hayes with bootstrapping (10,000 samples), providing 95% CIs.

Results: Physical activity habit strength was negatively related to depressive symptoms \((r=-.13, P=.006)\), but this interrelation disappeared when controlling for perceived social support \((\beta=-.14, SE 0.09, P=.11)\). However, there was an indirect relationship between physical activity habit strength and depressive symptoms, which was mediated via perceived social support \((\beta=-.13; SE 0.04, 95\% \text{ CI} -0.21 \text{ to } 0.06)\). The negative relationship between physical activity habit strength and depressive symptoms was fully mediated by perceived social support.

Conclusions: We suggest that physical activity treatment in people interested in reducing their cardiovascular risk should also embed social support to target depressive symptoms. Internet-based interventions and electronic health may provide a good option for doing so.


\(^{10.2196/11124}\)
KEYWORDS
physical activity; habit; social support; depressive symptoms; cardiac diseases

Introduction

Cardiovascular Diseases and Their Burdens
Cardiovascular diseases (CVDs) are the most prominent group of chronic diseases contributing to the global burden of disease. In Germany alone, CVDs, such as heart attacks, coronary heart disease, or strokes, accounted for around 40% of all deaths and 15% of inpatient hospital treatment in the year 2015 [1,2]. CVD is often caused by a person’s lifestyle: besides smoking [3], high blood pressure [4], a diet rich in fat and salt [5,6], and especially physical inactivity [7] are part of the most far-reaching modifiable lifestyle-related risk factors. Meta-analyses of systematic reviews conclude that even 150 min of moderate physical activity per week can reduce CVD mortality by approximately 25% [8,9]. Thus, national and international prevention and intervention programs are often based on these recommendations [10,11].

Cardiovascular Diseases and Depression
Common concomitant mental illnesses of CVD are depressive symptoms, depression, and anxiety disorders, and depression, in particular, significantly worsens the prognosis of those who are already ill [12]. In a Europe-wide study with over 8500 coronary heart disease patients, it was found that about 25% of those examined had a clinically relevant depression [13]. For example, a person suffering from heart failure may also suffer from a depressed mood as a result of, for example, a prolonged stay in hospital or rehabilitation, surgery, or uncertainty of outcome after a heart attack. In contrast, in a representative sample of 7988 healthy people, aged 18 to 79 years, only 8.1% reported depressive symptoms [14].

Many factors suggest a multicausal relationship between depressiveness and CVDs, which can be interpreted in both directions [15]. Depressiveness and depressive symptoms itself represents a risk factor both for the development of CVD [12] and for the course of patients already suffering from CVD [16]. For example, depressive symptoms in terms of lack of motivation and loss of interest can minimize motivation to implement healthy behaviors [17]. This can, for example, result in moving less and paying less attention to a healthy diet and, thus, might increase the risk of further CVD despite a previously healthy lifestyle. The behavioral treatment approaches in CVD patients, therefore, focus not only on reducing risk behaviors and promoting health behaviors [18] but typically also on depressive symptoms [19,20]. Therefore, the relationship between depressive symptoms and lifestyle factors should be further investigated. This study will focus on one of the main lifestyle factors, namely, physical activity.

Physical Activity and Its Preventive and Rehabilitative Benefits
Regular physical activity behavior has already been shown to be beneficial in reducing depressive symptoms in clinical depression [21,22], in people with mild depressive disorders [22,23], and in people with long-term stress [24].

Researchers explain the positive effect of physical activity on mental health using, among others, a bio-psycho-social causal model. The biological or neurophysiological perspective assumes that the increased release of messenger substances in the brain has a positive effect on a person’s mood [25,26]. The psychological argumentation of Vancampfort et al [27] is based, in particular, on the role of self-efficacy maintenance. According to the authors, physical activity can improve self-efficacy and help overcoming learned helplessness, thereby reducing depressive symptoms. A distraction of anxiety-triggering situations or the interruption of brooding loops can also play an important role [28].

Changing physical activity to be more habitual is a desired goal in primary and secondary prevention of CVDs because once a behavior has become habitual, it requires less conscious effort and relapses become less likely [29,30]. Habituation of healthy behavior may be the final phase in the health behavior change chain, whereby the behavior has stabilized and its strength has plateaued [29]. There is also evidence that habit predicts future behavior and health outcomes better than intention [31]. Thus, instead of investigating behavior, this study will focus on habituation.

Social Support as an Important Factor for Health
Despite evidence regarding the relationship between physical activity and depressive symptoms [32,33], the mediating mechanisms of this relationship are so far rather unexplored. In addition to neurophysiological and psychological changes, regular physical activity seems to be accompanied by changes in perceived social support and the mobilization of support, which are particularly important for people with depressive symptoms.

Perceived social support, in the form of interpersonal relationships and interactions, is considered an important factor for physical and mental health. Social interactions, as experienced in group activities, can help people to cope with stress and overcome challenges better [34]. Fehres and Pauly [35] describe group-based physical activity (eg, in an association) as a “place of open social communication, also with topics that go beyond sport,” such as the individual state of health. A high level of perceived social support, because of regular participation in walking, swimming, or heart training groups, may, therefore, also have an impact on depressive symptoms in individuals. For instance, physical activity in a group can provide positive feedback or help to cope with physical challenges (mastery experience), thus increasing self-esteem [36,37].

One’s own physical activity behavior may also have to be related to the physical activity behavior of one’s own social environment (eg, partner and friends). The use of physical activity and exercise therapy in the prevention and rehabilitation of CVDs can only succeed if the needs of the target group are identified and precisely addressed in appropriate support measures. As physical activity behavior depends, among others, on individual psychosocial determinants such as self-efficacy,
the level of depression, or perceived social support, appropriate measurements of these determinants are essential to personalize treatment. Thus, this study aims to investigate the needs of the target group in terms of identifying psychosocial determinants that are relevant in the promotion of health behavior and mental health. In particular, this study aims to unveil the relationship between physical activity habit strength, depressive symptoms, and perceived social support.

Hypotheses

In this study, we examined the following 2 hypotheses: (1) physical activity habit strength is negatively correlated with depressive symptoms and (2) the negative correlation between physical activity habit strength and depressive symptoms is mediated by perceived social support.

Methods

Study Protocol

A detailed description of the study protocol has been described before [38,39]. This study presents secondary analyses of data obtained from the baseline measurement. However, this is the first time depressive symptoms and perceived social support were investigated within this study sample. For this study, only a summary of the study methodology and procedures relevant for this study are provided.

Study Design, Procedure, and Participants

This is a cross-sectional study using baseline data taken from a randomized controlled trial that was used to investigate the effectiveness of a Web-based intervention to promote physical activity and fruit and vegetable intake [38,39].

The study received ethical approval by the Deutsche Gesellschaft für Psychologie (German Psychological Society; EK-A-022013) and the medical ethics committee of Atrium Medical Centre Heerlen in the Netherlands (12-N-124). The recruitment took place between 2013 and 2015 in cardiac rehabilitation facilities and heart training groups in Germany and the Netherlands. In addition, we called for participation via internet platforms on diabetes and CVDs as well as via an email invitation from 2 research agency’s Web-based panels in Germany and the Netherlands. The inclusion criteria were as follows: (1) age between 20 and 85 years, (2) no contraindications for physical activity and fruit and vegetable consumption, (3) having an interest in improving physical activity and fruit and vegetable consumption, (4) sufficient reading and writing skills in the relevant language (German or Dutch), and (5) computer literacy and internet access. Participation in the study was voluntary, and data were anonymized. Participants were informed about the aims of the study and provided informed consent before participation. In total, 790 participants from Germany (371/790, 47.0%) and the Netherlands participated in this internet-based study.

Instruments

The internet-based self-report data collection was done via a Web-based questionnaire, which was programmed using the content management system Tailorbuilder. The questionnaires were used in German and Dutch, depending on the country the participants were recruited in.

Sociodemographic Variables

We assessed various sociodemographic information such as gender (1=male and 2=female), year of birth, country (1=Netherlands and 2=Germany), employment status (1=working part-time, 2=working full-time, 3=in training, 4=unemployed, 5=retired, and 6=housewife or husband), marital status (1=single, 2=close relationship but not living together, 3=close relationship and living together, 4=marital partnership or common law marriage, 5=divorced, and 6=widowed), and highest level of education (1=no school graduation, 2=primary school education, 3=secondary school education, 4=vocational school graduation, 5=university entrance diploma, and 6=other) in the baseline questionnaire. The participants additionally reported body height and body weight to calculate their body mass index (BMI).

Depressive Symptoms

We obtained depressive symptoms via the Center for Epidemiologic Studies Depression Scale-Revised 10-item (CESD-R-10) by Eaton et al [40] (Cronbach alpha=.79) that covers the domains depressed affect, positive affect, somatic complaints, and interpersonal problems. The CESD-R-10 consists of 10 statements, each of which is rated by the participants on a 4-point scale, ranging from 0 (rarely or none of the time) to 3 (most of or all the time). The values of these response categories were reversed for the positive and added to a sum score. The sum scores provided by the participants ranged from 0 to 30. Higher values indicate a higher level of depressive symptoms. To categorize the participants into either depressed or not depressed, we used a cut-off value of 10, which is proposed by Eaton et al [40].

Physical Activity Habit Strength

The strength of habit for physical activity (Pearson r=.88) was measured with an abbreviated version of the Self-Report Habit Index by Verplanken and Orbell [41,42] and included the following 2 items: “Being physically active for at least 30 minutes on 5 days a week is something that...” (1) “has become a confirmed habit” and (2) “I do without thinking about it.” In all analyses, the mean of these 2 items was used as the dependent variable.

Perceived Social Support

Perceived social support [43] was measured with the following 3 items: “My partner helps me to be physically active,” “My family helps me to be physically active,” and “Friends or peers help me to be physically active” (Cronbach alpha=.79). Study participants indicated all items on Likert scales ranging from 1=not true to 7=exactly true. In all analyses, the means of these 3 items were used as the independent variable.

Data Analysis

Data analysis was done with SPSS version 24. The mediation analysis was performed using a SPSS PROCESS version 2 16.3 Macro by Hayes [44,45]. We followed the principles of mediation analysis as described by Baron and Kenny [46]. Our model describes path c as the total direct effect of physical...
activity habit strength regressed on depression. Path \(a\) is described as the direct effect of physical activity habit regressed on perceived social support and path \(b\) the direct effect of perceived social support regressed on depression. The total effect \(c\) is the sum of the direct and indirect effect, that is, \(c = a * b + c'\). A reduction of the direct effect \(c\), compared with \(c'\), indicates a mediation effect of perceived social support. As indirect effects violate the assumption of normal distribution, we used a bootstrapping approach (10,000 bootstrap samples) to provide robust estimates of 95% CIs of the standardized effects. Gender, country of birth, BMI, highest educational status, and age were included as control variables. The level of statistical significance was set at \(P<.05\). All reported \(P\) values are two-tailed. We used no statistical measures to correct for multiple testing.

**Results**

**Participation and Sample Characteristics**
The mean age of the participants was 50.9 years (SD 12.2; range 20-84), 62.9% were female (497/790), 66.3% (524/790) were married, and 72.0% (569/790) were working full-time or part-time. The mean BMI was 27.5 (SD 5.0; range 17.9-47.3). In total, 38.1% (301/790) of the participants were categorized as depressive. Baseline differences between German and Dutch participants regarding age, gender, and BMI have been reported critically discussed before [47].

**Intercorrelations Between Study Variables**
Intercorrelations between the main study variables were calculated with Bonferroni corrections \((K=4, P<.01)\). Table 1 reports intercorrelations, ranges, as well as means and SDs. Physical activity habit strength was negatively related to depressive symptoms \((R=-.13, P=.006)\), and depressive symptoms were negatively interrelated with perceived social support \((R=-.17, P=.004; Table 1)\).

Age was positively associated with physical activity habit strength \((R=.16, P=.004)\) and BMI \((R=.12, P=.01)\). This means that older participants reported stronger physical activity habit strength and a higher BMI. Among our sample, BMI and depressive symptoms were not significantly related \((R=.08, P=.36)\). There was a small negative association between BMI and physical activity habit strength \((R=-.10, P=.001)\), indicating that those persons with a higher BMI had lower physical activity habit strength. Finally, physical activity habit strength was positively associated with perceived social support \((R=.39, P<.001)\), which means that those with stronger habit strength perceived more social support regarding their physical activity.

To control for shared variance between the variables and to test for potential psychological mechanisms, a regression analysis was computed next.

**Direct and Indirect Effects of Habit Strength on Depressive Symptoms via Perceived Social Support**
The regression analysis was employed to test hypothesis 1 and hypothesis 2 in a mediation model. As shown in Figure 1, physical activity habit strength significantly related to perceived social support \((path a: B=.31, SE 0.03, P<.001)\) while controlling for depressive symptoms.

Perceived social support significantly correlated with depressive symptoms \((path b: B=-.40, SE 0.10, P<.001)\): the higher the perceived social support, the lower the reported depressive symptoms.

In contrast to our bivariate results \((Table 1)\), physical activity habit strength was not correlated with depressive symptoms \((path c: B=-.14, SE 0.09, P=.11)\) when controlling for perceived social support. However, in accordance with hypothesis 2, there was an *indirect* effect of physical activity habit strength on depressive symptoms via perceived social support \((path d: B=-.13; bootstrapped SE 0.04, 95% bootstrapped CI –0.21 to –0.06)\). This means that the negative relationship between physical activity habit strength and depressive symptoms was fully mediated by perceived social support. In other words, physical activity habit strength and depression only correlated negatively via perceived social support.

**Table 1.** Descriptive information of the sample.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Correlation, (R)</th>
<th>Range</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Age</td>
<td></td>
<td>2. BMI (b)</td>
</tr>
<tr>
<td>1. Age</td>
<td>—</td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>2. BMI</td>
<td>.12 (b)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>3. Perceived social support</td>
<td>.06</td>
<td>&lt;.01</td>
<td>—</td>
</tr>
<tr>
<td>4. Depressive symptoms (continual)</td>
<td>.08</td>
<td>.08</td>
<td>.17 (b)</td>
</tr>
<tr>
<td>5. Physical activity habit strength</td>
<td>.16 (b)</td>
<td>-.10 (b)</td>
<td>.39 (b)</td>
</tr>
</tbody>
</table>

\(a\)BMI: body mass index.

\(b\)Correlation \((R)\) significant at \(P<.05\).
Figure 1. Direct effects (a, b, c, solid lines) of physical activity habit strength and perceived social support on depressive symptoms and indirect effect (d, dotted line) of physical activity habit strength on depression via perceived social support; control variables included age, gender, country of birth, body mass index, and highest educational status. B=standardized beta coefficient.

Discussion

Objective of the Study

In the prevention and rehabilitation of CVD, the presence of comorbid depressive symptoms remains a factor that should not be neglected, especially when it comes to motivation to adopt or maintain physical activity. In this internet-based study, the relationship between physical activity habit strength and depressive symptoms in 790 people seeking to reduce their cardiovascular risk was investigated, and the explanatory social-cognitive mechanisms of this relationship were analyzed.

Discussion of Findings Regarding the Hypotheses

Matching our first hypothesis, there was a bivariate correlation between physical activity–related habitual strength and depressive symptoms, showing that the stronger the physical activity habit strength, the lower the depression scores. It is conceivable that physical activity can improve self-esteem and overcome learned helplessness and, thus, alleviate depressive symptoms [28] or serve as a distraction from anxiety-inducing situations [32,33]. Exercise therapy could be a good complement to psychotherapeutic or pharmacological treatment actually provided in a Web-based format.

In line with hypothesis 2, the relationship between physical activity habit strength and depressiveness was mediated by the perceived social support of the study participants. Physical activity often takes place in a social setting, for example, with training partners, exercise instructors, physiotherapists, or other persons in the form of, for example, heart training groups. Physical activity may also have an influence on the level of physical activity of one’s own social environment, for example, one’s partner and friends. Studies revealed that perceived social support from significant others (eg, family and friends) is positively related to physical activity [48]. Differences in health behaviors that are relevant to CVD prevention and rehabilitation can also be because of the impact of the partner or close family member. This has already been shown for smoking behavior and body weight [36], fruit and vegetable consumption, and alcohol consumption [37]. Thus, the lifestyle of one’s partner can significantly influence one’s own lifestyle through model learning (eg, social cognitive theory [49]), setting the subjective norm (cf. theory of planned behavior [50]), and providing or inhibiting social support. The physical activity behavior of a partner can either adapt to one’s own during the partnership or determine the choice of partner in advance. The negative correlations between physical activity habit strength and depressive symptoms can, therefore, probably be explained by mutual perceived support and the shared experience of (physical activity) successes and failures [47].

According to clinical experience, the use of exercise therapy as a structured antidepressive treatment often fails because of a patient’s lack of motivation or their limited ability because of illness [51,52]. It might be worth trying to implement social support from other sources such as peers in internet-based interventions to increase the effects of social support and help to change health behavior among people with smaller social networks. In times of increasing prevalence of single homes, providing such social support or facilitating social support by digital devices appears contemporary.

Limitations and Implications for Future Research

Our study has several limitations that need to be taken into account and discussed. First, because of the cross-sectional
nature of this study, only interrelations, but no causal effects, could be investigated. Future randomized controlled trials with larger sample sizes and additional measurement points can provide information on the direction and sequencing of the effect.

Second, the sample is very heterogeneous in terms of the individual health status of the patients. Although the desire to promote their own heart health was considered a prerequisite for participation, the patients reported very different diseases of their cardiovascular system that could have influenced their depressive symptoms and their physical activity behavior. A medical control variable (such as type and severity of the disease) is recommended for future research.

Third, the measure of physical activity habit strength must be addressed. The self-report habit index we used has good internal consistency [39,41,42]. However, for future studies, because of possible memory effects or social desirability [53,54], objective markers for physical activity such as pedometers [54] or fitness trackers are recommended to be used in addition to the habit measure. A direct indicator of physical activity should be taken into account, and ideally, a distinction should be made between the intensity of the activity (light, moderate, and strenuous): a review by Firth et al [17] showed that strenuous physical activity was more effective in reducing depressive symptoms than moderate or light physical activity. This needs to be taken into consideration for future research.

Fourth, although the correlation between physical activity and perceived social support is supported statistically within this study, this topic needs more attention in future internet research and interventions for patients seeking to decrease their cardiovascular risk. Currently, many questions remain, such as which kind of social support is perceived as most beneficial. Emotional support could help to overcome personal barriers such as low motivation, and informal social support might help to find physical activity patterns, which help to maintain this behavior [55]. Furthermore, the source of the perceived social support might have an influence on habit strengths.

Finally, in our study, just under 38.1% (301/790) of all study participants are classified as depressive, whereas the number of depressive patients among the CVD patients in other studies is typically lower at 23% to 30% [12-16,56,57]. Thus, it does appear that depressive patients are well accommodated by internet approaches as the barriers to disclose their own mental health status are perceived as lower. However, it cannot be ruled out that the questionnaire exaggerates the depressive symptoms, and therefore, the results should be interpreted with caution as the study sample is not representative for other groups of patients.

Conclusions

Our study adds to the literature because the relationship between regular physical activity and depressiveness could be validated, and the importance of social support in this relationship could be taken into account in this regard. The identified needs of the target group can be seen in terms of not only helping patients to adopt a physically active lifestyle and to habituate to it but also to mobilize social support because only then the beneficial effect for depression results.

The bio-psycho-social aspects of physical activity should be used in the prevention and rehabilitation of CVD. There is still a need for further medical internet research, particularly with regard to the type, duration, and intensity of optimal physical training for depressive symptoms and the embedding of social support in the context of individual clinical constellations. Further research should investigate whether physical activity should be included in the therapeutic repertoire for the treatment of depressive symptoms and in the prevention and rehabilitation of CVD, taking patients’ social environment into account, and how an internet approach should look like best.

Acknowledgments

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Conflicts of Interest

None declared.

References


Abbreviations

BMI: body mass index
CESD-R-10: Center for Epidemiologic Studies Depression Scale-Revised 10-item
CVD: cardiovascular disease

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Video-Delivered Family Therapy for Home Visited Young Mothers With Perinatal Depressive Symptoms: Quasi-Experimental Implementation-Effectiveness Hybrid Trial

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Abstract

Background: The Federal Maternal, Infant, and Early Childhood Home Visiting Program is a national child abuse prevention strategy that serves families at risk for child maltreatment throughout the United States. Significant portions of the clients are young mothers who screen positive for clinically significant perinatal depressive symptoms and experience relational discord that worsens their symptoms. Although home visitors refer those who screen positive for depression to community-based treatment, they infrequently obtain treatment because of multiple barriers. These barriers are compounded for home visited families in rural areas.

Objective: This pilot study aimed to explore the feasibility, acceptability, and effectiveness of a video-delivered family therapy intervention on reducing maternal depressive symptoms and improving family functioning and emotion regulation.

Methods: A total of 13 home visited families received the video-delivered family therapy intervention. This study included a historical comparison group of mothers (N=13) who were previously enrolled in home visiting and screened positive for clinically significant perinatal depressive symptoms but refused treatment. A licensed marriage and family therapist delivered the family therapy intervention using Health Insurance Portability and Accountability Act–compliant videoconferencing technology on a computer from an office. Families participated in sessions in their homes using cell phones, tablets, and computers equipped with microphones and video cameras. Outcomes were measured following the final therapy session (post intervention) and 2 months later (follow-up). Depressive symptom scores of mothers who received the video-delivered family therapy intervention were compared with those of mothers in the historical comparison group over a 6-month period. Univariate statistics and correlations were calculated to assess measures of feasibility. Percentages and qualitative thematic analysis were used to assess acceptability. Wilcoxon signed-rank tests were used to assess changes in maternal and family outcomes.

Results: No families dropped out of the study. All families reported that the technology was convenient and easy to use. All families reported high satisfaction with the video-delivered intervention. Nearly all families reported that they preferred video-delivered family therapy instead of clinic-based therapy. Therapeutic alliance was strong. Mothers demonstrated a statistically
significant reduction in depressive symptoms \((P=.001)\). When compared with mothers in the historical comparison group, those in the family therapy intervention showed a significant reduction in depressive symptoms \((P=.001)\). Families demonstrated statistically significant improvements in family functioning \((P=.02)\) and cognitive reappraisal \((P=.004)\).

**Conclusions:** This pilot study yielded preliminary findings that support the feasibility, acceptability, and effectiveness of the video-delivered family therapy intervention for underserved home visited families in rural areas. Our findings are very promising, but more research is needed to ultimately influence mental health practices and policies that pertain to video-delivered mental health interventions in unsupervised settings (eg, homes).

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**KEYWORDS**
videoconferencing; family therapy, depression

**Introduction**

**Background**

The Federal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program serves over 100,000 vulnerable families at risk for child abuse throughout the United States and aims to improve several outcomes, including maternal mental health [1]. Over half of the families served include young mothers (pregnant and postdelivery) under the age of 25 years [2]. Depressed young mothers make up a significant portion of home visited clients. Between 34% and 60% of home visited young mothers screen positive for clinically significant perinatal depressive symptoms [3-7]. Home visited mothers infrequently access treatment because of barriers (eg, no child care, lack of transportation, geographical distance, and stigma) [8-10]. These logistical barriers are compounded for mothers in rural regions.

Home visitors refer depressed mothers for treatment but they infrequently obtain it or complete it [7-12]. Between 8% and 32% of depressed home visited mothers report receipt of some mental health treatment [3,6,7,12-14]. One study showed that about 19% of home visited mothers recover from depression as a result of the illness’s natural course, reduced stressors, or mental health treatment in the community [3]. Untreated maternal depression leads to poor maternal and child outcomes [15,16]. Furthermore, studies have shown that home visiting outcomes are very poor for mothers with severe depressive symptoms and high levels of discomfort with trust. One study showed that home visiting did not impact cognitive development or behavior in children of mothers with both severe depressive symptoms and high levels of discomfort with trust [17]. Another study showed that in depressed mothers with both low relationship anxiety and high discomfort with trust, home visiting increased the likelihood of substantiated child maltreatment [18]. Untreated maternal depression is associated with child abuse and neglect [19,20].

Integrating mental health services in home visiting has been shown to reduce logistical barriers experienced by some families [8-10]. There are currently 4 individual-level psychosocial interventions that target maternal depression as a primary outcome [21,22,24]. One intervention has been delivered in a group format [23] and requires mothers to travel to the location of the group. The other 3 interventions require providers to travel to mothers’ homes [21,22,24]. Feasibility and sustainability problems exist with these current interventions [21-24] in rural areas because of even greater provider/maternal travel time that nearly triples the cost of the intervention. MIECHV serves families in 22% of all rural US counties [2], and with enrollment expected to increase in the coming years, the delivery method of these existing models [21-24] is likely not feasible or sustainable in rural areas.

Furthermore, these existing interventions do not include family members in the mother’s treatment to address family dynamics that result in family conflict. Family conflict is a risk factor for and a consequence of perinatal depression [25-32]. Family conflict (nonviolent) precipitates clinically significant perinatal depressive symptoms in adolescent and young adult mothers [25,28-31,33]. Family conflict (eg, frequent arguments and criticism) worsens perinatal depressive symptoms in young mothers, and if conflict is untreated, their depressive symptoms often persist [26,30,31,33-37]. Technology permits convenient access to treatment for mothers and their families in rural areas. Given that 60% of low-income families and nearly 68% of those in rural areas own handheld devices with internet access in the United States [38], technology bypasses logistical barriers to increase treatment access and eliminates the clinician’s travel time to family homes. The use of Health Insurance Portability and Accountability Act (HIPAA)–compliant video-based communication technology is not novel in rural areas and ample evidence supports its use (eg, [39,40]). Studies have been conducted on video-delivered family interventions for some populations [41-44], but none have targeted perinatal depressive symptoms in home visited mothers [45].

**Aims of This Study**

This 1-year pilot study had the following 2 aims: (1) to explore the feasibility and acceptability of the video-delivered family therapy intervention among home visited families and (2) to explore preliminary impacts of the video-delivered family therapy intervention on maternal depressive symptoms, family functioning, and emotion regulation from baseline to 2 months after the final family therapy session (follow-up). We hypothesize that mothers will show a clinically meaningful reduction in depressive symptoms at the 2-month follow-up [46]. When compared with depressed mothers who were previously enrolled in home visiting but refused treatment, those who received the video-delivered family therapy intervention will show preliminary evidence of a greater reduction in depression [46]. Finally, we hypothesize that families will show
clinically meaningful improvement in family functioning and emotion regulation at the 2-month follow-up [46].

As described in our published study protocol [46], our research trial originally included maternal attitudes toward parenting practices as an outcome. Unfortunately, the measure (Adult-Adolescent Parenting Inventory, second edition) that was selected for this outcome was found to be unreliable with the home visited mothers that participated in our pilot study. The principal investigator (PI; first author) received reports from research staff that mothers did not understand the items, and the Cronbach alphas for the different subscales of this measure reflected the mothers’ poor understanding of the items. For these reasons, this outcome could not be tested and was eliminated from this study. Our research trial included an additional aim to explore the feasibility and acceptability of integrating the video-delivered family therapy intervention into home visiting [46]. The findings for this additional aim will be reported in a subsequent manuscript.

Methods

Study Design

This study is a quasi-experimental, implementation-effectiveness hybrid trial. Although participants were not randomized, our study included a historical comparison group of mothers (n=13) who were previously enrolled in the home visiting programs at the 2 MIECHV agencies. The mothers in the historical comparison group were matched on baseline depression scores, age, and number of children. This study is registered at ClinicalTrials.gov (ID: NCT03282448).

Participants

Families were recruited from 2 MIECHV agencies in New England. These 2 agencies serve families in 3 rural counties in New England. Home visitors presented an institutional review board (IRB)–approved study information sheet to eligible families in their caseloads that included a brief overview of the study goals, intervention, study measures, potential benefits, and risks. Home visitors provided each interested family’s contact information to research assistants, who scheduled a meeting with each family to review the IRB consent forms, and obtained written informed consent from all willing participants. During the consent process, families were informed that study participation was voluntary and they could receive home visiting regardless of whether or not they decided to participate in the study.

Of the 28 potentially eligible families, 13 were excluded from the study because of the severity of psychiatric illnesses (eg, pervasive developmental disorder and bipolar disorder), maternal age that exceeded the age cut-off, domestic violence, and recent completion of standard dialectical behavior therapy (DBT) treatment. Overall, 2 families were excluded before the first therapy session because the home visitor was unable to locate them after they signed the consent form. Our final sample size for the intervention group was 13 families.

Textbox 1 includes the family inclusion criteria and Textbox 2 includes the family exclusion criteria.

Textbox 1. Family inclusion criteria.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home visited mothers, ages 13-25, in the first trimester of pregnancy through 18 months postpartum;</td>
</tr>
<tr>
<td>Mothers with Edinburgh Postnatal Depression Scale (EPDS) [47] scores of ≥8;</td>
</tr>
<tr>
<td>At least one of the mother’s adult family members (“Family member” is defined as one who is biologically related to the mother or a significant close other with whom she is not biologically related) must be available to participate in 8 of the 10 sessions;</td>
</tr>
<tr>
<td>Mothers and family members must be fluent in English;</td>
</tr>
<tr>
<td>Families with consistent internet access (i.e., subscribe to an internet service provider and do not experience weekly disruptions in service); and</td>
</tr>
<tr>
<td>Family owns cell phone, tablet or computer equipped with a camera and microphone.</td>
</tr>
</tbody>
</table>
Textbox 2. Family exclusion criteria.

**Exclusion criteria**

- Current substance abuse in mothers;
- Current domestic violence;
- Mothers who report or exhibit current suicidal ideation, self-injurious behavior, and psychotic symptoms during a home visit or in a therapy session;
- Mothers experiencing a severe Major Depressive Episode;
- Mothers who report homicidal ideation to the home visitor or study therapist;
- Mothers with pervasive developmental disorders;
- Mothers with a diagnosis of Post-Traumatic Stress Disorder;
- Current family therapy;
- Current individual therapy for mothers or recent completion of Dialectical Behavior Therapy; and/or
- Child Protective Services (CPS) involvement as reported by the home visitor.

Table 1. Study measures by aim, construct, respondent, and time point.

<table>
<thead>
<tr>
<th>Constructs</th>
<th>Measure</th>
<th>Time point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mother</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Quality of the therapeutic alliance</td>
<td>Working Alliance Inventories-Short Forms therapist and client versions⁴ [50,51]</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Retention</td>
<td>Percent of families who complete treatment</td>
</tr>
<tr>
<td>Family</td>
<td>Percent of completed homework assignments</td>
<td>X</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>Satisfaction Questionnaireᵇ</td>
<td>X</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Depression</td>
<td>BDI-IIᶜ [52]</td>
</tr>
<tr>
<td>Family functioning</td>
<td>Protective Factors Survey, Family Functioning/Resiliency subscale [53]</td>
<td>X</td>
</tr>
<tr>
<td>Emotion regulation</td>
<td>Emotion Regulation Questionnaire [54]</td>
<td>X</td>
</tr>
</tbody>
</table>

⁴Monitoring measure, also completed by therapist, at the end of therapy session 6.
ᵇDeveloped by research team.
ᶜBeck Depression Inventory-second edition; monitoring measures completed at the end of therapy sessions 4 and 8.

This study used standard home visiting screening procedures for depression, substance abuse, and domestic violence to identify eligible families for participation. Home visitors are expected to routinely screen mothers for depression and provide mental health referrals to those who screen positive for depression on the Edinburgh Postnatal Depression Scale (EPDS). Home visitors are also expected to routinely screen mothers for substance abuse (e.g., cut-annoyed-guilty-eye, CAGE [48]) and domestic violence (Relationship Assessment Scale [49]). Home visitors used the mothers’ most recent scores on these measures to determine if they were eligible for study participation.

**Data Collection**

The study measures and time points that align with each aim are presented in Table 1. Study measures were completed at 3 time points: family baseline (O₁); treatment phase (O₂); and post intervention (immediately after the final therapy session) and 2 months later (follow-up; O₃). Family baseline measures were completed in O₁ within 3 weeks before the first therapy session. Demographic information was collected on mothers, infants (age only), and family members. Monitoring measures were completed in O₂. Postintervention measures and the 2-month follow-up were completed in O₃.

**Feasibility and Acceptability Measures**

The Working Alliance Inventories-Short Forms (therapist and client versions) were used to measure quality of the therapeutic alliance. The developer recommends for therapists and clients to complete this measure beginning after the third, 60-min, therapy session [50,51]. As each family therapy session lasted only 30 min, the therapist and families completed it after the third.
sixth family therapy session instead and also completed it after the final family therapy session, post intervention. The measure includes 3 subscales to evaluate the strength of the therapeutic alliance: goals, bond, and task [50,51]. Each subscale includes response choices that range from seldom to always, but the numeric order is reversed for some of the items [50,51]. Two of the subscales demonstrated good reliability for families at the session 6 time point (goals, Cronbach alpha=.92; bond, Cronbach alpha=.85). The third subscale did not demonstrate good reliability at the session 6 time point (task, Cronbach alpha=.43) for families but demonstrated good reliability post intervention (task, Cronbach alpha=.72). Family retention was measured by calculating the percentage of families who completed treatment.

The PI and coinvestigators developed the Satisfaction Questionnaire for this study. It includes 7 quantitative items that include 6 multiple-choice questions, with response choices that range from 1 (strongly agree) to 4 (strongly disagree), and the seventh question is rated as true or false. In total, 5 of the items assess overall satisfaction with the therapy and satisfaction with each of the 4 skills modules. The last 2 items are on the usefulness of the HIPAA-compliant video-based communication technology. The Satisfaction Questionnaire also includes 3 open-ended questions about changes families would like to see to the video-delivered family therapy intervention, the helpfulness of the skills, and a section for general comments. The Satisfaction Questionnaire was administered to families post intervention. All the quantitative items on it demonstrated good reliability (Cronbach alpha=.85) post intervention. Completion of homework assignments was based on the family report to the therapist. The percentages of families who completed homework assignments for each of the 4 skills modules were calculated.

Outcome Measures

The Beck Depression Inventory-second edition (BDI-II) [52] was used to measure maternal depressive symptoms at baseline, post intervention, and at the 2-month follow-up. Maternal depressive symptoms were also monitored after the fourth and eighth therapy sessions using the BDI-II. This 21-item measure demonstrated good reliability in this study at baseline (Cronbach alpha=.88). The Protective Factors Survey-Family Functioning/Resiliency subscale [53] was used to measure family functioning at baseline, post intervention, and at the 2-month follow-up in mothers and their family members. This 5-item measure includes items on verbal communication, collaborative problem solving, cohesion, and family conflict. Response choices range from 1 (never) to 7 (always), with higher scores indicating better functioning [53]. It demonstrated good reliability in this study at baseline (Cronbach alpha=.90). The Emotion Regulation Questionnaire [54] was used to measure emotion regulation, and it includes 2 subscales: cognitive reappraisal and expressive suppression. This 10-item measure includes response choices ranging from 1 (strongly disagree) to 7 (strongly agree), with higher scores indicating greater use of the emotion regulation strategy [54]. Emotion regulation was measured in mothers and their family members at baseline, post intervention, and at the 2-month follow-up. The cognitive reappraisal subscale demonstrated good reliability at baseline (Cronbach alpha=.81). The expressive suppression subscale demonstrated adequate reliability at baseline (Cronbach alpha=.68).

The EPDS [47] is a depression screening measure that is routinely used in home visiting. One MIECHV agency was unable to recover 1 mother’s baseline EPDS but did have this mother’s baseline total EPDS score. For this reason, the mother’s baseline EPDS could not be included in the baseline EPDS reliability analysis. The EPDS demonstrated good reliability at baseline (Cronbach alpha=.76) and follow-up (Cronbach alpha=.89) in this study. EPDS scores of mothers who received the video-delivered family therapy intervention were compared with those of depressed mothers who were previously enrolled in home visiting but refused treatment.

Intervention

The video-delivered family therapy intervention consisted of 10, 30-min, weekly family therapy sessions that are concurrent with ongoing home visits [46]. The systemic treatment model was informed by DBT skills training for adolescents [55] and general systems theory [56]. It included skills that addressed 3 types of regulation: cognitive, emotion, and behavior [55]. The family therapy intervention included some skills from the following 4 DBT modules: mindfulness, distress tolerance, emotion regulation, and interpersonal effectiveness. The first author received written permission from the developers, Dr Jill Rathus and Dr Alec Miller, to adapt some skill teaching content from their model for use in the study intervention [55]. The study intervention addressed relational functioning but not parenting skills. Systemic interventions were woven into each skills module. The sessions were referred to as skills training sessions instead of family therapy sessions to reduce family stigma attitudes [46].

Home visitors were educated in how to use the HIPAA-compliant video-based communication technology (Vidyo) [57], and they educated families in its use [46]. Home visitors delivered most of the written skills handouts to families, but there were a few instances where these handouts had to be emailed to families because the families either misplaced the handouts or the home visitor was unable to deliver the handouts before the family therapy session.

Statistical Analysis

Sample Size

A total of 13 families participated in the video-delivered family therapy intervention. The target sample size for the intervention group was 12 families, and it was determined in consultation with our external community stakeholders [46]. They recommended that we implement the protocol in the 2 MIECHV agencies with a small number of families to obtain early evidence of feasibility and acceptability in preparation for larger studies of potential effectiveness and scalability [46]. The historical comparison group was made up of 13 depressed mothers who were previously enrolled in home visiting but refused treatment. Pilot studies are used to assess the feasibility of an intervention for a larger-scale study, and the use of pilot study effect size for sample size estimation can lead to type I and II errors [58]. For these reasons, this study was not powered.

Feasibility and Acceptability

For the first aim, univariate statistics (eg, means and proportions) were used to characterize family baseline characteristics and indicators of feasibility (quality of the therapeutic alliance and retention). For quality of the therapeutic alliance, average therapist scores and family scores were calculated for each subscale on the Working Alliance Inventories-Short Forms [50,51] after family therapy sessions 6 and 10. Spearman rank correlations (rho) were performed to assess associations between family scores and therapist scores after family therapy sessions 6 and 10. For retention, the total number of attended family therapy sessions was calculated for each family and overall.

For acceptability (family responsiveness), univariate statistics and qualitative data analytic methods [59] were used. For family completion of homework assignments, the percentage of completed assignments was calculated overall and for each of the 4 skills modules [46]. Per the study protocol [46], averages were calculated for multiple-choice items and responses to the open-ended questions were coded [59] on the Satisfaction Questionnaire. A thematic analytic approach [59] was used for the semistructured, open-ended questions on the Satisfaction Questionnaire. Codes were grouped into categories to create themes, and the emergent themes were identified and summarized [59]. For the question on the most helpful skills, numeric values were assigned to each theme, and themes were rank-ordered by the percentage of mothers and family members that reported the skill was helpful.

Maternal and Family Outcomes

For the second aim, basic sample statistics (eg, means and proportions) were used to summarize family measures at baseline, post intervention, and at follow-up. Wilcoxon signed-rank tests were used to assess changes in maternal and family outcomes from baseline to post intervention and from baseline to follow-up.

The historical comparison group included depressed mothers who were previously enrolled in home visiting at the 2 MIECHV agencies but refused treatment. The mothers in the historical comparison group were matched with mothers who received the video-delivered family therapy intervention on 3 key baseline variables: EPDS baseline score, maternal age, and number of biological children. As we were unable to find previously enrolled mothers with EPDS scores that were exactly the same as baseline EPDS scores for mothers who received the study intervention, we matched mothers based on the similarity of their EPDS scores. A total of 39% (5/13) of comparison group mothers had EPDS scores that were exactly the same as those of intervention group mothers. A total of 39% (5/13) of comparison group mothers had EPDS scores that were within 1 point of those of intervention group mothers. A total of 15% (2/13) of comparison group mothers had EPDS scores that were within 2 points of those of intervention group mothers. Only 1 comparison group mother’s EPDS score was 3 points higher than that of an intervention group mother. A Wilcoxon signed-rank test was used to assess changes in EPDS scores in the matched pairs over a 6-month period.

Results

Family Characteristics

The intervention group family baseline characteristics are presented in Table 2. Mothers ranged in age from 18 to 25 years. Mothers’ family members ranged in age from 19 to 49 years. Most families (88% [23/26] individual family members) were white, and 77% (10/13) of families were enrolled in home visiting for 5 or fewer months.
Table 2. Family baseline characteristics (N=13).

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mothers</strong></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>22.23 (1.92)</td>
</tr>
<tr>
<td>First time mothers (pregnant and postdelivery), n (%)</td>
<td>8 (61)</td>
</tr>
<tr>
<td>Pregnant, n (%)</td>
<td>5 (39)</td>
</tr>
<tr>
<td>Months postpartum, mean (SD)</td>
<td>4.81 (4.24)</td>
</tr>
<tr>
<td><strong>Highest level of education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>11th grade</td>
<td>1 (8)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>7 (54)</td>
</tr>
<tr>
<td>Some college</td>
<td>4 (31)</td>
</tr>
<tr>
<td>College graduate</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Enrolled in school or employed for pay, n (%)</td>
<td>4 (31)</td>
</tr>
<tr>
<td><strong>Mother’s relationship with family member, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Partner/spouse</td>
<td>7 (54)</td>
</tr>
<tr>
<td>Biological family member or close friend</td>
<td>6 (46)</td>
</tr>
<tr>
<td><strong>Severity of depressive symptoms, BDI-II(^a), mean (SD)</strong></td>
<td>25.62 (10.98)</td>
</tr>
<tr>
<td>Minimal</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Moderately severe</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Severe</td>
<td>6 (46)</td>
</tr>
<tr>
<td><strong>Family members</strong></td>
<td></td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>30.15 (10.61)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>7 (54)</td>
</tr>
<tr>
<td><strong>Highest level of education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>11th grade</td>
<td>1 (8)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>6 (46)</td>
</tr>
<tr>
<td>Some college</td>
<td>3 (23)</td>
</tr>
<tr>
<td>College graduate</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>1 (8)</td>
</tr>
</tbody>
</table>

\(^a\)Beck Depression Inventory-second edition.
Table 3. Comparison of maternal baseline characteristics by study group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n=13)</th>
<th>Historical comparison group (n=13)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>22.23 (1.92)</td>
<td>21.69 (1.55)</td>
<td>.44</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td>.32</td>
</tr>
<tr>
<td>White</td>
<td>12 (92)</td>
<td>0 (100)</td>
<td>1a</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (8)</td>
<td>0 (0)</td>
<td>—</td>
</tr>
<tr>
<td>Biological children, mean (SD)</td>
<td>1.00 (0.58)</td>
<td>1.23 (0.44)</td>
<td>.26</td>
</tr>
<tr>
<td>Highest level of education, n (%)</td>
<td></td>
<td></td>
<td>.17</td>
</tr>
<tr>
<td>High school</td>
<td>8 (61)</td>
<td>12 (92)</td>
<td>—</td>
</tr>
<tr>
<td>Some college</td>
<td>4 (31)</td>
<td>1 (8)</td>
<td>—</td>
</tr>
<tr>
<td>College graduate</td>
<td>1 (8)</td>
<td>0 (0)</td>
<td>—</td>
</tr>
<tr>
<td>Serious relationship or married, n (%)</td>
<td></td>
<td>9 (69)</td>
<td>0 (100)</td>
</tr>
</tbody>
</table>

aNot applicable.

There were no statistically significant differences in baseline characteristics of mothers who received the video-delivered family therapy intervention and those in the historical comparison group. Table 3 shows the baseline characteristics of mothers in both study groups.

The therapist consistently used a computer in her office to deliver the family therapy sessions using the HIPAA-compliant video-based communication technology. Families varied in the types of devices they used to participate in the family therapy sessions. About 31% (4/13) of families used only a tablet (eg, iPad and Amazon Fire) to participate in the family therapy sessions, and 31% (4/13) of families used only a computer to participate in these sessions. About 15% (2/13) of families used more than 1 device (eg, cell phone for some sessions and tablet for some sessions). Approximately 15% (2/13) of families used only a cell phone to participate in the family therapy sessions, and 1 family used an iPod Touch to participate in the sessions. Only 2 families had to reschedule family therapy sessions because of disruptions in internet service.

Feasibility and Acceptability

For quality of the therapeutic alliance, family ratings on the 5-point subscales for the Working Alliance Inventories-Short Forms, goals (mean=4.8, SD=0.2), bond (mean=4.9, SD=0.3), and task (mean=4.4, SD=0.3), were very strong. As shown in Table 4, the family ratings were positively correlated with therapist ratings (P<.05) post intervention.

All families were retained, and no families dropped out of the intervention or the study. All mothers attended all 10 therapy sessions. Family members attended an average of 8.4 therapy sessions. One family included a home visited mother, her boyfriend, and her friend (also a home visited mother). After the fourth session, the couple decided to complete the family therapy without the other home visited mother. For this reason, the other home visited mother attended the remaining 6 therapy sessions without a family member.

All mothers and family members completed homework assignments from each of the 4 skills modules. Only 1 mother reported that she would prefer in-person delivered sessions, instead of video-delivered sessions, in the future. For the qualitative item on the helpfulness of the skills on the Satisfaction Questionnaire, all families reported that the mindfulness skills were most helpful for them, followed by emotion regulation (9/13, 69%), distress tolerance (6/13, 46%), and interpersonal effectiveness (5/13, 39%). Families did not report any suggestions for changes to the intervention. No families reported any complaints. The results for the remaining quantitative items on the Satisfaction Questionnaire are included in Table 5.

Maternal and Family Outcomes

The results showed statistically significant reductions in maternal depressive symptoms (P=.001) at the 2-month follow-up. Figure 1 shows the decrease in maternal depressive symptoms by time point.

The results showed statistically significant improvements in family functioning (P=.02) and cognitive reappraisal (P=.004) at the 2-month follow-up. Table 6 includes the impacts of the video-delivered family therapy intervention on maternal and family outcomes.

Although maternal school enrollment and job attainment were not proposed outcomes in this study, 39% (5/13) of mothers either enrolled in school or were employed for pay by the 2-month follow-up. Furthermore, 31% (4/13) of mothers who were in school or employed for pay at baseline maintained this status post intervention. This finding indicates that the significant reduction in maternal depressive symptoms resulted in improved functioning.

This study included a historical comparison group of 13 mothers who were previously enrolled in home visiting and screened positive for depression but refused treatment. Home visiting programs routinely use the EPDS to screen for maternal depressive symptoms at different time points. The EPDS scores of mothers who received the video-delivered family therapy intervention were compared with those of previously enrolled depressed mothers who refused treatment. Table 7 includes the differences in EPDS scores by study group.
Table 4. Correlations between therapist and family therapeutic alliance ratings post intervention.

<table>
<thead>
<tr>
<th>Working Alliance Inventories-Short Forms Subscale</th>
<th>Correlation coefficient</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals</td>
<td>.571</td>
<td>.04</td>
</tr>
<tr>
<td>Bond</td>
<td>.607</td>
<td>.03</td>
</tr>
<tr>
<td>Task</td>
<td>.567</td>
<td>.04</td>
</tr>
</tbody>
</table>

Table 5. Family satisfaction with video-delivered family therapy intervention (N=13).

<table>
<thead>
<tr>
<th>Questionnaire item</th>
<th>Strongly agree, n (%)</th>
<th>Agree, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am satisfied with the video-delivered skills training that I received in this study</td>
<td>13 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>In the sessions, I learned skills to help me stay focused on the present moment</td>
<td>13 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>In the sessions, I learned skills to help me to manage problems that could not be immediately resolved</td>
<td>10 (77)</td>
<td>3 (23)</td>
</tr>
<tr>
<td>In the sessions, I learned skills to help me to manage my emotions</td>
<td>12 (92)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>In the sessions, I learned skills that strengthened my relationships</td>
<td>12 (92)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>The video-based technology was convenient and easy to use</td>
<td>11 (85)</td>
<td>2 (15)</td>
</tr>
</tbody>
</table>

Figure 1. Decrease in maternal depressive symptoms by time point (n=13). BDI-II: Beck Depression Inventory-second edition.

Table 6. Video-delivered family therapy intervention impacts on outcomes.

<table>
<thead>
<tr>
<th>Families (N=13)</th>
<th>Baseline, mean (SD)</th>
<th>Post intervention, mean (SD)</th>
<th>Follow-up, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal depressive symptoms&lt;sup&gt;a&lt;/sup&gt;</td>
<td>25.62 (10.98)</td>
<td>5.54 (4.68)</td>
<td>5.31 (4.35)</td>
<td>≤.001</td>
</tr>
<tr>
<td>Family functioning&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4.82 (1.05)</td>
<td>5.96 (0.72)</td>
<td>5.65 (0.85)</td>
<td>.02</td>
</tr>
<tr>
<td>Family emotion regulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive reappraisal&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4.47 (0.76)</td>
<td>5.66 (0.88)</td>
<td>5.49 (0.40)</td>
<td>.004</td>
</tr>
<tr>
<td>Expressive suppression&lt;sup&gt;c&lt;/sup&gt;</td>
<td>3.47 (0.85)</td>
<td>3.51 (1.03)</td>
<td>3.56 (0.84)</td>
<td>.65</td>
</tr>
</tbody>
</table>

<sup>a</sup>Beck Depression Inventory-second edition.
<sup>b</sup>Protective Factors Survey-Family Functioning/Resiliency subscale item mean.
<sup>c</sup>Emotion Regulation Questionnaire subscale total item means.

Table 7. Comparison of maternal depressive symptoms by study group.

<table>
<thead>
<tr>
<th>Depressive symptoms&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Intervention group, mean (SD)</th>
<th>Historical comparison group, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>13.62 (4.75)</td>
<td>13.46 (4.33)</td>
<td>.57</td>
</tr>
<tr>
<td>Follow-up&lt;sup&gt;b&lt;/sup&gt;</td>
<td>6.08 (6.22)</td>
<td>15.31 (5.01)</td>
<td>≤.001</td>
</tr>
</tbody>
</table>

<sup>a</sup>Depressive symptoms were measured by home visitors using the Edinburgh Postnatal Depression Scale.
<sup>b</sup>The follow-up period was about 6 months.
Discussion

Principal Findings
This study explored the feasibility, acceptability, and preliminary impacts of a video-delivered family therapy intervention for home visited young mothers with perinatal depressive symptoms and their adult family members. Our findings showed that mothers experienced a statistically significant reduction in depressive symptoms, and families experienced statistically significant improvements in family functioning and the emotion regulation strategy of cognitive reappraisal. This study demonstrated the preliminary safety of the video-delivered family therapy for home visited depressed young mothers as our results showed that maternal depressive symptoms consistently decreased from baseline to the 2-month follow-up (see Figure 1). We found that the significant reduction in maternal depressive symptoms also resulted in an improvement in maternal occupational functioning in that 39% (5/13) of mothers either enrolled in school or were employed for pay by the 2-month follow-up. Furthermore, 31% (4/13) of mothers who were either enrolled in school or employed for pay at baseline maintained this status at the 2-month follow-up.

Some technology-based interventions (eg, short message service text messages, Web-based peer support, and internet therapy) have been tested in perinatal and postpartum women with depression and have been shown to be effective in reducing their depressive symptoms [60-63]. For example, a recent systematic review and meta-analysis showed that therapist-supported internet-based cognitive behavioral therapy significantly reduced depressive symptoms in postpartum women [64]. The video-delivered family therapy intervention presented in this study is unique, and to our knowledge, this is the first study of a technology-based family therapy intervention with home visited women with perinatal depressive symptoms.

To date, 4 individual-level psychosocial interventions have been developed for and tested in home visited depressed mothers [21-24]. Either mothers travel to receive the intervention [23] or providers travel to mothers’ homes to deliver these interventions [21,22,24]. Young mothers experience family conflict [25-31,33-35], and these interventions do not include family members to resolve the conflict. Although maternal depressive symptoms are primary outcomes in these interventions [21-24], systemic interventions are not included to create second-order change by shifting family dynamics to improve family functioning. Furthermore, the video-delivered family therapy intervention differs from other similar family therapy models used with home visited families [65-67] in that it does not focus on parenting practices or parenting skills and it is delivered using HIPAA-compliant video-based communication technology. This study fills an important gap in the existing literature in that it provides preliminary support for a technology-based family therapy intervention that targets home visited young women with clinically significant perinatal depressive symptoms.

This study demonstrated the feasibility and acceptability of the video-delivered family therapy intervention. We found support for all 3 of our hypotheses. First, we hypothesized that mothers would show a clinically meaningful reduction in depressive symptoms at the 2-month follow-up [46]. The results showed that mothers demonstrated a statistically significant reduction in depressive symptoms at the 2-month follow-up. Second, we hypothesized that mothers who received the video-delivered family therapy intervention would show a greater reduction in depressive symptoms when compared with depressed mothers who were previously enrolled in home visiting but refused treatment [46]. We found that mothers who received the video-delivered family therapy intervention had a significantly greater reduction in depressive symptoms than did those who received home visiting but refused treatment for depression. Finally, we hypothesized that families would show clinically meaningful improvements in family functioning and emotion regulation at the 2-month follow-up [46]. Our results showed that families demonstrated statistically significant improvements in family functioning and 1 emotion regulation strategy, cognitive reappraisal. Families did not show a statistically significant improvement in expressive suppression. We believe that there are 2 possible reasons why they did not show a significant improvement in expressive suppression. First, the Emotion Regulation Questionnaire-Expressive Suppression subscale did not demonstrate very strong reliability in our sample of families (Cronbach alpha=.68) at baseline. Second, their scores were similar to the norm [54] for this subscale.

The significant reduction in maternal depressive symptoms and significant improvements in family functioning and cognitive reappraisal hold promise for future research on this intervention. Concordantly, we plan to conduct a randomized trial of the study intervention to formally test its impacts on these outcomes.

Limitations
This study had several limitations. First, the results must be interpreted with caution, given the small sample size. Second, we were unable to conduct a long-term follow-up because of the short-term nature of the grant received to conduct this study. Third, this study did not include a control group. Fourth, the majority of the participants were white, and the lack of ethnic diversity limits the generalizability of our findings. Fifth, most of the participants graduated from high school, and our findings may not generalize to those with lower levels of education. Sixth, the study included heterosexual mothers, and although we did not exclude mothers who identify as lesbian from participating in the study, it is possible that the findings may not be generalizable to mothers who identify as lesbian. Finally, the findings from this type of study intervention may not be generalizable to home visited families in urban communities, given they may face fewer logistical barriers and may prefer traveling to providers’ offices for family therapy.

Conclusions
There is a scarcity of research on the use of HIPAA-compliant video-based communication technology to deliver family therapy for treatment of perinatal depression in rural regions of the United States. The studies that have been conducted on this method of delivery focus on family therapy interventions for behavioral problems in children [41-44], but none have targeted perinatal depressive symptoms in young mothers with family dysfunction.
Acknowledgments

The authors gratefully acknowledge all the home visitors and families who participated in this study and the research assistants for their help with the study activities. Research reported in this publication was supported by The Dartmouth Clinical and Translational Science Institute, under award number UL1TR001086 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Conflicts of Interest

None declared.

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Abbreviations

BDI-II: Beck Depression Inventory-second edition
CAGE: cut down-annoyed-guilty-eye opener
DBT: dialectical behavior therapy
EPDS: Edinburgh Postnatal Depression Scale
HIPAA: Health Insurance Portability and Accountability Act
IRB: institutional review board
MIECHV: Maternal, Infant, and Early Childhood Home Visiting
PI: principal investigator

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Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial

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Abstract

Background: Students in need of mental health care face many barriers including cost, location, availability, and stigma. Studies show that computer-assisted therapy and 1 conversational chatbot delivering cognitive behavioral therapy (CBT) offer a less-intensive and more cost-effective alternative for treating depression and anxiety. Although CBT is one of the most effective treatment methods, applying an integrative approach has been linked to equally effective posttreatment improvement. Integrative psychological artificial intelligence (AI) offers a scalable solution as the demand for affordable, convenient, lasting, and secure support grows.

Objective: This study aimed to assess the feasibility and efficacy of using an integrative psychological AI, Tess, to reduce self-identified symptoms of depression and anxiety in college students.

Methods: In this randomized controlled trial, 75 participants were recruited from 15 universities across the United States. All participants completed Web-based surveys, including the Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder Scale (GAD-7), and Positive and Negative Affect Scale (PANAS) at baseline and 2 to 4 weeks later (T2). The 2 test groups consisted of 50 participants in total and were randomized to receive unlimited access to Tess for either 2 weeks (n=24) or 4 weeks (n=26). The information-only control group participants (n=24) received an electronic link to the National Institute of Mental Health’s (NIMH) eBook on depression among college students and were only granted access to Tess after completion of the study.

Results: A sample of 74 participants completed this study with 0% attrition from the test group and less than 1% attrition from the control group (1/24). The average age of participants was 22.9 years, with 70% of participants being female (52/74), mostly Asian (37/74, 51%), and white (32/74, 41%). Group 1 received unlimited access to Tess, with daily check-ins for 2 weeks. Group 2 received unlimited access to Tess with biweekly check-ins for 4 weeks. The information-only control group was provided with an electronic link to the NIMH’s eBook. Multivariate analysis of covariance was conducted. We used an alpha level of .05 for all statistical tests. Results revealed a statistically significant difference between the control group and group 1, such that group 1 reported a significant reduction in symptoms of depression as measured by the PHQ-9 (P=.03), whereas those in the control group did not. A statistically significant difference was found between the control group and both test groups 1 and 2 for symptoms of anxiety as measured by the GAD-7. Group 1 (P=.045) and group 2 (P=.02) reported a significant reduction in symptoms of anxiety, whereas the control group did not. A statistically significant difference was found on the PANAS between the control group and group 1 (P=.03) and suggests that Tess did impact scores.
Conclusions: This study offers evidence that AI can serve as a cost-effective and accessible therapeutic agent. Although not designed to appropriate the role of a trained therapist, integrative psychological AI emerges as a feasible option for delivering support.

Trial Registration: International Standard Randomized Controlled Trial Number: ISRCTN61214172; https://doi.org/10.1186/ISRCTN61214172.

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KEYWORDS
artificial intelligence; mental health services; depression; anxiety; students

Introduction

Background
Approximately 20 million college students suffer from mental illness in the United States alone [1]. More than 50% of college students report experiencing symptoms of depression and anxiety that impact daily functioning within the last year [2]. Despite a clear need for clinical services, up to 75% of college students do not access adequate mental health care [3]. With a growing desire for on-demand services that engage students and reduce stigma, Web- and mobile-based mental health interventions offer a scalable solution.

Mental health care solutions such as computer-assisted therapy (CAT) have been shown to be a less-intensive and more cost-effective method to deliver empirically validated treatments for depression and anxiety [4,5]. Although traditional in-person treatment remains the standard of care for those with clinical levels of depression, preliminary studies suggest that self-help computer-based cognitive and behavioral interventions produce similar outcomes [6] and are efficacious in the treatment of subthreshold mood disorders.

Moreover, 1 study revealed that nearly 70% of patients expressed interest in using mobile health (mHealth) apps to self-monitor and self-manage their mental health [7]. Early evidence suggests that patients open up more while using an mHealth app than during face-to-face therapy [8]. With 1 app for patients suffering from suicidal thoughts, more subjects reported suicidal ideation using the app than they did on the traditionally administered Patient Health Questionnaire (PHQ-9) [9]. Psychological artificial intelligence (AI) delivering cognitive behavioral therapy (CBT) has been shown to be a feasible, engaging, and effective solution for reducing symptoms of depression and anxiety in college students [10-12]. However, the efficacy of using psychological AI to deliver integrative mental health care, including CBT, requires further exploration. Although CBT is one of the most effective methods for treating anxiety and depression, evidence shows that alternative forms of therapy lead to equally successful outcomes [13]. Applying an integrative approach to therapy for treating patients with depression has been linked to similar levels of posttreatment improvement as those receiving cognitive therapy [14].

Objective
The objective of this study was to assess the efficacy of using the integrative psychological AI, Tess, to reduce symptoms of depression and anxiety in an engaging way. Tess was designed to deliver personalized conversations based on the expressed emotions and mental health concerns of participants, not to replace trained therapists. Tess focuses on language as the most explicit form of communication, with the proposition that communication between people reveals individual conceptualizations of specific emotions (unpublished data [15]) [16].

This study compared outcomes from 2 to 4 weeks of using integrative psychological AI (Tess) with an information control group (National Institute of Mental Health’s [NIMH] eBook) in a nonclinical college population. It was hypothesized that engaging in conversations with Tess would lead to greater improvement in symptoms relative to the information control group. In addition, we predicted that the duration of time in which participants interacted with Tess would impact the level of symptom reduction. To assess this, participants in the test group were randomly selected to participate in 1 of the 2 groups, which received either 2 or 4 weeks of unlimited access to Tess.

Methods

Recruitment
Participants were recruited using a flyer (Multimedia Appendix 1) distributed to professors and alumni via email and posted through social media outlets such as Facebook and university community channels targeting students across 15 universities across the United States. Inclusion criteria included current enrollment at a university in the United States, aged 18 years and older (screened at the first level via checkbox confirmation), and able to read English (implied). To guard against compromise, for example, from malicious bots, all potential participants were sent an email requesting that they respond using their university email denoting their confirmation.

Confirmed participants were randomized via a computer algorithm that automatically generated a number between 0 and 2 (Figure 1). All participants completed the baseline questionnaires. Participants with number 0 were sent a link to NIMH’s eBook [17] on depression among college students. Participants with numbers 1 and 2 were allocated to receive a direct link to begin chatting with Tess via an instant messenger app. To assess the impact on duration of access on symptom reduction, group 1 participants were granted unlimited access to Tess for 2 weeks and group 2 participants for 4 weeks. Because the randomization allocation occurred algorithmically, allocation concealment was in place. However, the condition to which each participant was allocated was not masked for the service providers (Tess). After approximately 2 weeks (group...
1) or 4 weeks (group 0+2), participants were contacted again to complete a second set of questionnaires online. Participants were offered a prorated incentive of US $20 for completion of both assessments.

**Figure 1.** Participant recruitment flow. AI: artificial intelligence.

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**Ethics and Informed Consent**

This study was retrospectively registered under the trial number of ISRCTN61214172, and involved a nonclinical population of college students. Refer to the Multimedia Appendix 2 for this study’s Consolidated Standards of Reporting Trials-eHealth checklist [18].

Participants indicated their consent to the study’s terms via a checkbox (e-signature) on a closed form (Multimedia Appendix 3) sent via email. The consent informed participants about the study criteria, intervention details, confidentiality, incentives, participant rights, and whom to contact for questions or request to withdraw. Participants who expressed suicidal ideation or self-harm were provided with numbers to a crisis helpline and suicide prevention text line. A total of 75 participants signed the informed consent, and 74 of those completed this study with 0% attrition from the test group and less than 1% attrition from the control group (1/24).

The third author of this paper served as an external representative to support data collection and analysis, which was provided by X2AI Inc. All data, including usage, was deidentified so as to protect the privacy of participants and was reported in aggregate only.

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**Interventions**

**Tess**

Tess is a psychological AI chatbot designed by X2AI Inc to deliver brief conversations in the form of integrative mental health support, psychoeducation, and reminders. Tess serves as a therapeutic tool or resource that can be used as an adjunct to therapy that supports an integrative approach and is not intended to replace the role of a therapist.

Tess was inspired by the first conversational AI, ELIZA, which examined natural language communication between people and machines in the 1960s [19]. Where ELIZA was limited, Tess has excelled with the rapid advancement of technology and machine learning strategies that help improve AI memory and emotion identification.

The novelty of Tess is that it is a customizable platform, which allows for content to be tailored aligning with a specific form of treatment or user demographics, for example, 1 large health system in the United States customized Tess to deliver interventions based on motivational interviewing and behavioral activation to help reinforce weight management goals in a group of adolescents suffering from prediabetes symptoms (unpublished data [20]). To prevent misuse of the system, organizations are educated on Tess’ ethical AI code, which includes principles from the 2018 Lords Report [21] and the American Psychological Association Code of Conduct [22].
Technical Overview
Tess is maintained using a combination of technologies, emotion algorithms, and machine learning techniques to support a variety of features. Collaboration with mental health and emotion experts is a critical element of Tess’ capacity for success. All content is developed, screened, and matched to specific user inputs (ie, emotions and topics) by experienced professionals. The partnership required between humans and technology to create and maintain the chatbot is made possible through an administration panel that may be integrated with existing electronic health record systems. Each organization or clinician is provided a log-in with restricted access to manage their clients (Tess users) and content. For this study, the principal investigator and authors were provided with unique log-ins to a restricted view of participant interactions with Tess. Personally identifiable information was removed from all transcripts. Processing and storage are done on secure servers that meet Health Insurance Portability and Accountability Act–compliant regulations. Data are stored within the country of residence for all participants given access.

Tess can be configured to deliver services through existing communication channels such as Facebook messenger, Slack, and short messaging service text messaging, without requiring users to download an app. Users can access Tess using a mobile phone number or through their personal accounts associated with a specific communication channel. Tess is capable of interpreting free text messages; alternatively, users can opt for preselected responses similar to existing chatbots. This enhances Tess’ capacity to deliver more personalized and integrative interventions.

Customization
Content was specially selected, expanded upon, and tested by mental health professionals for the purpose of this study. Furthermore, 30 min to 1-hour interviews were conducted with students, professors, and university counselors to support content development. User acceptance testing was conducted with a small group of students, which provided feedback to enhance the quality and reliability of interventions and scripts. A modest amount of emojis were included in the conversations to increase user engagement.

To support the evaluation of duration and frequency of automatic messages from Tess, the test groups were assigned to 1 of the 2 experiments. Group 1 received daily messages from Tess over a 2-week period, introducing new topics or following up on previously discussed concerns. Group 2 received the same content and option for follow-up messages from Tess, but with biweekly messages over a 4-week period. It is of note that Tess was disguised as Zara for this study to prevent bias in the unlikely chance that participants had been exposed to Tess through another initiative.

Although Tess is capable of connecting users with a counselor in case of crisis, this study limited crisis support to match the methodology of a previous study [10]. If users reported suicidal or homicidal ideation or indicated a crisis, Tess provided numbers to the national suicide prevention hotline, crisis text line, and 911 and encouraged the user to end the chat and reach out for professional help.

Integrative Support Approach
Tess delivers mental health interventions that have repeatedly been shown to reduce symptoms of depression and anxiety, such as CBT [23], which maintains a strong evidence base [24]. In addition to CBT, Tess can also deliver a variety of similar, clinically proven therapies, dependent on both the emotions reported by the individual and the nature of their concern. These include interventions based on the transtheoretical model [25], emotionally focused therapy [26,27], solution-focused brief therapy [28], motivational interviewing [29], and more. By interacting with Tess, users experience the benefits of journaling, which has been shown to increase the positive perception of experiences [30] and significantly improve self-efficacy [31]. During the study, Tess delivered interventions rooted in a variety of psychological modalities such as CBT, mindfulness-based therapy, emotionally focused therapy, acceptance and commitment therapy, motivational interviewing, self-compassion therapy, and interpersonal psychotherapy. For example, journaling and relaxation strategies are used across multiple modalities, although the strategy and language used to deliver these interventions vary. Tess is structured to reply with prescribed statements, reviewed by mental health professionals, to replicate an empathic response that is appropriate to the participants’ inputted emotion or concern [32]. For example, in response to endorsed loneliness, Tess replied “I’m so sorry you’re feeling lonely. I guess we all feel a little lonely sometimes,” or Tess showed excitement by replying, “Yay, always good to hear that!!” Specific interventions are delivered based on the users’ reported mood. For example, a participant indicating that he or she feels anxious may be offered a relaxation strategy to cope in the moment.

Just as therapists adjust their style to accommodate a client’s therapeutic preference over time, Tess gathers feedback to deliver interventions that best meet a user’s needs. After every intervention, Tess asks a simple question such as “was that helpful?,” to which user replies are coded as either positive, negative, or neutral. For example, if a user responds positively (ie, yes, thank you) to a CBT-based intervention and negatively (ie, no, not really) to self-compassion therapy, Tess will deliver more interventions rooted in CBT. For users who respond negatively or neutrally, Tess will continue to offer alternative interventions until the user responds positively or voluntarily ends the conversation.

Information Control Condition
Participants in the information-only control group were provided with an electronic link to the NIMH’s eBook on depression among college students [33]. The eBook is free for the public and provides evidence-based information and resources to help students identify, and seek treatment for, symptoms of depression. It also recommends additional literature and provides helpline numbers. Although participants in this group were not granted access to Tess during the course of the study, they were provided access on completion as an additional source of support.
Measures
Participants were invited to take the following assessments via a closed email survey so that only those who were invited could gain access. All assessments were delivered through Google Forms.

The Patient Health Questionnaire-9
The PHQ-9 [34] is a 9-item, self-report questionnaire that evaluates the frequency and severity of symptoms of depression within the previous 2 weeks. Each of the 9 items is based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-4) criteria for major depressive disorder and can be scored on a 0 (not at all) to 3 (nearly every day) scale. The PHQ-9 is one of the most widely used, reliable, and validated measures of depressive symptoms. If a participant scores between 0 and 5, this indicates they do not experience symptoms of depression. Scores of 5 to 9, 10 to 14, 15 to 20, and >20 indicate mild, moderate, moderately severe, and severe depression, respectively.

Generalized Anxiety Disorder-7
The Generalized Anxiety Disorder 7-item scale (GAD-7) [35] is a valid, brief self-report tool to assess the frequency and severity of anxious thoughts and behaviors over the past 2 weeks. On the basis of the DSM-4 diagnostic criteria for GAD-7, the scores of all 7 items range from 0 (not at all) to 3 (nearly every day). If a participant scores less than 10, it indicates moderate anxiety. A score greater than 15 indicates severe anxiety.

Positive and Negative Affect Schedule
The Positive and Negative Affect Schedule (PANAS) [36] is a 20-item self-report measure of current positive and negative affect. Half of the items represent positive affect (ie, interested, excited, and determined), whereas the other half are indicative of negative affect (ie, hostile, scared, and ashamed). Items are scored on a 1 (very slightly or not at all) to 5 (extremely) scale, with higher scores representing higher affect. Scores range from 10 to 50, and positive and negative affect are summed independent of each other.

User Satisfaction and Engagement
A user satisfaction survey was created, tested for usability and technical functionality, and delivered to all participants at the end of the study to gather qualitative results. The survey included 9 questions, with 4 scaled questions, such as: "How satisfied were you overall?" and "How satisfied were you with the content?" as well as 2 open-ended questions, such as "What was the best thing about using the chatbot?" and "Did you learn anything new?". Finally, for test group participants only, we measured engagement based on the number of messages exchanged between Tess and the participants per group and in total.

Statistical Analysis
Analyses were conducted using SPSS. A multivariate analysis of covariance (MANOVA) was used to compare the anxiety (GAD-7), depression (PHQ-9), and PANAS scale means of male and female students for the 3 groups, namely, control, group 1 (Tess for 2 weeks), and group 2 (Tess for 4 weeks). The multivariate analysis showed significance between the control group and group 1, $F_1=3.146$, $P=.03$. The univariate $F$ tests for anxiety and depression were significant across all scales, between control and group 1, $F_1=3.491$, $P=.03$ for PANAS, $F_2=4.037$, $P=.02$ for PHQ, and $F_2=4.497$, $P=.01$ for GAD-7. Thus, anxiety and depression were significantly decreased through students’ use of Tess.

A post hoc analysis showed a significant difference was found with the Tukey's Honestly Significant Difference Test (Multimedia Appendix 4) on the PANAS between the control and group 1. A statistically significant difference was found on the PHQ-9 between the control and group 1 at an alpha level of $.05$. For multivariate tests, the tests of between-subject effects, and intervention sample GIF, see Multimedia Appendix 5, Multimedia Appendix 6, and Multimedia Appendix 7, respectively. This finding confirms Tess was helpful in decreasing depressive symptoms. A statistically significant difference was found on the GAD-7 between the control group and both groups 1 and 2, at an alpha level of $.05$. This finding supports the hypothesis that Tess would be helpful in decreasing anxiety symptoms. Due to attrition, 1 control group participant was dropped out and not included in the total N for the control group.

Results

Participant Demographics
Table 1 shows the demographic information and baseline scores on clinical variables for those with data from the entire sample (N=74). Participants were aged on average 22.9 years and over two-thirds were female. The majority of participants were Asian (37/74, 51%) and white (32/74, 41%).

In the control group, 67% (16/24) of participants were females, 29% (7/24) were males, and 4% (1/24) identified as nonconforming. The average age for the control group was 22.5 years. The majority of the control group participants were white (11/24, 46%). The remainder of the control group participants were Asian (8/24, 33%), other (3/24, 13%), and African American (2/24, 8%).

Group 1 consisted of 17 (17/24, 71%) females and 7 (7/24, 29%) males out of 24 participants. The average age for group 1 was 24.1 years. This group consisted of mostly white (13/24, 54%) and Asian (11/24, 46%) participants.

Group 2 consisted of 19 (19/26, 73%) females and 7 (7/26, 27%) males out of 26 participants. The average age for group 2 was 22.2 years. This group had mostly Asian participants (18/26, 69%), with 31% (8/26) being white.

Participants’ Clinical Variables
Table 1 shows the scores for the 2 scales and for the subscales of the PANAS. In the control group, the average PHQ-9 score was 8.17, for group 1 it was 6.67, and for group 2 it was 7.04. The GAD-7 had an average score of 9.46 for the control group, 6.71 for group 1, and 7.5 for group 2. The average positive affect scale of the PANAS for the control group was 22.13, for group
it was 19.88, and for group 2 it was 21.31. The average negative affect scale of the PANAS for the control group was 15.75, for group 1 it was 13.08, and for group 2 it was 14.38.

Table 1. Demographic and clinical variables of participants at baseline.

<table>
<thead>
<tr>
<th>Demographic and clinical variables</th>
<th>Information control</th>
<th>Tess group 1</th>
<th>Tess group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scale, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression (PHQ⁹-9)</td>
<td>8.17 (4.2)</td>
<td>6.67 (4.6)</td>
<td>7.04 (4.9)</td>
</tr>
<tr>
<td>Anxiety (GAD⁶-7)</td>
<td>9.46 (3.9)</td>
<td>6.71 (4.0)</td>
<td>7.5 (4.9)</td>
</tr>
<tr>
<td>Positive affect</td>
<td>22.13 (1.4)</td>
<td>19.88 (1.4)</td>
<td>21.31 (1.3)</td>
</tr>
<tr>
<td>Negative affect</td>
<td>15.75 (1.3)</td>
<td>13.08 (1.3)</td>
<td>14.38 (1.3)</td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>22.5 (4.0)</td>
<td>24.1 (5.4)</td>
<td>22.19 (2.8)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (67)</td>
<td>17 (71)</td>
<td>19 (73)</td>
</tr>
<tr>
<td>Male</td>
<td>7 (29)</td>
<td>7 (29)</td>
<td>7 (27)</td>
</tr>
<tr>
<td>Nonconforming</td>
<td>1 (4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>2 (8)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Asian</td>
<td>8 (33)</td>
<td>11 (46)</td>
<td>18 (69)</td>
</tr>
<tr>
<td>White</td>
<td>11 (46)</td>
<td>13 (54)</td>
<td>8 (31)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (13)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

⁹PHQ: Patient Health Questionnaire.
⁶GAD: Generalized Anxiety Disorder Scale.

Analysis

Statistical power calculations using MANOVA revealed a moderate to large effect size (Cohen d=0.68) for depression, with an alpha at 5%.

The Patient Health Questionnaire-9

A statistically significant difference was found between the control group and group 1, which had unlimited access to Tess with daily check-ins for 2 weeks (P=.02) as measured by the PHQ-9. Figure 2 shows that MANOVA revealed a significant group difference on depression such that for the test group participants, symptoms of depression over the study period were significantly reduced, whereas for the information control group, their symptoms of depression were increased. Although the increase found in the control group is probably because of the inability to adjust for potential confounding variables, participants in this group may have experienced a slight increase in symptoms over time. Overall, these findings suggest that Tess was helpful in decreasing depressive symptoms.

Figure 2. Change in depression by group (patient health questionnaire-9 score).
**Generalized Anxiety Disorder-7**

A statistically significant difference was found between the control group and both test groups 1 and 2 for symptoms of anxiety as measured by the GAD-7. Group 1 ($P=.045$) and group 2 ($P=.02$) reported a significant reduction in symptoms of anxiety, whereas the control group did not.

A statistically significant difference was found on the GAD-7 between the control group and both groups 1 and 2. For group 1, the $P$ value of .045 was statistically significant at an alpha level of .05. For group 2, the $P$ value of .02 was statistically significant at an alpha level of .05. Figure 3 shows that MANOVA revealed a significant group difference on anxiety such that those in the test group experienced significantly reduced symptoms of anxiety over the study period as measured by the GAD-7, whereas those in the information control group experienced increased symptoms of anxiety. This increase might be explained similarly to the aforementioned depressive scores— inability to adjust for potential confounding variables, or simply that, participants may have experienced a slight increase in symptoms over time. These findings support the hypothesis that Tess would be helpful in decreasing anxiety symptoms.

**Figure 3.** Change in anxiety by group (generalized anxiety disorder-7 score).

**Positive and Negative Affect Schedule**

A statistically significant difference was found on the PANAS between the control group and group 1 ($P=.03$) and suggests that Tess did impact the scores.

**User Satisfaction and Engagement**

Table 2 shows the difference between the information control group and the test group based on answers for the user satisfaction survey to gather qualitative results. This table shows a significant difference between both groups. For example, 86% (43/50) participants were overall satisfied with Tess and only 60% (14/24) with the eBook. Moreover, 80% (40/50) learned something new from Tess, and 43% (10/24) learned something new from the eBook.

**Figure 4** shows a thematic map of participants’ responses to the question “What was the best thing about your experience using Tess?” Two major themes emerged in respect to this question: process and content. In the process theme, the subthemes that emerged were accountability from accessibility (noted by 15/50 participants); the empathy that the bot showed (6/50 participants); and the learning that the bot facilitated (11/50 participants), which in turn was divided into further subthemes of emotions and general insights.

**Table 2.** Qualitative results to post survey questions.

<table>
<thead>
<tr>
<th>Post survey questions</th>
<th>Control group (N=24), n (%)</th>
<th>Tess group (N=50), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall satisfaction</td>
<td>14 (60)</td>
<td>43 (86)</td>
</tr>
<tr>
<td>Content satisfaction</td>
<td>15 (65)</td>
<td>40 (80)</td>
</tr>
<tr>
<td>Extend emotional awareness</td>
<td>17 (73)</td>
<td>43 (86)</td>
</tr>
<tr>
<td>Learned something new</td>
<td>10 (43)</td>
<td>40 (80)</td>
</tr>
<tr>
<td>Information relevant to everyday life</td>
<td>11 (47)</td>
<td>40 (80)</td>
</tr>
<tr>
<td>More comfortable with therapeutic process</td>
<td>11 (47)</td>
<td>32 (64)</td>
</tr>
</tbody>
</table>
**Figure 4.** Thematic flow of participants’ most favored features while interacting with Tess.

**Figure 5** illustrates a thematic map of participants’ responses to the question, “What was the worst thing about your experience with Tess?” Two themes emerged: process (31/50 participants) and problems with content (19/50). The most common subtheme to emerge among the process violations related to the limitations in natural conversation (12/50) and the bot not being able to understand some responses or getting confused when unexpected answers were provided by participants (11/50). Problems with content were described by 20% (10/50) of participants, most of which related to not enough interactivity (7/50, 14%).

A total of 48 open comments were received as feedback from 50 participants. Overall, 2 participants appeared to find their interaction with Tess to be particularly meaningful:

*Based on our interactions I do somewhat feel like I’m talking to a real person and I do enjoy the tips you’ve given. In that sense, you’re better than my therapist in that she doesn’t necessarily provide specific ways I can better myself and problems. I’ve been learning new things and I have some ideas on ways I can make small changes that could help me!*

Engagement was measured based on the number of messages exchanged between Tess and the participants. The X2AI Inc administration panel was used to calculate engagement metrics reported in this section. Participants from both test groups exchanged a total of 14,238 messages with Tess. Group 1 exchanged an average of 283 messages with daily pings and unlimited access to Tess for 2 weeks (SD 147.6; median 278; range 72-755). Group 2 exchanged an average of 286 messages with biweekly pings and unlimited access to Tess for 4 weeks (SD 104.6; median 288; range 133-535). Although we were unable to measure engagement of the NIMH eBook as it was not possible to track page views or URL click rates, 15 (15/24, 63%) control group participants reported that they were satisfied with the content supplied.
Discussion

Principal Findings

The objective of this study was to assess the feasibility and efficacy of using an integrative psychological AI to reduce self-identified symptoms of depression and anxiety in college students. The methodology and results aligned with those from a previous randomized trial, which examined the potential for a chatbot to deliver CBT-based interventions to college students [10]. Our hypotheses were that students would experience a greater reduction in symptoms of (1) depression and (2) anxiety after interacting with the integrative psychological AI for a period of 2 or 4 weeks when compared with participants in the information-only control group. Furthermore, we predicted that the test groups would report a more engaging and convenient experience than participants from the control group.

Results revealed that both test groups 1 and 2 experienced a significant reduction in symptoms of anxiety with unlimited
access to Tess over the course of 2 or 4 weeks. Furthermore, the test group that received daily check-ins from Tess over 2 weeks experienced a significant reduction in symptoms of depression. Participants who interacted with Tess displayed higher levels of engagement and overall satisfaction than those from the control group. Test group participants indicated that the content was more relevant to their everyday life and made them more comfortable with the therapeutic experience.

Limitations

Although this study included participants across 15 universities across the United States, the generalizability of results is limited, particularly as socioeconomic status was not formally assessed. The recruitment method further limits generalizability as we are unable to evaluate differences between the participants in this study who were recruited via social media and individuals who may use Tess but are not active on social media. The methodology called for 2 test groups and 1 control group, making the number of participants per group more limited. In addition, this study did not collect follow-up data to assess if benefits were sustained over time. Alternative to previous studies, the control group experienced a slight increase in symptoms of anxiety and depression, suggesting that the eBook was not a sufficient form of mental health support. One possible explanation for this outcome is that the eBook may have increased awareness of symptoms without providing ongoing treatment, leading to an increase over time. One study revealed that consumers of self-help books are more sensitive to stress and show higher depressive symptomatology [37]. Due to recruiting participants from a nonclinical sample, baseline depression (measured by PHQ-9) and anxiety (measured by GAD-7) scores were low. Therefore, additional research needs to be done to assess the feasibility of Tess in supporting individuals with clinical levels of depression and anxiety. Future studies should include control conditions that allow for a more direct comparison between delivery of services such as traditional therapy, as well as tech-based solutions, including teletherapy, interactive Web-based courses, and virtual reality.

Traditional therapeutic methods allow for emotional assessment on many different levels, including facial expressions, body cues, tone of voice, and language. The psychological AI used in this study delivered interventions via conversation, and therefore emotion identification was limited to language. It is unclear how much this limited the psychological AI’s assessment of emotion, as language is the most readily available nonphenomenal access people have to emotions. Assessing emotion through facial expressions [38,39] appears unreliable because of the overlap of expressive characteristics among seemingly basic emotions, resulting in the taxonomy of facial expressions not adequately describing the taxonomy of emotions [15].

Finally, the system errors, as expressed during qualitative feedback, are explained by the research team’s limited resources and attempt to keep all content approved by experts intact. During the study, changes to the system were restricted, and so the research team was unable to report errors related to natural language processing or emotion mismatch until the completion of the study.

Comparison With Prior Work

Aligned with results from a previous study, using Tess was associated with a significant reduction in depression and anxiety as measured by the PHQ-9 and GAD-7, respectively. The effect size (Cohen d=0.68) for depression was moderate and greater than previously published studies [10,40-42] that measured the efficacy of using alternative mobile app interventions to relieve symptoms of depression. This study included 2 test groups to evaluate differences in symptom reduction based on 2- to 4-week intervention periods. The effect size for reduction of symptoms is aligned with that found by a previous study when delivering a CBT-based chatbot to college students in the United States [10]. Although speculative, the greater effect size found in this study may be due, in part, to the integrative mental health approach applied to deliver more personalized interventions. In addition, the content used to create Tess conversations was derived from written transcripts that allowed participants to respond with free text, versus predominantly using buttons to receive videos and other resources on a timely basis as the chatbot in a previous study did [10].

With a growing demand for scalable solutions that deliver more cost-effective mental health support, it has been shown that CAT is capable of delivering empirically validated treatments for depression and anxiety [26]. Preliminary studies suggest that self-help computer-based cognitive and behavioral interventions produce similar outcomes to in-person treatment [27]. Clinical treatment outcomes have been higher for patients prescribed to use psychotherapeutic computer programs compared with programs that are delivered in a self-help format with no clinician involvement [38].

Previous studies suggest that individuals are more willing to disclose personal information to a psychological AI than to a virtual therapist purportedly operated by a human [9,10,43]. This was supported by feedback given by student participants who engaged on a more personal level with Tess for this study. Students reported:

*I do somewhat feel like I’m talking to a real person.*

*I do somewhat feel like I’m talking to a real person.*

*...you’re better than my therapist [who] doesn’t necessarily provide specific ways I can better myself.*

And that Tess was able to:

*coach [the participant] through a difficulty.*

These comments reinforce the potential for psychological AI to remove barriers and stigma and operate as an adjunct to traditional therapeutic methods.

Conclusions

This study reveals that AI offers a cost-effective and accessible mental health solution and may serve as a scalable tool to complement traditional treatment methods. Although integrative psychological AI is not designed or intended to replace the role of a trained therapist, Tess emerges as a feasible option for delivering emotional support. The results support and expand on findings from a previous randomized controlled trial [10] and demonstrate that psychological AI has the potential to reduce symptoms of depression and anxiety by delivering CBT-based interventions in the form of conversations.

http://mental.jmir.org/2018/4/e64/
Acknowledgments
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Editorial notice: This randomized study was only retrospectively registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Conflicts of Interest
AJ and MR are employees of X2AI Inc that created the intervention (Tess) that was used in this trial and, therefore, have financial interest in that company. X2AI Inc covered the cost of participant incentives.

Multimedia Appendix 1
Recruitment flyer.
[PDF File (Adobe PDF File), 1MB - mental_v5i4e64_app1.pdf]

Multimedia Appendix 2
Consolidated Standards of Reporting Trials-eHealth checklist.
[PDF File (Adobe PDF File), 596KB - mental_v5i4e64_app2.pdf]

Multimedia Appendix 3
Informed consent.
[PDF File (Adobe PDF File), 141KB - mental_v5i4e64_app3.pdf]

Multimedia Appendix 4
Multiple comparisons table.
[PNG File, 195KB - mental_v5i4e64_app4.png]

Multimedia Appendix 5
Multivariate test table.
[PNG File, 177KB - mental_v5i4e64_app5.png]

Multimedia Appendix 6
Tests of between-subjects effects.
[PNG File, 235KB - mental_v5i4e64_app6.png]

Multimedia Appendix 7
Intervention sample GIF.
[MP4 File (MP4 Video), 558KB - mental_v5i4e64_app7.mp4]

References


34. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [Medline: 11556941]


Abbreviations

- **AI**: artificial intelligence
- **CAT**: computer-assisted therapy
- **CBT**: cognitive-behavioral therapy
- **DSM**: Diagnostic and Statistical Manual of Mental Disorders
- **GAD**: generalized anxiety disorder
- **MANOVA**: multivariate analysis of covariance
- **mHealth**: mobile health
- **NIMH**: National Institute of Mental Health
- **PANAS**: positive and negative affect scale
- **PHQ**: Patient Health Questionnaire

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Supported Internet-Delivered Cognitive Behavioral Therapy Programs for Depression, Anxiety, and Stress in University Students: Open, Non-Randomised Trial of Acceptability, Effectiveness, and Satisfaction

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Abstract

Background: Many university campuses have limited mental health services that cannot cope with the high demand. One alternative is to use internet-delivered cognitive behavioral therapy (iCBT) as a way of tackling barriers such as lack of availability and scheduling issues.

Objective: This study aimed to assess feasibility, acceptability, effectiveness, and satisfaction of a supported iCBT intervention offering 3 programs on depression, anxiety, and stress to university students. The design was an open or nonrandomized feasibility trial.

Methods: Participants were recruited from 3 counseling centers at a large midwestern University in the United States. Those agreeing to take part chose 1 of 3 iCBT programs—Space from Depression, Space from Anxiety, or Space from Stress—all comprised 8 modules of media-rich interactive content. Participants were supported throughout the trial by a trained professional. The Patient Health Questionnaire 9 (PHQ-9), Generalized Anxiety Disorder 7 (GAD-7) questionnaire, and stress subscale of the Depression Anxiety and Stress Scale (DASS-21) were completed at baseline, 8 weeks, and 3-month follow-up. A Satisfaction With Treatment (SAT) questionnaire was completed at 8 weeks, and qualitative interviews were completed by a subsample of participants at 3 months.

Results: A total of 102 participants were recruited, with 52 choosing Space from Anxiety, 31 choosing Space from Depression, and 19 choosing Space from Stress. Mixed-effects models showed a significant decrease in symptoms of depression ($F_4=6.36$, $P<.001$), anxiety ($F_4=7.97$, $P<.001$), and stress ($F_4=8.50$, $P<.001$) over time across all 3 programs. The largest decreases in PHQ-9 scores at 8 weeks were among participants who chose the Space from Depression program ($d=0.84$); at 3 months, the largest decreases in PHQ-9 scores were among those who chose the Space from Stress program ($d=0.74$). The largest decreases in GAD-7 scores were among those who chose the Space from Anxiety program ($d=0.74$ at 8 weeks and $d=0.94$ at 3 months). The largest decrease in DASS-21 stress subscale scores was among those who chose the Space from Stress program ($d=0.49$ at 8 weeks and $d=1.16$ at 3 months). The mean time spent using the platform per session was 27.4 min (SD 33.8), and participants completed 53% (SD 37.6) of the total program content on average. Most (37/53, 69%) participants found the programs helpful or very helpful.
and liked the convenience and flexibility of the intervention. Qualitative interviews (n=14) indicated the intervention met students’ expectations, and they saw it as a valuable complement to face-to-face treatment.

**Conclusions**: The iCBT programs tested in our study appear to be feasible, acceptable, and effective in a university environment. Participants described the benefits of having a flexible, supported Web-based intervention available on campus. Larger trials should be conducted to further test the effectiveness of supported Web-based interventions that give students a choice of program depending on their symptom profile.

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**KEYWORDS**
depression; anxiety; cognitive therapy; students

**Introduction**

**Background**
Within the university student population, depression and anxiety are among the most prevalent mental health conditions [1]. The 2017 American College Health Survey found that 61% of college and university students reported experiencing overwhelming anxiety on at least one occasion in the previous 12 months, and 39% reported feeling so depressed that it was difficult to function at least once in the same time period [2]. These numbers reflect the difficulties young people might experience on entering higher education, including academic pressure [3,4], managing social demands [5], and developmental changes that might give rise to mental health difficulties [1]. Counseling center directors report that there has been an increase in recent years in the number of students seeking help for serious psychological problems [6].

Current mental health resources on campus often do not adequately address the needs of the student population [6]. For example, because of the increased demand for services, counseling centers often have long waiting lists [7]. In addition, many students with mental health issues do not seek services [8]: the primary barriers include stigma, lack of time, and scheduling concerns [9].

Internet-delivered mental health interventions might be one way to address the increased demand for mental health care. A recent meta-analysis of 48 studies supported the effectiveness of technology-based mental health interventions (mostly delivered via computer) in college student samples [10] (relative primarily to wait-list control groups). Most Web-based mental health interventions are based on cognitive behavioral therapy (CBT), which is an empirically supported treatment for many mental health disorders [11]. Although interventions can be self-guided, those that are clinician-supported are generally more effective than those that are self-guided [10,12]. Web-based mental health interventions can be disseminated widely and, therefore, might address the limited availability of in-person counseling services. In addition, because these interventions can be accessed remotely and at the students’ convenience, they allow for flexibility in working around busy schedules and alleviate concerns about stigma.

Although internet-delivered CBT (iCBT) has been shown to be effective for college students [10], some gaps remain in our understanding of how best to implement these interventions on campus. Many studies have used convenience samples of undergraduate students, particularly students in psychology classes [10]; however, few studies have tested the feasibility and effectiveness of iCBT when implemented as part of a campus service delivery system. In addition, previous meta-analyses have highlighted the need for more user feedback from interviews and other qualitative methods to better tailor Web-based interventions to the needs of college students [13]. For example, 1 qualitative study found that college student users of a Web-based stress management intervention not only liked the flexibility and anonymity of using the program but also would have liked greater individualization to the specific stressors faced by college students [14].

**Objectives**
The aims of this mixed-methods study were to assess feasibility, acceptability, effectiveness, and satisfaction with iCBT interventions embedded within the care delivery system of a large university. Feasibility was defined in terms of the number of students recruited and the percentage of those that started a program. Acceptability was measured using data on usage and engagement with the intervention acquired via the Web-based system. Effectiveness was assessed using standard measures of symptoms of depression, anxiety, and stress completed at baseline, endpoint (8 weeks), and follow-up (3 months). Finally, satisfaction was measured via a questionnaire at the end of the 8-week intervention period and a semistructured phone interview at 3-month follow-up.

**Methods**

**Procedures**
The trial protocol containing the complete methodology has been published [15] and was approved by the University of Minnesota institutional review board (code number: 1503S64741). This was an open trial in which recruited participants were asked to choose between 3 interventions targeting depression, anxiety, or stress. Recruitment took place from October 2015 to September 2017 at the University of Minnesota-Twin Cities, which is a large urban campus, with approximately 52,000 students (6588/52,000, 12.67% international students). Approximately 15.37% (8512/52,000) of the students use campus mental health services, and there often is a wait-list.

Students were recruited through 3 campus centers: the student counseling center, a mental health clinic associated with the student health service, and the international student office. The
counseling center and mental health clinic both provide individual and group psychotherapy to students, with the latter tending to serve students with more serious issues. The international student office does not provide psychotherapy but has licensed providers on staff who refer students to the other offices. Information about the programs was made available to students through posters, websites, and staff at each office. Interested students were emailed a link with more information about the program and an invitation to participate in the study. If there was a wait-list at the student counseling center or mental health clinic (which varied over time), students were told that they could access SilverCloud immediately. They were also asked to complete the Web-based program before starting face-to-face counseling. In addition, they completed the following screening measures: the Patient Health Questionnaire 9 (PHQ-9), the Generalized Anxiety Disorder 7 (GAD-7) questionnaire, and the stress subscale of the Depression, Anxiety, and Stress Scale (DASS-21). Students were provided with scores on these measures along with explanatory text (eg, “your score on the PHQ-9 would indicate mild depressive symptoms”) so that they could make an informed decision as to which of the 3 programs they wanted to select. Information regarding the programs was limited to general information regarding their basis in CBT techniques and that each was tailored to address either depression, anxiety, or stress more specifically. On choosing their preferred program, they were assigned a supporter. The intervention was intended to last for 8 weeks, with measures taken at initial assessment (screening), after 8 weeks, and at a 3-month follow-up. At 8 weeks, a Satisfaction With Treatment (SAT) questionnaire [16] was also sent as part of the follow-up. Finally, during the second year of the trial, participants were invited to complete a follow-up interview at 3 months on their perceptions, attitudes, and experiences of the intervention.

Inclusion and Exclusion Criteria

All students over 18 years of age with computer and internet literacy enrolled at the University of Minnesota were eligible for recruitment. On completion of screening measures, students had to meet the threshold for mild depression (score of 5+ on the PHQ-9), anxiety (5+ on the GAD-7), or stress (15+ on the DASS-21 stress subscale, after multiplying score by 2). The protocol stated that participants would not be included in analyses if they did not meet the threshold for the program they chose. This occurred in only 5 cases, and in every case, the student met criteria on another measure. Therefore, these participants were not excluded from the analyses. All students were above the threshold on at least one measure.

Clients attending in-person therapy, either individually or in a group setting, were excluded from the study. Students at particular risk, based on self-harm questions, were referred to a clinician for further assessment. Throughout the trial, there was a help button on the program that could be accessed at any time that directed students to available resources.

Intervention

The 3 iCBT programs (Space from Depression, Space from Anxiety, and Space from Stress) were delivered via a Web 2.0 platform and comprised 8 modules of media-rich interactive content. These programs were developed by SilverCloud Health, a multidisciplinary clinical, design, and development team. The SilverCloud platform employs several strategies aimed at improving the user experience, including personal, interactive, supportive, and social tools. All 3 programs incorporate core concepts of CBT, such as behavioral activation, cognitive restructuring, and challenging core beliefs. Space from Depression embeds these concepts into a program detailing the concept of depression, understanding negative thinking and its consequences, and including personal stories from people with a history of depression. Space from Anxiety includes a module on facing one’s fears and working through the hierarchy of fears. Space from Stress primarily focuses on improving positive well-being (eg, finding meaning, happiness, and adapting to one’s environment), addressing stress in university settings, and developing a more balanced and meaningful life. All content of these programs follows evidence-based CBT principles. Each program also incorporates introductory quizzes, videos, informational content (including stories from other users), interactive activities, and a personal journal. More detailed information on the content of the platform can be found in the published protocol [15] and in previous research [17]. The standard recommendation was to complete 1 module per week over the 8-week period, with weekly reviews provided by the supporter. Students could access the program at any moment from any computer with an internet connection.

Support

Each study participant was assigned a staff member (who was a licensed psychologist or social worker) from the office through which they were recruited to act as supporters throughout the trial. These supporters received training in the program and how to give feedback through the Web-based system. The supporters initially sent a welcome message to the participants encouraging their use of the program and highlighting key aspects such as potential benefits and navigation through the different modules. Thereafter, the supporters logged in each week, reviewed the participants’ progress, and left feedback that included a response to the work the participants had completed that week. Participants were also able to share more information via journal entries, although this was not obligatory. The feedback given by the supporter typically took between 10 and 15 min per participant per session. Finally, if the supporter detected a long period of inactivity (more than 1 week), they sent a message prompting the student to use the program.

Measures

All measures were completed on the SilverCloud platform. Sociodemographic data included age, gender, ethnicity, employment, relationship status, school year, and international student status. Measures gathered through active use of the platform were collected using the SilverCloud back-end data capture. These include log-ins, time spent on the platform (total and per session), modules completed, page views, and journal entries. A total of 3 primary outcome measures were used to assess effectiveness. The first was the PHQ-9 [18,19], a widely used screening tool reflecting the diagnostic criteria for depression in the Diagnostic Manual of Mental Disorders, Fifth Edition (DSM-5) [20]. The PHQ-9 comprises 9 items scored...
on a scale of 0 to 3, with total scores of 0 to 27. The second was the GAD-7 questionnaire [21], designed to assess anxiety per the criteria for generalized anxiety disorder in the DSM-5. It comprises 7 items scored from 0 to 3 each, with total scores of 0 to 21. The third was the DASS-21 [22] stress subscale. Items are rated on a 0 to 3 scale, with total scores ranging from 0 to 21. On all 3 measures, higher scores indicate higher symptom severity. The SAT questionnaire included 4 quantitative questions regarding satisfaction with Web-based treatment (eg, “How did this online treatment compare to previous treatments?”) measured on a 5-point scale (0=Much better to 4=Not at all good) as well as 2 open-ended questions asking participants to describe what they most and least liked about the program.

Structured Interviews
In the second year of the trial, all students enrolled in the study were emailed to see if they were interested in completing a structured interview regarding their perceptions of the program. A follow-up email was sent if no response was received after 1 week. A total of 30 participants were contacted, and 14 agreed to be interviewed. Interviews were conducted via phone by a PhD student in counseling psychology. Interviews were recorded and then transcribed. Transcriptions were independently double-checked for accuracy. Interviews typically lasted for 10 to 15 min. In 1 case, the student declined to be interviewed and instead submitted written responses to the questions.

The interview was intended to further explore the participants’ perceptions, attitudes, and experiences regarding the intervention beyond the 2 open-ended questions on the SAT. Questions were derived by consensus among a group that included intervention supporters, counseling center administrators, a faculty member, and a graduate student. Questions focused on how and why students accessed SilverCloud (eg, “How did you hear about SilverCloud?” and “Why did you decide to use SilverCloud instead of in-person counseling?”), what they thought about specific aspects of it (eg, “Did you like that you could complete the program in any order, or would you have preferred that the program had more structure?” and “What did you think about having a supporter?”), and a more general evaluation of how well it met their needs (eg, “In general, how did you feel about using the Silver Cloud program?” and “If you have done in-person counseling before, how did it compare to SilverCloud?”).

Data Analysis
Feasibility was measured by calculating the percentage of participants logging in to their chosen platform from those initially recruited and invited. Acceptability was assessed in terms of the total time spent on the programs, average number of log-ins, average time per session, modules completed, average page views, and average number of journal entries completed. Effectiveness was assessed using a linear mixed model (LMM) to determine the significance of changes in depression, anxiety, and stress scores from baseline to 8 weeks to 3 months in the sample as a whole. This model was then expanded to include program type to measure changes in symptoms for each of the 3 programs. LMM was used rather than the original analysis described in the protocol (repeated measures analysis of variance; ANOVA) because it is better able to handle missing data. Repeated measures ANOVA has been criticized because it uses listwise deletion [23], whereas LMM allows for more data points and subjects to be included in the model [24]. The LMM model used intent-to-treat analysis (ie, all participants who completed baseline measures were included in analyses). Missing data were estimated using maximum likelihood estimation. Within-group effect sizes (Cohen d) were calculated to quantify change from baseline to 8 weeks and 3 months as per the procedure suggested by Morris and Deshon [25], which takes the correlation between pre- and posttest scores into account. The reliable change index (RCI) was also calculated according to Jacobson and Truax criteria [26] for each of the outcome measures. Users achieved reliable change if their scores decreased by more than the RCI for that measure. Cohen d s and RCIs used data from participants who completed the 8-week and 3-month measures (ie, completer vs intent-to-treat analyses).

All quantitative analyses were conducted using Stata Statistical Software 15 (StataCorp LLC, College Station, TX).

For the SAT, a descriptive analysis of the quantitative questions was followed by a thematic analysis of the qualitative questions to establish common themes regarding what participants liked most and least liked about the iCBT interventions [27]. Following an initial review of the raw data, initial themes were generated, coded, and these were then reviewed by a coresearcher.

The semistructured phone interviews were analyzed using content analysis, which is a means of identifying and interpreting patterns within a qualitative dataset. These patterns can be coded across participants and quantified [28]. The researchers chose this method to convey a sense of how frequently important themes came up in the subsample. All the responses were reviewed by 2 researchers. Each researcher first independently reviewed all the interview transcripts, noting patterns as they went. The researchers then developed codes, again independently, that described these patterns. Following this, they met in person to agree on codes and resolve discrepancies and finally sorted the responses accordingly. For example, each researcher noticed patterns in students’ responses to the question of why they chose to use SilverCloud over in-person counseling. Many mentioned that their busy schedules prevented them from attending in-person counseling and that SilverCloud was more accessible; others described being uncomfortable with the idea of seeing a counselor because the experience would be more intense. On the basis of these responses, the researchers developed 2 codes: scheduling and convenience and level of comfort with in-person counseling. The percentage of participants whose responses fell into each code was calculated.

Results
Feasibility
Participants were recruited between September 2015 and May 2017. Those who expressed interest (n=182) were sent a link with more information and invited to use the Web-based platform. Of those invited, 56.0% (102/182) opted into the study (75 from student counseling services, 20 from the mental health clinic, and 7 from the international student office) and engaged
in their chosen program. The majority chose *Space from Anxiety* (52/102, 51.0%), a smaller percentage chose *Space from Depression* (31/102, 30.4%), and a minority chose *Space from Stress* (19/102, 18.6%). The majority screened positive for all 3 conditions (57.8%, 59/102). Of these, 32 (32/59, 54%) chose *Space from Anxiety*, 14 (14/59, 24%) chose *Space from Depression*, and 13 (13/59, 22%) chose *Space from Stress*. Of those who screened positive for 2 conditions (24/102, 23.6%), 15 (15/24, 62%) chose the *Space from Anxiety* program, 7 (7/24, 29%) chose *Space from Depression*, and 2 (2/24, 8%) chose *Space from Stress*. In total, 95.1% (97/102) chose programs for which they screened positive. Our goal was to recruit 35 in each arm. We fell short of that goal, especially for *Space from Stress*, but opted not to recruit data for an additional academic year to reach the target recruitment goal for that program. Among the 102 participants, 52.0% (53/102) completed outcome assessments at 8 weeks. Of those 53, 79% (42/53) completed assessments at 3 months. Furthermore, 8 participants provided data at 3 months but not at 8 weeks. The full flowchart from recruitment to allocation and follow-up is shown in the Consolidated Standards of Reporting Trials diagram (Multimedia Appendix 1). Little Missing Completely at Random (MCAR) test for missing data was nonsignificant for the PHQ-9 (*P* = .87), GAD-7 (*P* = .54), and DASS-21 (*P* = .71). We therefore assumed that the data were MCAR. The *t* tests and chi-squares were performed on those with missing data at 8 weeks and 3 months versus those with no missing data for demographics, program type, and baseline scores on each of the outcome measures. There were no statistically significant differences between groups on any baseline variables tested.

**Baseline Characteristics**

The sample of 102 participants was mostly female (75/102, 73.5%), white (81/102, 79.4%), and in the 18 to 21 age group (56/102, 54.9%). A small percentage were international students (12/102, 11.8%). Most were undergraduate students (61/102, 59.8%), working part-time (51/102, 50.0%), and single or dating (66/102, 64.7%). Full baseline characteristics are reported in Table 1.

### Table 1. Baseline characteristics of study sample.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total sample (N=102), n (%)</th>
<th>Space from depression (n=31), n (%)</th>
<th>Space from anxiety (n=52), n (%)</th>
<th>Space from stress (n=19), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-21</td>
<td>56 (54.9)</td>
<td>17 (55)</td>
<td>28 (54)</td>
<td>11 (58)</td>
</tr>
<tr>
<td>22-30</td>
<td>37 (36.3)</td>
<td>11 (35)</td>
<td>19 (36)</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Over 30</td>
<td>9 (8.8)</td>
<td>3 (10)</td>
<td>5 (10)</td>
<td>1 (5)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>75 (73.5)</td>
<td>20 (65)</td>
<td>39 (75)</td>
<td>16 (84)</td>
</tr>
<tr>
<td>Male</td>
<td>27 (26.5)</td>
<td>11 (35)</td>
<td>13 (25)</td>
<td>3 (16)</td>
</tr>
<tr>
<td><strong>Student status</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Undergraduate</td>
<td>61 (59.8)</td>
<td>18 (58)</td>
<td>31 (60)</td>
<td>12 (63)</td>
</tr>
<tr>
<td>Graduate</td>
<td>41 (40.2)</td>
<td>13 (42)</td>
<td>21 (40)</td>
<td>7 (37)</td>
</tr>
<tr>
<td><strong>International student status</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>90 (88.2)</td>
<td>28 (90)</td>
<td>47 (90)</td>
<td>15 (79)</td>
</tr>
<tr>
<td>International</td>
<td>12 (11.8)</td>
<td>3 (10)</td>
<td>5 (10)</td>
<td>4 (21)</td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>34 (33.3)</td>
<td>10 (32)</td>
<td>16 (31)</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Part-time</td>
<td>51 (50.0)</td>
<td>16 (52)</td>
<td>26 (50)</td>
<td>9 (47)</td>
</tr>
<tr>
<td>Full-time</td>
<td>17 (16.7)</td>
<td>5 (16)</td>
<td>10 (19)</td>
<td>2 (11)</td>
</tr>
<tr>
<td><strong>Relationship status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single or dating</td>
<td>66 (64.7)</td>
<td>22 (71)</td>
<td>34 (65)</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Committed relationship or married</td>
<td>36 (35.3)</td>
<td>9 (29)</td>
<td>18 (35)</td>
<td>9 (47)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>European American or white</td>
<td>81 (79.4)</td>
<td>25 (81)</td>
<td>40 (77)</td>
<td>16 (84)</td>
</tr>
<tr>
<td>Asian or Asian American</td>
<td>8 (7.8)</td>
<td>4 (13)</td>
<td>3 (6)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>6 (5.9)</td>
<td>1 (3)</td>
<td>4 (8)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>African American or black</td>
<td>3 (2.9)</td>
<td>1 (3)</td>
<td>2 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (3.9)</td>
<td>0 (0)</td>
<td>3 (6)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>
Acceptability

The number of log-ins per participant was 14.3 (SD 12.1), with an interquartile range (IQR) of 4 to 21. Mean total time spent on the platform was 295.7 min (SD 377.3), IQR of 71.15 to 325.8, and the mean time spent using the platform per session was 27.4 min (SD 33.8), IQR of 8 to 30.8. The number of modules completed was 4.4 (SD 2.6), IQR of 2 to 7, and the mean number of journal entries was 6.0 (SD 8.2), IQR of 1 to 7. Participants completed a mean of 53.4% (SD 37.6), IQR of 18.1 to 98.6, of the total program content.

Effectiveness

The linear model showed a significant decrease in mean PHQ-9, GAD-7, and DASS-21 stress subscale scores from baseline to 8 weeks, and from baseline to 3 months. The overall effect for depression was \( F_{2,6} = 6.36, P < .001 \), the overall effect for anxiety was \( F_{2,6} = 7.97, P < .001 \), and the overall effect for stress was \( F_{2,6} = 8.50, P < .001 \).

Table 2 shows the means and SDs for each of the 3 measures at all 3 time points, along with the effect sizes (Cohen \( d \)) comparing 8-week and 3-month scores with baseline scores for the completer sample.

Analysis by Program Type

The mixed-effects linear model for depression as measured by the PHQ-9 (Figure 1) showed highly significant changes in scores over time for those who chose the Space from Depression program \( (F_{2,6} = 13.7, P < .001) \), with decreases from baseline to 8-week (mean difference 5.0, 95% CI 3.0-7.1) and 3-month (mean difference 4.3, 95% CI 2.1-6.4) follow-up. Those who chose the Space from Anxiety program had nonsignificant decreases in PHQ-9 scores over time \( (F_{2,6} = 2.4, P = .09) \), with scores at 8 weeks (mean difference 1.9, 95% CI 0.2-3.6) and 3 months (mean difference 1.1, 95% CI 0.7-2.9) decreasing slightly. The decrease in depression symptoms in those who chose the Space from Stress program was significant \( (F_{2,6} = 3.0, P = .04) \), with decreases at 8 weeks (mean difference 2.0, 95% CI 0.7 to 4.7) and 3 months (mean difference 3.1, 95% CI 0.3-5.7).

The GAD-7 scores for all 3 program types significantly decreased over time according to the LMM (Figure 2). The largest effect was among those who chose the Space from Anxiety program \( (F_{2,6} = 13.6, P < .001) \), with decreases in scores at 8 weeks (mean difference 2.5, 95% CI 1.1-3.9) and 3 months (mean difference 3.6, 95% CI 2.1-5.0). Those in the Space from Depression program had a significant decrease over time \( (F_{2,6} = 5.9, P = .01) \), with scores decreasing at 8 weeks (mean difference 2.6, 95% CI 0.3-3.9) and 3 months (2.7, 95% CI 1.0-4.4). Finally, those in the Space from Stress program also showed significant decreases over time \( (F_{2,6} = 4.3, P = .01) \) and lower scores at both 8 weeks (mean difference 1.4, 95% CI 0.7-3.6) and at 3 months (mean difference 3.0, 95% CI 1.0-5.0).

The DASS-21 stress scores in the linear model also showed significant decreases over time among all program types (Figure 3). Space from Stress \( (F_{2,6} = 6.0, P = .01) \) users had decreased stress scores at both 8 weeks (mean difference 2.3, 95% CI 0.2-4.5) and 3 months (mean difference 3.5, 95% CI 1.4-5.5).

Space from Anxiety \( (F_{2,6} = 6.7, P = .01) \) users decreased their scores at 8 weeks (mean difference 1.7, 95% CI 0.3-3.0) and 3 months (mean difference 2.6, 95% CI 1.1-4.0). Finally, Space from Depression \( (F_{2,6} = 12.8, P < .001) \) users also had decreased scores at both 8 weeks (mean difference 2.8, 95% CI 1.1-4.4) and 3 months (mean difference 4.3, 95% CI 2.6-6.0).

The means and SDs by program type, for baseline through 3 months, can be seen in Table 3, along with the effect sizes (Cohen \( d \)) for the difference between 8-week and 3-month means compared with baseline for the completer sample.

Reliable Change

The RCIs for each of the 3 outcome measures were 5.38 for PHQ-9, 3.49 for GAD-7, and 4.88 for DASS-21.

As measured by the PHQ-9, among the 53 participants with 8-week follow-up data, 30% (16/53) decreased their scores by more than the RCI (6+), and thus had reliable change; 68% (36/53) did not have reliable change; and 2% (1/53) had reliable deterioration (increase of 6 or more). Of the 50 participants with 3-month data, 30% (15/50) had reliable change, 62% (31/50) had no reliable change, and 8% (4/50) had reliable deterioration.

Table 2. Mean (SD) scores for the Patient Health Questionnaire 9 (PHQ-9), the Generalized Anxiety Disorder 7 (GAD-7) questionnaire, and the stress subscale of the Depression, Anxiety, and Stress Scale (DASS-21) at baseline, 8 weeks, and 3 months.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Baseline, mean (SD)</th>
<th>8 week, mean (SD)</th>
<th>Cohen ( d ) (95% CI)</th>
<th>3 month, mean (SD)</th>
<th>Cohen ( d ) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHQ-9</td>
<td>9.5 (5.1)</td>
<td>6.5 (4.1)</td>
<td>0.59 (0.14-0.92)</td>
<td>7.1 (4.8)</td>
<td>0.46 (0.06-0.83)</td>
</tr>
<tr>
<td>GAD-7</td>
<td>9.4 (4.6)</td>
<td>6.9 (4.8)</td>
<td>0.58 (0.20-0.98)</td>
<td>6.1 (4.1)</td>
<td>0.82 (0.38-1.17)</td>
</tr>
<tr>
<td>DASS-21</td>
<td>8.5 (4.3)</td>
<td>6.3 (4.2)</td>
<td>0.49 (0.10-0.87)</td>
<td>5.2 (3.9)</td>
<td>0.77 (0.34-1.13)</td>
</tr>
</tbody>
</table>
Figure 1. Linear mixed model adjusted Patient Health Questionnaire 9 (PHQ-9) scores over time, by program type.
Figure 2. Linear mixed model adjusted Generalized Anxiety Disorder 7 (GAD-7) scores over time, by program type.
Figure 3. Linear mixed model adjusted Depression Anxiety and Stress Scale (DASS-21; stress subscale) scores over time, by program type.

Table 3. Mean (SD) scores for the Patient Health Questionnaire 9 (PHQ-9), the Generalized Anxiety Disorder 7 (GAD-7) questionnaire, and the stress subscale of the Depression, Anxiety, and Stress Scale (DASS-21) at baseline, 8 weeks, and 3 months, in users of Space from Depression program, Space from Anxiety program, and Space from Stress program.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Baseline, mean (SD)</th>
<th>8 week, mean (SD)</th>
<th>Cohen d (95% CI)</th>
<th>3 month, mean (SD)</th>
<th>Cohen d (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Space from Depression program</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=31 PHQ-9</td>
<td>11.3 (5.8)</td>
<td>6.2 (4.3)</td>
<td>0.84 (0.06-1.41)</td>
<td>7.3 (6.5)</td>
<td>0.54 (0.08-1.25)</td>
</tr>
<tr>
<td>n=18 GAD-7</td>
<td>7.2 (4.3)</td>
<td>5.4 (4.8)</td>
<td>0.44 (0.02-1.13)</td>
<td>5.2 (3.6)</td>
<td>0.56 (0.14-1.18)</td>
</tr>
<tr>
<td>n=16 DASS-21</td>
<td>7.3 (4.8)</td>
<td>4.8 (3.2)</td>
<td>0.49 (0.24-1.07)</td>
<td>3.4 (2.2)</td>
<td>1.12 (0.15-1.60)</td>
</tr>
<tr>
<td><strong>Space from Anxiety program</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=52 PHQ-9</td>
<td>8.4 (4.4)</td>
<td>6.1 (4.1)</td>
<td>0.60 (0.02-1.15)</td>
<td>7.3 (4.3)</td>
<td>0.28 (0.27-0.84)</td>
</tr>
<tr>
<td>n=25 GAD-7</td>
<td>10.9 (4.3)</td>
<td>7.5 (4.9)</td>
<td>0.74 (0.21-1.36)</td>
<td>6.7 (4.6)</td>
<td>0.94 (0.39-1.56)</td>
</tr>
<tr>
<td>n=22 DASS-21</td>
<td>9.0 (3.9)</td>
<td>6.8 (4.6)</td>
<td>0.51 (0.00-1.12)</td>
<td>6.0 (4.9)</td>
<td>0.75 (0.24-1.47)</td>
</tr>
<tr>
<td><strong>Space from Stress program</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=19 PHQ-9</td>
<td>9.3 (5.0)</td>
<td>7.9 (4.0)</td>
<td>0.30 (–0.60 to 1.16)</td>
<td>6.3 (2.8)</td>
<td>0.74 (–0.27 to 1.49)</td>
</tr>
<tr>
<td>n=10 GAD-7</td>
<td>9.0 (4.2)</td>
<td>8.0 (4.2)</td>
<td>0.32 (–0.48 to 1.12)</td>
<td>6.3 (4.1)</td>
<td>0.88 (0.03 to 1.71)</td>
</tr>
<tr>
<td>n=12 DASS-21</td>
<td>9.3 (4.1)</td>
<td>7.4 (4.5)</td>
<td>0.49 (–0.37 to 1.40)</td>
<td>5.9 (3.0)</td>
<td>1.16 (0.17 to 1.87)</td>
</tr>
</tbody>
</table>

On the GAD-7, among those with 8-week follow-up data, 17 (17/53, 32%) decreased their scores by more than the RCI (4+), and thus had reliable change; 30 (30/53, 57%) had no reliable change; and 6 (6/53, 11%) had reliable deterioration (increase of 4 or more). At 3 months, 26 (26/50, 52%) had reliable change, 22 (22/50, 44%) had no reliable change, and 2 (2/50, 4%) had reliable deterioration.

Finally, as measured by the DASS-21 stress subscale, 31% (16/53) achieved reliable change (decrease of 5+) at 8 weeks and 42% (21/50) did so at 3 months. In contrast, 6% (3/53) and 4% (2/50) reliably deteriorated (increasing symptoms by 5 or
more points) at 8 weeks and 3 months, respectively. In total, 34 (34/53, 64%) had no reliable change at 8 weeks, and 27 (27/50, 54%) had no reliable change at 8 weeks and 3 months, respectively.

Satisfaction

The SAT questionnaire was included as part of the 8-week follow-up and, thus, given to all 53 participants who responded to the other follow-up questionnaires at 8 weeks. In total, 4 quantitative questions produced the following results: (Q1) “I was happy to use the computer to access treatment”: 83% (44/53) agreed or strongly agreed, 13% (7/53) were neutral, 4% (2/53) disagreed; (Q2) “I found the online treatment easy to use”: 82% (43/53) agreed or strongly agreed, 13% (7/53) were neutral, 5% (3/53) disagreed; (Q3) “I feel the treatment received will have a long lasting effect”: 45% (24/53) agreed or strongly agreed, 38% (20/53) were neutral, and 17% (9/53) disagreed or strongly disagreed; and (Q4) “Please rate how helpful you found the online treatment programme”: 69% (37/53) found it helpful or very helpful, 27% (14/53) found it not really or not at all helpful, and 4% (2/53) had no opinion.

On the 2 open-ended questions, participants reported different helpful aspects of the iCBT intervention, which were grouped into 3 categories: the delivery format (n=16), the content and CBT tools (n=13), and the supporter (n=1). In addition, participants indicated a number of unhelpful aspects grouped into the categories of format of support (n=8), lack of tailoring (n=6), and internal factors (n=4).

With regard to delivery format, participants reported the Web-based format to be helpful owing to convenience, flexibility, time management, access, and feeling in control of the pace of the use of the intervention. The following user quotes support these aspects of the format of delivery:

- I could do it on my time when I wanted to. If I felt anxious or nervous or I had a bad day, I could just log on for a few minutes and focus on myself.
- As a student it makes it easier to focus on my mental health in my free time. Scheduling mental health appointments can be stressful, but I can do this whenever and it just makes it a lot easier.

In addition, aspects of the content of the intervention and specific CBT tools were identified as helpful to participants. In general, participants noted how they learned from the intervention and that they used various tools to learn new skills. Specifically, participants indicated that the mood monitor, activity scheduling, and journal were particularly helpful tools:

- I really liked the online journal, which is what I mostly used to express my feelings.
- I feel like I learned a lot more about each CBT technique than I did when I was enrolled in in-person counseling.

The Supporter was also important in the delivery of the intervention:

- I like supporter’s review the most. The fact that some professional is willing to invest their time in following

my activities for the treatment means a great deal to me.

Participants found 2 aspects of the format in which the support was delivered to be unhelpful. The first was that in-person counseling would have been preferred:

- The fact that it’s online. I personally prefer in-person meetings.

I felt like it was more difficult to convey how I was feeling on an online platform than it would have been in in-person counseling. This was due to a lack of a connection I felt with my supporter [in comparison to in-person counseling] and because there is only so much I could convey in writing [in comparison to face-to-face conversations].

The second unhelpful theme focused on the reviews that supporters gave to participants:

- I was hoping it would be a little more interactive, where I would have more feedback with a therapist about my individual problems and things that are specific to me.

Some participants reported a lack of tailoring to their specific needs. For example, the content was perceived to be too generic or not applicable for those who had done CBT before:

- Some of the activities were hard or didn’t really apply to my situation.

Finally, internal factors, including lack of motivation and being busy contributed to participants finding the experience unhelpful:

- Not quite as good at holding me accountable for doing it as an actual appointment.
- Not a ton of motivation to finish a session every week, sometimes I would forget. Maybe reminder emails or an app would be helpful?

Structured Interviews

The structured interviews provided further information regarding how students perceived the SilverCloud programs. Their responses are grouped into 3 categories: accessing SilverCloud, specific aspects of SilverCloud, and satisfaction with the SilverCloud programs.

A total of 14 structured interviews were conducted. Those who completed interviews were similar to the overall sample, in that they were mostly female: 71% (10/14) versus 73.5% (75/102) and mostly white: 86% (12/14) versus 79.4% (81/102), although a much larger percentage were graduate students: 71% (10/14) versus 40.2% (41/102). In total, 14% (2/14) were international students, a similar percentage to the overall sample (11.8%, 12/102). The mean baseline PHQ-9 score was 10.3 (SD 4.5), and the mean baseline GAD-7 score was 10.6 (SD 4.9), both of which were similar to the baseline scores of the overall sample (9.5 and 9.4, respectively). The mean baseline DASS-21 stress score was 9.6 (SD 4.2), similar to the overall sample (8.5).

Similar to the whole sample, 64% (9/14) completed 8-week follow-up measures (compared with 52.0% (53/102) in full sample), and 50% (7/14) completed 3-month follow-up measures.
Accessing SilverCloud

The interviewer asked students how they found out about the program and why they chose to use it. Most students found out about the intervention on the internet (11/14, 79%), in the process of looking for mental health treatment. All the participants mentioned scheduling and convenience as a reason for using the Web-based programs over in-person therapy. One student, for example, mentioned choosing SilverCloud:

...because my schedule is very busy and I wasn’t really sure whether I wanted to do counseling or not, so it felt like a good way to kind of check it out without much commitment.

Some also noted that they did not feel comfortable with the idea of in-person counseling, citing worries about confidentiality and intensity (4/14, 29%). Only 1 had done anything like it before.

Students were also asked when they used the program. Their responses were divided: some scheduled specific times for it (10/14, 71%); some used it when they were feeling depressed, anxious, or stressed (8/14, 57%); and others worked on it when they had free time (4/14, 29%). For those who used it on more than one of these occasions (n=7), there were mixed results in terms of when it was perceived to be most effective. Some described being able to get more out of it when they were not distressed, as they could approach it with a clear mind:

I would say when I actually sat down to do it just to complete it, that actually was more helpful than doing it when I was down, because when I was down I was looking for answers, whereas I was in a more rational and clear mindset when I was just doing it out of my own.

Others noted that it was most helpful when they were feeling distressed:

It probably felt more helpful when I was coming off of a particularly stressed time, or like when I felt like a serious failure or that sort of thing. So yeah, when I felt worse, it probably helped me a little bit more than doing it on a day when I felt totally fine.

One student noted that it was particularly helpful to journal when they were feeling distressed but that they read the informative parts of the modules when they were not feeling distressed.

Specific Aspects of SilverCloud

In general, students appreciated having choices about different aspects of the intervention. For example, students were asked what they thought about the ability to complete the intervention in any order. Most enjoyed this about the program (13/14, 94%) because it allowed them to access the parts they wanted and also allowed them to go back and engage with previous parts of the program that they found helpful. However, 1 was unaware that it could be completed in any order, and others completed it in order anyway (3/14, 21%). Students generally reported feeling positive about having a choice about whether they used the stress, anxiety, or depression program (8/14, 57%), although some would have preferred to be assigned one (2/14, 14%), and some were confused about the process (2/14, 14%), with 1 student noting:

I just kind of chose one at random, I wasn’t really sure which one to choose, and then, I don’t know if they have practically different programs, or if there, if they have some overlap, I’m not sure.

One student specifically expressed that they would have liked to access multiple programs.

The interview also included questions about having a supporter. Almost all participants appreciated having a supporter (13/14, 94%), and some noted that they specifically liked receiving feedback (5/14, 36%):

It kind of presented the opportunity to have someone to reach out to and ask some other questions. She gave me some really good guidance on what to do next step.

Some participants also said that the supporter helped them feel accountable (2/14, 14%):

Sometimes I feel like I wouldn’t have gone on or I was really lazy and didn’t really do anything, so I felt really guilty when she would take the time, like my supporter would take the time to look over everything and that I didn’t like do anything. So I felt bad sometimes. But I liked having that.

A large portion (11/14, 79%) of the participants would have liked more from the supporter. Participants specifically wanted more detailed and personalized feedback and felt like they lacked a connection with the supporter. Some participants would have liked to be able to speak directly with their supporter over the phone or video chat service:

Personally, I think that I was hoping for a little bit more of a personalized approach, and that maybe I would get more feedback about me personally and my issues from the person that was assigned to me. It was a lot more general feedback, like I could tell she [the supporter] had read the things I had done, but she wasn’t there, you know, to talk to me about my problems. So I guess I was expecting it to be a little bit more communication based.

Satisfaction With SilverCloud Programs

When asked how they felt about using SilverCloud, some participants noted that they felt positive about the program and that it met their needs (6/14, 43%), some expressed more mixed feelings (6/14, 43%), and others did not find it helpful (2/14, 14%). Some students with mixed feelings reported that it was helpful to some degree but thought that they would need to seek other treatment to more fully address their concerns. Another student noted that they learned a lot but had not yet noticed a change in symptoms.
Those who had experience with in-person therapy (8/14, 57%) were asked how that experience compared with using SilverCloud. They noted strengths and weaknesses of both. In-person therapy was described as more personalized, specific, and flexible in terms of content. Some specifically noted that SilverCloud could not replace in-person therapy:

_I think there’s something in-person offers you when it becomes so much more personalized, that SilverCloud just can’t reach._

One student noted that they felt like the program would have been more helpful for them if they had not already done in-person therapy. Participants generally noted that SilverCloud was more flexible in terms of time and was less intense than in-person therapy, and 1 person specifically noted that they liked SilverCloud better than in-person therapy, explaining that:

...while it was nice having the one-on-one time, I think specifically for me, having the information all set there that I could read and kind of understand on my own terms was very very nice.

When directly asked, most participants (11/14, 79%) had positive reactions to the idea of completing SilverCloud in conjunction with in-person therapy, as this would help address the issue of personalization. Some suggested that they would like to see their supporter in person infrequently while using SilverCloud in between sessions:

_I think that that would be more beneficial than how it is right now. Like with the therapist, if you had an initial in-person session, and then you had like a few, like several online sessions before you went back again, I feel like um that would alleviate a lot of the problems you’re facing. And maybe they could personalize the material that they like sent you between sessions as well._

One student noted that, having used SilverCloud, they would be more likely to try in-person therapy. One participant sought additional mental health treatment while they used SilverCloud.

**Discussion**

**Key Findings**

The aims of this mixed-methods study were to assess feasibility, acceptability, effectiveness, and satisfaction with iCBT interventions embedded within the care delivery system of a large university. Below, we discuss key findings along with limitations and future directions.

The feasibility of offering the iCBT interventions as part of service delivery at the university was evaluated primarily in terms of the number of students who expressed interest and began one of the programs. Approximately 100 students began a program, which was 56% of those who received an invitation and brief overview. Thus, it is feasible to incorporate iCBT into service delivery. It is important to note that most students who were referred to iCBT were seeking in-person counseling; the number recruited might be higher among students who were not already seeking this kind of care. In addition, more students likely would have been recruited if we had launched a larger marketing campaign (eg, posters in dorms and around campus and mass emails). It is not clear whether fewer students were recruited from the international student office because of cultural differences related to the acceptability of help seeking or some other reason, although that is something to explore in future research.

Most students chose the *Space from Anxiety* program, even among those who scored above our threshold for moderate symptoms on all 3 measures. They were much less likely to choose the *Space from Stress* program. This might reflect students’ perception of their own symptoms and which seem most urgent or best addressed through a Web-based program. Other iCBT courses offer patients a choice of programs such as the MindSpot clinic (offering well-being, well-being plus, obsessive compulsive disorder, and posttraumatic stress disorder programs) [29]; however, their well-being programs combine depression and anxiety. Other studies have observed a relationship between patient choice and improved outcome [30], but the reasons why a particular program was chosen over another and the balance between choice and clinical recommendation should be explored further to optimize treatment outcomes. This is especially important given the overlap of depression, anxiety, and stress symptoms.

Acceptability was assessed in terms of the extent to which participants used the program after they began. In total, participants navigated through approximately 50% of the program content during an average of 14 sessions lasting approximately 5 hours in total. One systematic review found similar results, with users completing 50% to 70% of the content in Web-based interventions [31]. A possible reason behind the completion rates might be that users who have obtained a desired outcome stop usage altogether. However, the programs tested here are constructed in a nonlinear way, and not all of the specific content needs to be accessed for the modules or program to be completed or for the benefit achieved from each module to be obtained. Nevertheless, it would be worthwhile to identify usage thresholds needed to achieve the biggest effect on desired outcomes in future research. This is important as usage can vary substantially from person to person, as exemplified in our sample. For example, although 18 students did not post a single journal entry, 9 posted more than 20. Pinpointing the ideal cut-off for the usage variables is key to maximizing the potential of Web-based interventions.

With regard to effectiveness, symptoms of depression, anxiety, and stress decreased over time in users of all 3 programs, with small (0.3) to very large (1.2) within-group effect sizes. The results are in line with previous research on the SilverCloud *Space from Depression* program [32]. A recent randomized controlled trial (RCT) [33] measuring the effects on stress of a Web-based and app-based intervention among college students found similar medium effect sizes (0.59 at 7 weeks) to the ones reported in our study for the stress subscale of the DASS-21 at 8 weeks (0.49-0.51), although our study had larger (0.75-1.16) effect sizes at 3-month follow-up (vs a 3-month effect size of 0.67 in this RCT). However, there was an increase in PHQ-9 symptoms from 8 weeks to 3 months in users of the *Space from Depression* and *Space from Anxiety* programs, whereas *Space from Stress* users continued to show decreases in PHQ-9 scores.
from 8 weeks to 3 months. This suggests the latter was best at maintaining low depressive symptoms, although larger trials are needed to replicate these findings.

In addition, a recent meta-analysis of 48 studies assessing the effectiveness of universal and indicated prevention approaches to delivering technology-based mental health intervention to college students found that the overall mean between-group effect sizes for indicated interventions (0.37) was larger than the overall mean between-group effect size for universal approaches (0.19) [10]. Although both effects were significant, these results favor an indicated prevention approach. This meta-analysis also indicated that Web-based interventions with some form of additional support such as prompts, feedback, or guidance through emails, further improved the outcomes for indicated interventions ($d=0.55$) [10]. Overall, these results are similar to the findings of this study and support an indicated approach to Web-based mental health interventions and suggest the benefit of providing clinician support within the framework of the intervention.

The reliable change analyses indicated that approximately one-third of the users had reliable change on the outcome measures at 8 weeks. Slightly higher percentages of participants achieved reliable change at 3 months (30%-52% across measures). These results positively reflect on the clinical utility of the interventions and their ability to maintain clinical changes beyond the acute treatment period. However, slightly fewer subjects completed the measures at the 3-month follow-up, and it is unclear if those who dropped out maintained their gains. As the RCI analyses excluded participants with missing data, there is a risk of bias in these results. However, the reliable change results are similar to other research on SilverCloud [32], also using per-protocol analysis and previous work in the field of internet-delivered interventions. For instance, clinical recovery rates between 25% and 49% have been reported [33,34,12].

Finally, participants’ responses to the satisfaction questionnaire and the interviews suggested several strengths and limitations of the programs. Students generally found the programs to be helpful, with few saying that they found them unhelpful. Factors mentioned as helpful included flexibility, convenience, and having control over the pace of the intervention. Some students noted that they found the content of the interventions helpful, along with the tools available to learn new skills. In contrast, other students found that the content was not tailored enough to their specific needs. Participants also felt that having a supporter was helpful, although many wanted more contact with and feedback from the supporter. One solution to offer students the opportunity to complete iCBT interventions along with less frequent (eg, monthly) in-person therapy; more research is needed to determine the feasibility and effectiveness of such a delivery format. Finally, despite having a supporter, some found it difficult to stay motivated to complete the program on their own, especially given busy schedules. Taken as a whole, the qualitative results provide a more nuanced and comprehensive understanding of the program, which can be used to guide future research on how to improve Web-based interventions.

These results are consistent with another qualitative study of students’ perceptions of Web-based interventions [14]. In both studies, participants used Web-based interventions because of the scheduling flexibility. In addition, participants from both studies called for interventions that were more personalized to their specific needs and life circumstances. Participants in the Fleischmann et al’s study wanted greater flexibility in terms of the order in which they completed the program, and participants in this study spoke positively of that flexibility. Future studies should examine whether this flexibility actually increases adherence, effectiveness, and satisfaction.

**Limitations and Future Directions**

This study also has limitations, including the lack of a control group and the lack of follow-up data on a sizable portion of the initial sample. Without a control group, we cannot be sure that decreases in symptoms were because of the intervention rather than the natural course of symptoms over time. As the purpose of this study was to integrate Web-based interventions into natural service delivery, to randomize help-seeking students into a placebo arm would have been difficult. Our conclusions regarding the effectiveness of the interventions would be strengthened by a larger RCT. The lack of follow-up data could be because of several factors. Supporters might not have encouraged the continued use of the program by study participants strongly enough, in some cases. Some study participants might have dropped out because of unmet expectations with regard to their Web-based program, and some might have completed the program early and met all their needs before the 8-week period. The rates of missing data at follow-up are similar to previous studies, and indeed younger persons are more likely to drop out than older participants in studies on self-managed internet interventions [35]. Although it is not possible to determine if the missing data positively or negatively affected the results, because the data appeared to be missing completely at random and individuals with missing data were no different as a group than those without missing data, the likelihood of bias is reduced. Future trials could attempt to follow-up with those dropping out altogether, as the reasons for dropout are important to understand who benefits most from these interventions and what personal characteristics predict positive outcomes. Larger, controlled studies are warranted to replicate these findings and to assess whether improving adherence improves outcomes.

**Conclusion**

In conclusion, we echo the call that Web-based interventions are a useful addition to the list of solutions for addressing growing mental health service needs on campus [6]. Overall, the iCBT programs tested in our study appear to be feasible, acceptable, and effective in a university environment. Participants described the benefits of having a flexible, supported Web-based intervention available on campus. Larger trials should be conducted to further test the significance of supported Web-based interventions that also give students a choice of program depending on their symptom profiles. Improving the delivery and reach of these programs has the potential to positively affect students’ mental health at this key life stage.
Conflicts of Interest

JEP is a clinical researcher at SilverCloud Health. DR is Chief Science Officer at SilverCloud Health. The other authors declare no conflicts of interest related to this study.

Multimedia Appendix 1

Study CONSORT diagram.

References


Abbreviations

ANOVA: analysis of variance

CBT: cognitive behavioral therapy

GAD-7: Generalized Anxiety Disorder 7

DASS-21: Depression Anxiety Stress Scale

DSM-5: Diagnostic Manual of Mental Disorders, Fifth Edition

iCBT: internet-delivered cognitive behavioral therapy

IQR: interquartile range

LMM: linear mixed model

MCAR: missing completely at random

PHQ-9: Patient Health Questionnaire 9

RCI: reliable change index

RCT: randomized controlled trial
SAT: Satisfaction With Treatment

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Lamotrigine Therapy for Bipolar Depression: Analysis of Self-Reported Patient Data

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Abstract

Background: Depression in people with bipolar disorder is a major cause of long-term disability, possibly leading to early mortality and currently, limited safe and effective therapies exist. Although existing monotherapies such as quetiapine have limited proven efficacy and practical tolerability, treatment combinations may lead to improved outcomes. Lamotrigine is an anticonvulsant currently licensed for the prevention of depressive relapses in individuals with bipolar disorder. A double-blinded randomized placebo-controlled trial (comparative evaluation of Quetiapine-Lamotrigine [CEQUEL] study) was conducted to evaluate the efficacy of lamotrigine plus quetiapine versus quetiapine monotherapy in patients with bipolar type I or type II disorders.

Objective: Because the original CEQUEL study found significant depressive symptom improvements, the objective of this study was to reanalyze CEQUEL data and determine an unbiased classification accuracy for active lamotrigine versus placebo. We also wanted to establish the time it took for the drug to provide statistically significant outcomes.

Methods: Between October 21, 2008 and April 27, 2012, 202 participants from 27 sites in United Kingdom were randomly assigned to two treatments; 101: lamotrigine, 101: placebo. The primary variable used for estimating depressive symptoms was based on the Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16). The original CEQUEL study findings were confirmed by performing t test and linear regression. Multiple features were computed from the QIDS-SR16 time series; different linear and nonlinear binary classifiers were trained to distinguish between the two groups. Various feature-selection techniques were used to select a feature set with the greatest explanatory power; a 10-fold cross-validation was used.

Results: From weeks 10 to 14, the mean difference in QIDS-SR16 ratings between the groups was −1.6317 (P=.09; sample size=81, 77; 95% CI −0.2403 to 3.5036). From weeks 48 to 52, the mean difference was −2.0032 (P=.09; sample size=54, 48; 95% CI −0.3433 to 4.3497). The coefficient of variation (σ/μ) and detrended fluctuation analysis (DFA) exponent alpha had the greatest explanatory power. The out-of-sample classification accuracy for the 138 participants who reported more than 10 times after week 12 was 62%. A consistent classification accuracy higher than the no-information benchmark was obtained in week 44.

Conclusions: Adding lamotrigine to quetiapine treatment decreased depressive symptoms in patients with bipolar disorder. Our classification model suggested that lamotrigine increased the coefficient of variation in the QIDS-SR16 scores. The lamotrigine group also tended to have a lower DFA exponent, implying a substantial temporal instability in the time series. The performance of the model over time suggested that a trial of at least 44 weeks was required to achieve consistent results. The selected model

http://mental.jmir.org/2018/4/e63/
confirmed the original CEQUEL study findings and helped in understanding the temporal dynamics of bipolar depression during treatment.


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**KEYWORDS**

bipolar disorder; CEQUEL study; data analysis; depressive symptoms; lamotrigine; time series

**Introduction**

Bipolar disorder, a psychiatric condition characterized by repeated elevated mood (mania) and low mood (depression) states [1], has been ranked the sixth cause of disability worldwide, affecting nearly 1% of the adult population [2,3]. People with bipolar disorder [4] spend up to a third of their lives depressed, and it is these depressive symptoms that result in long-term disability and early mortality.

There is, however, no consensus on the effectiveness or safety of antidepressant drugs, such as fluoxetine, for bipolar depression [5]. Lamotrigine, a sodium channel inhibitor, is an anticonvulsant that is also being used to treat bipolar depression [6]; however, its action mechanism for bipolar disorder remains unclear [7]. Although Lamotrigine has been licensed for the prevention of bipolar disorder depressive relapses, its acute effects are less well known. A pooled analysis of all randomized data has revealed that although there appears to be a modest treatment effect in the acute phases of bipolar depression, this has not been observed in individual trials, which may have been because of the short treatment durations in these trials (8 weeks). Because lamotrigine requires a 6-week titration period, the majority of trials therefore only assessed 2 weeks of treatment at the therapeutic dose. There is still no consensus on the proven efficacy and practical tolerability of current monotherapies for bipolar depression such as quetiapine; however, it has been suggested that treatment combinations could lead to improved outcomes.

The comparative evaluation of quetiapine plus lamotrigine versus quetiapine monotherapy (CEQUEL) trial was a double-blind randomized placebo-controlled parallel group trial comparing a lamotrigine plus quetiapine treatment and a quetiapine monotherapy treatment in patients diagnosed with a bipolar I or II disorder (EudraCT Number: 2007-004513-33) [8]. A minimum level of depressive symptoms was not required for entry to either the run-in or randomized phases of the trial because the relevant criterion was the clinical judgment that new pharmacological treatments were required for depressive episodes. The randomization procedure used an adaptive minimization algorithm that was balanced for center, age, sex, bipolar disorder I or II, baseline depression severity, quetiapine dose, concurrent medication, pretrial use of quetiapine, pretrial use of lamotrigine, and mood episodes in past year (<4 or ≥4).

The primary outcome measure for the trial was the presence of depressive symptoms at 12 weeks as self-reported by the subjects using the Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16) [9]. Symptoms of mania were also assessed using the Altman self-rating scale (ASRM) [10]. The resulting scores ranged from 0-27 for the QIDS-SR16 and 0-25 for ASRM. The subjects were prompted weekly by text or email to report their mood symptoms using the True Colours platform, which is described in more detail in a study [11].

The original analysis reported significant depressive symptom improvements for the lamotrigine subjects compared with the placebo subjects. In this paper, the data collected in the trial were reanalyzed using machine learning approaches with the main objective being the identification of the most appropriate binary classifier to distinguish between the lamotrigine and the placebo effects. In addition to replicating the findings obtained from the original statistical analysis, we also wanted to determine the time it took for the drug to provide statistically significant outcomes to provide some guidance with respect to the minimum amount of time required to undertake trials that aim to establish the treatment or drug efficacy.

To assess the differences between patients taking lamotrigine and those taking the placebo, a binary classification approach was used to identify the relevant features to be extracted from the time series. This approach considered the different characteristics in the collected data and sought to classify the participants into 2 distinct groups based on the observed features; in this case, the group taking lamotrigine and the group taking the placebo. The features were determined based on the different statistical metrics computed from the data, and the analysis determined which features would facilitate the classification; for example, it was expected that the mean QIDS-SR16 scores would differ between the 2 groups. For every feature, a kernel based density estimation was used to examine its probability distribution between the 2 groups and to test whether the 2 distributions were different; the bigger the differences, the greater was the explanatory power of the feature. For the same reason, the performance of a classifier for each individual feature was also examined. Finally, the features and classifier with the best cross-validated accuracies were identified.

**Methods**

**Data**

Data were collected from 202 participants over a period of 52 weeks; 149 with bipolar type I disorder and 53 with bipolar type II disorder; of which 90 were male and 112 were female. Figure 1 shows the number of responses received each week over the 52 week data collection period.
Initially, there were 202 registered participants. After the first 2 weeks, there was a large drop in the number of people who continued to report; however, there were almost equal numbers of subjects in both the lamotrigine and placebo groups. A more detailed trial profile is presented elsewhere [8].

There was a 60% overall compliance with the self-reported mood ratings at 12 weeks; however, even though fewer participants submitted ratings for the entire 52 weeks, no between group differences were observed. For this reason, 2 data subsets were explored; 153 participants who submitted mood data for at least 5 weeks and 138 participants who reported for at least 10 weeks. Another challenge was that the participants did not submit mood ratings at regular time intervals; therefore, the target frequency of one report per week was not always achieved because patients were able to submit scores at any time during the week, which resulted in unevenly sampled data.

As a result, extra care was required when using the general time series techniques that had been originally developed for uniformly sampled data.

Statistical Analysis

Because the overall goal was to build a binary classifier that could differentiate the patients taking the lamotrigine from those taking the placebo, the first exploratory step was to study the different statistical metrics, called features, that were calculated using the dataset with the aim of identifying the "good" features to feed into the classifier, that is, those features that had sufficient explanatory power to facilitate the classification task. Therefore, how each feature contributed to the classification accuracy when used individually was also investigated.

A common approach when evaluating the explanatory power of a feature has been to assess its associated probability distribution. Kernel smoothing density estimation [12,13] is a nonparametric technique that can estimate the probability distribution of a random variable based on a small data sample. A Gaussian kernel is commonly used with its kernel function being the standard normal distribution because this method is smoother than a histogram when estimating probability distributions.

A receiver operating characteristic (ROC) curve is a graphical plot that shows the classification threshold variations of a binary classifier. Given a labeled dataset, a binary classifier is able to produce the following 4 results from the comparisons of the predicted class to the original labels: true positives, false positives, true negatives, and false negatives. Because the classification threshold is varied, the ROC curve plots the true positive rate versus the false positive rate with the area under the (ROC) curve providing the single metric for the evaluation of the classification model; the larger the area under the curve, the greater the possibility of realizing a high true positive rate and a low false positive rate.

In practice, using one single variable or using all available variables for the classification may not result in an optimal classifier. Various feature selection techniques can be used to select the best model from among the set of available variables, which involves selecting those variables that are representative
of the data variability, while improving the classification accuracy. Two types of techniques for feature selection were considered. On one hand, lasso, elasticnet and ridge regression [14] were selected to optimize the deviance of the model. The deviance is calculated based on L_1 and L_2 norms of the error obtained on a cross-validation set. With these techniques, the best performing features were added to the model one by one up to the point at which the cross-validation error did not reduce. On the other hand, sequential feature selection techniques work in a similar manner but use the classification rate as an error metric. We studied both techniques for feature selection to test the robustness of our results.

The different variables computed from the original dataset were investigated as candidate features to feed into the classifiers. The raw dataset contained different subject attributes, such as demographic information (age and gender) and bipolar type, and reported QIDS-SR16 and ASRM values. The age, gender, and bipolar type were kept as they were, and a range of statistics was computed from the QIDS-SR16 values. The ASRM values were not investigated further as these did not indicate any valuable information in the early exploratory stage. Further, because the lamotrigine was being used to treat bipolar depression, the QIDS-SR16 values offered greater information. The QIDS-SR16 mean and SD were the initial candidate features, that is, if the drug worked, the mean QIDS-SR16 value would be lower for the subjects taking the lamotrigine than for those taking the placebo. The coefficient of variation, which is defined as the ratio of SD to the mean, was also used as a separate feature. Other simple statistics considered were the skewness and kurtosis in each subject’s QIDS-SR16 time series, which summarized the QIDS-SR16 data distribution but did not reflect the temporal dynamics.

In addition to these basic statistics, other more complicated features were computed from the QIDS-SR16 time series data. The Lomb periodogram [15,16], also known as least-squares spectral analysis, was seen to be an appropriate technique for estimating the power spectral density of the unevenly sampled time series. The Lomb periodogram can be used to estimate the power for a wide range of frequencies. A frequency threshold of 0.2 was arbitrarily defined and 2 features computed, the sum of the low frequency (f ≤0.2) power and the sum of the high frequency (f >0.2) power. The ratio between the amount of power at these high and low frequencies was also calculated as an additional feature.

Detrended fluctuation analysis (DFA) [17] is another commonly used technique for analyzing biomedical signals. DFA basically measures the statistical self-affinity of a signal. McSharry and Malamud give details of the DFA algorithm and related methods in [18]. Essentially, DFA scaling exponent alpha measures the roughness of a time series; for example, white noise, which fluctuates a lot has alpha of 0.5; for pink noise alpha is 1, and a random walk has alpha of 1.5. The DFA exponent alpha was computed for each individual subject and used as another feature in the classification model.

To maximize the classification performance, a number of linear and nonlinear classifiers were also investigated. A linear classifier is a classification algorithm, the objective function of which is a function of a linear combination of features. A binary linear classifier has a linear decision boundary, and a nonlinear classifier has a nonlinear decision boundary. Detailed algorithmic procedures for the classifiers used here are not given and interested readers can consult the relevant references. The linear classifiers investigated were logistic regression [19], linear discriminant analysis [20], and linear support vector machines [21], and the nonlinear classifiers investigated were quadratic discriminant analysis, Gaussian kernel support vector machines, and K-nearest neighbors [22].

In short, the classification performances were evaluated using the different linear and nonlinear methods for each of the individual features and the subset of features obtained in the feature selection step. However, when using complex nonlinear models, it is relatively easy to overfit the data; therefore, to avoid this problem, the evaluation metric was based on the classification accuracy obtained from the out-of-sample data for which 10-fold cross-validation was used to evaluate the out-of-sample performances. The construction, evaluation, and comparison of the many different models for the several features involved an exhaustive search and comparison of the performance of the quantitative classifiers. In reality, because there was no perfect model, the more these different models agreed with each other, the more confidence there was in the results. Parsimonious models are attractive not only because the risk of overfitting is reduced but also because the simpler the model, the easier it is to interpret the results and improve understanding. Data from one, two, and three quarters of the trial period were also considered so that the performance of the classifier could be monitored over time to assess the optimal trial durations for the lamotrigine and placebo comparison.

Results

The initial data exploration analyzed the trends in the QIDS-SR16 time series. Figure 2 shows the comparative trend analysis for the 2 patient groups, those taking the lamotrigine and those taking the placebo. The results clearly show that there was a more pronounced decreasing trend in the participants taking the lamotrigine. This simple analysis showed that although both groups improved, the rate of improvement was higher throughout the trial for those taking lamotrigine.

The probability distributions for the reported QIDS-SR16 and ASRM values were also investigated. The kernel density estimates shown in Figure 3 revealed that there was a clear difference between the QIDS-SR16 values reported by the 2 groups. The expanding window average for the QIDS-SR16 and ASRM values are also shown in the same figure. The mean value of the data available up to week n was computed and plotted against the time (number of weeks), which found that the ASRM data were unable to offer any predictive information for the classification of the 2 groups.

The results in Figure 3 show that the overall differences in the QIDS-SR16 scores between the 2 groups was about −2.2 at the end of the 52-week period. Two-tailed t test on the mean QIDS-SR16 scores of each participant were performed for different 4 week periods, and the results are summarized in Table 1. The data were randomly shuffled and the 2 groups
randomly selected regardless of whether the samples belonged to the placebo or lamotrigine groups. The same process was repeated to measure the average distribution differences in the QIDS-SR16 values for any 2 groups. The results again indicated that the decrease of 2.2 was statistically significant ($P<.001$).

After designing many features to feed into the classifier, feature selection was conducted using lasso, elasticnet, ridge regression, and the sequential feature selection techniques. All these methods agreed on the choice of only 2 variables, the scaling exponent alpha from DFA and the coefficient of variation ($\sigma/\mu$). The performance evaluations for these 2 features are summarized in Figure 4. The results suggested that the lamotrigine group had a lower DFA exponent alpha, which corresponded to a time series with greater fluctuations, such as in the case of white noise. It appeared that the lamotrigine group had a higher coefficient of variation ($\sigma/\mu$), which corresponded to a lower mean and a higher SD for the QIDS-SR16 values.

These 2 selected features produced easily understood information. The coefficient of variation ($\sigma/\mu$) reflected the shape of the QIDS-SR16 distribution and was not affected by the weekly fluctuations, and the DFA exponent alpha quantified the nature of the temporal weekly fluctuations and was not affected by the distribution. Therefore, intuitively, the coefficient of variation ($\sigma/\mu$) was seen as a standardized measure of the dispersion and the DFA exponent alpha as a measure of the temporal stability.

**Figure 2.** Trend analysis: The linear regression lines for the Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16) data were plotted.
Figure 3. Upper half: cumulative distribution function (CDF) density plot for the Quick Inventory of Depressive Symptomatology and Altman self-rating scale value estimates. Lower half: plot for the expanding window average for the Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16) and Altman self-rating scale (ASRM).

Table 1. Results from 2 sample t tests on the Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16) scores for different 4 week periods.

<table>
<thead>
<tr>
<th>Four-week period</th>
<th>Sample size</th>
<th>QIDS-SR16 difference</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lamotrigine</td>
<td>Placebo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-12</td>
<td>101</td>
<td>101</td>
<td>−0.33</td>
<td>.63</td>
</tr>
<tr>
<td>10-14</td>
<td>81</td>
<td>77</td>
<td>−1.63</td>
<td>.09</td>
</tr>
<tr>
<td>20-24</td>
<td>62</td>
<td>64</td>
<td>−1.52</td>
<td>.18</td>
</tr>
<tr>
<td>30-34</td>
<td>52</td>
<td>55</td>
<td>−3.03</td>
<td>.007</td>
</tr>
<tr>
<td>40-44</td>
<td>50</td>
<td>49</td>
<td>−2.09</td>
<td>.08</td>
</tr>
<tr>
<td>48-52</td>
<td>54</td>
<td>48</td>
<td>−2</td>
<td>.09</td>
</tr>
</tbody>
</table>
Because the chosen model only had 2 variables, it was easy to visualize the classification decision boundary. Figure 5 is a plot of the decision boundary in a two-dimensional space for the coefficient of variation (σ/μ) versus the DFA exponent alpha. The blue area corresponds to the classification of the lamotrigine group (blue dots), whereas the pink area depicts the classification of the placebo group (red crosses). The results suggested that the lamotrigine group had a higher coefficient of variation and a lower DFA exponent. The decision boundary plot emphasizes the same results that were suggested by the density plots and the ROC curves in Figure 4.

Given the linear separation of the dataset, it was also possible to visualize the time series for the participants lying in the 4 decision area corners; Figure 6 is a plot of these time series. The time series on the left (small alpha) showed greater instability whereas those on the right (large alpha) were smoother and more stable. The time series on the top (large σ/μ) showed less depression on average than those on the bottom (small coefficient of variation [σ/μ]). The time series in the top left corner corresponded to a typical participant in the lamotrigine group (large coefficient of variation [σ/μ] and small alpha), whereas the time series on the bottom right showed a typical participant in the placebo group (small coefficient of variation [σ/μ] and large alpha).

A binary classification analysis was conducted, for which a variety of linear and nonlinear models were applied to the individual features, all features, and to the 2 selected features (coefficient of variation and DFA exponent alpha). The results are summarized in Multimedia Appendix 1. These results suggested that the cross-validation classification accuracy was 62%. There was little evidence of any benefit to be gained from using the nonlinear classification models; therefore, the study was continued using logistic regression on the 2 selected features.

As mentioned, participant compliance was important and was found to yield time series of varying durations. A clinician who was using the classifier to test whether lamotrigine was better than the placebo would need to know how many weeks of data were required before a definitive decision could be made. For this reason, the performance of the logistic regression model was evaluated against the amount of data reported by participants. For this evaluation, the participants were selected if they had provided at least 10 QIDS-SR16 responses for trial durations of 13 to 52 weeks. Figure 7 shows the classification accuracy and SE versus the trial duration. The classification accuracy was plotted using available data after each week (from the 13th to the 52nd weeks). The maximum of the fractions for the lamotrigine and placebo participants served as the “no
information” benchmark for the classifier. In addition, for most periods from 20 weeks onwards, the classifier was outperforming the benchmark. For trials ranging from 44 to 52 weeks, the classification accuracy was greater than the benchmark and was statistically significant.

Figure 5. Classification decision boundary using logistic regression. BN: Brownian noise; DFA α: detrended fluctuation analysis alpha; N: pink noise; WN: white noise; σ/μ: coefficient of variation.

Figure 6. The four Quick Inventory of Depressive Symptomatology—self report version 16 (QIDS-SR16) time series for the subjects lying near the 4 decision boundary plot corners.
Discussion

Methods and Their Limitations

The results from the classification model confirmed the original findings of the CEQUEL study that the addition of lamotrigine to quetiapine for the treatment of severe bipolar depression decreased depressive symptoms compared with a placebo. Although the original CEQUEL data analysis had relied on linear regression model fitting, the classification model used in this study not only examined the data from a different perspective but also provided robust explanatory power because it allowed for an estimation of the extent to which the 2 groups of observations (ie, treatment allocation: active lamotrigine vs placebo) could be distinguished based only on the QIDS-SR16 scores. Therefore, a model was constructed without the need for any prior information about the clinical interventions during the treatment period. Using out-of-sample classification accuracy and simpler models allowed us to avoid overfitting that is problematic when employing complicated machine learning models on shallow datasets. Another advantage of the machine learning models was the ability to test multiple features computed from the raw data and select only those features that had sufficient explanatory power.

The use of DFA on the QIDS-SR16 time series allowed us to examine the temporal stability of the treatment, an aspect that was not considered in the original study. Future data analyses could attempt to explain why the QIDS-SR16 scores of the participants taking the active lamotrigine were generally temporally unstable. The effect of other clinical interventions and concurrent treatments during the study period could also be considered. Finally, it was demonstrated that machine learning techniques could be generally used in clinical trials to provide greater insights into what the data represent beyond classical statistical analyses, especially when there are large, complex datasets available. One drawback of using machine learning techniques, however, is that the analyst must deal with the bias-variance tradeoff. Another disadvantage is that some powerful machine learning models require very large datasets to be able to generalize well.

Conclusions

This study confirmed that the use of lamotrigine decreases depressive symptoms in bipolar patients. The selected classification features suggested that lamotrigine increased the coefficient of variation (achieved by increasing SD or decreasing the mean of the QIDS-SR16 time series). It was also found that patients taking lamotrigine tended to have rougher time series, which was indicative of a greater temporal instability in the time series. The 2 features, the coefficient of variation and DFA exponent, implied that a two-dimensional visualization diagram and linear decision boundary can be constructed to better understand bipolar disorder and the ways that the participants are affected by lamotrigine. The statistical significance of the classification was evaluated, from which it was determined that a trial of at least 44 weeks was required to distinguish between lamotrigine and the placebo. It would be useful to conduct additional studies to obtain a larger cohort of compliant participants. The selected features provided a deeper understanding of the temporal dynamics of subjects experiencing bipolar disorder and offered the potential for the better monitoring of symptoms over time.
Conflicts of Interest
None declared.

Multimedia Appendix 1
Comparison of models: Logistic regression (LR), Linear Discriminant Analysis (LDA), Quadratic Discriminant Analysis (QDA), Linear Support Vector Machine (LSVM), Gaussian Kernel SVM (GSVM) and K-Nearest Neighbors (KNN). We show both the in-sample and out-of-sample classification accuracy.

References
Abbreviations

**ASRM:** Altman self-rating scale  
**CEQUEL:** Comparative evaluation of Quetiapine-Lamotrigine  
**DFA:** detrended fluctuation analysis  
**QIDS-SR16:** Quick Inventory of Depressive Symptomatology–Self-Report version 16  
**ROC:** receiver operating characteristic
A Mobile App for the Self-Report of Psychological Well-Being During Pregnancy (BrightSelf): Qualitative Design Study

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Abstract

**Background:** Maternal mental health impacts both parental well-being and childhood development. In the United Kingdom, 15% of women are affected by depression during pregnancy or within 1 year of giving birth. Suicide is a leading cause of perinatal maternal mortality, and it is estimated that >50% of perinatal depression cases go undiagnosed. Mobile technologies are potentially valuable tools for the early recognition of depressive symptoms, but complex design challenges must be addressed to enable their use in public health screening.

**Objective:** The aim of this study was to explore the issues and challenges surrounding the use of mobile phones for the self-report of psychological well-being during pregnancy.

**Methods:** This paper presents design research carried out as part of the development of BrightSelf, a mobile app for the self-report of psychological well-being during pregnancy. Design sessions were carried out with 38 participants, including pregnant women, mothers, midwives, and other health professionals. Overall, 19 hours of audio were fully transcribed and used as the basis of thematic analysis.

**Results:** The study highlighted anxieties concerning the pregnancy journey, challenges surrounding current approaches to the appraisal of well-being in perinatal care, and the midwife-patient relationship. Designers should consider the framing of perinatal mental health technologies, the experience of self-report, supporting self-awareness and disclosure, providing value to users through both self-report and supplementary features, and designing for longitudinal engagement.

**Conclusions:** This study highlights the needs, motivations, and anxieties of women with respect to technology use in pregnancy and implications for the design of mobile health technologies.

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**KEYWORDS**
engagement; mental health; mHealth; midwifery; perinatal depression; pregnancy; self-report; well-being; mobile phone
Introduction

Background

Perinatal depression (PND) affects up to 15% of women during pregnancy or within 1 year of giving birth in the United Kingdom (UK) [1]. The occurrence of PND may be as high as 35% in certain demographic groups [2] and may affect up to 10% of men [3,4]. Suicide is the leading cause of maternal mortality within a year of birth [5].

Pregnant women suffering from depression are more likely to engage in unhealthy practices, including poor diet, substance abuse, and failure to enroll in prenatal care, and are at increased risk of self-harm and suicide [6,7]. A meta-analysis points to antenatal depression as the strongest predictor of postnatal depression [8]. In addition, antenatal depression can affect fetal development and has been identified as an independent risk factor for children’s behavioral, cognitive, and emotional development through adolescence [7,9-11].

Timely identification of depression and depressive symptoms can therefore enable early intervention, reduce the likelihood of developing postnatal depression, prevent more severe forms of the condition, reduce its intergenerational impact, and improve a woman’s overall health status [5,7]. In the context of the UK’s National Health Service (NHS), mental health assessments in pregnancy are typically carried out verbally and using paper-based questionnaires completed in the waiting rooms of midwifery clinics. The National Institute for Health and Care Excellence guidelines recommend the use of the 2-item Generalized Anxiety Disorder scale (GAD-2) to screen for anxiety in the early stages of pregnancy, followed by further screening using the GAD-7 scale, Edinburgh Postnatal Depression Scale (EPDS), or the Patient Health Questionnaire (PHQ-9) if a risk is identified [12].

However, it is estimated that at least 50% of PND cases go undiagnosed [13,14]. Depression during pregnancy is marked by an unwillingness to seek help at what parents believe should be a happy time and difficulty separating symptoms of mental illness from normal fluctuations in mood [15]. Almost all UK-based midwives (96%) report asking women about their mental well-being at their first appointment, only 1 in 10 women recall being asked and almost half report never being told about the possibility of mental health problems [16].

Perinatal Mental Health Technologies

Mobile devices have the potential to facilitate the remote screening and monitoring of mood and depression throughout the antenatal period, extending care to underserved and at-risk populations, enabling timely assessment and intervention, gathering ecologically valid and longitudinal data, overcoming stigma, supporting honest disclosure and fostering trust between women and midwives.

In the perinatal context, previous design research has examined prototype technologies for infant health tracking [17-19], as well as information provision and seeking behaviors, as in the case of Babywijzer, a prototype mobile app for Dutch women [20]; Baby+, a food and weight tracking and health information app for Pakistani expectant mothers [21]; a short message service text message-based system for the personalized communication of health information to pregnant women in Kenya [22]; and qualitative analyses of women’s use of technology for information seeking [23,24].

Other prototype apps have focused on health data tracking. Bloom supports recording of nutrition, hydration, activity, weight, symptoms, and mood [25]. Nuwa aims to facilitate communication between women and their partners [26]. Qualitative analysis has also examined women’s motivations for the use of mobile apps for menstrual tracking [27]. Peyton et al developed a set of design requirements for mobile health (mHealth) interventions to support physically healthy pregnancies in the context of a “pregnancy ecology” comprising physical, emotional, informational, and social support aspects [28]. Building on this work, Prabhakar et al have proposed a “design framework” for maternal support interventions, the Evolving Ecology of Support, entailing support needs, sources, and interventions [29].

However, design research has yet to address many of the public health challenges that pregnancy presents, including the pervasive stigma surrounding mental health, the potentially severe consequences reflected in mental illness, self-harm and suicide rates [5,7], and the clinical constraints that influence technology adoption, given the role midwives and other health professionals play in shaping the experience of pregnancy.

Self-Report Mechanisms

Whether conducted using the Whooley questions [30], the EPDS [31], or through conversation with a professional, perinatal mental health screening programs are retrospective in nature. Several decades of cognitive psychology and behavioral economics research have revealed striking differences between retrospective and momentary reports of well-being [32-37], and clinical psychology has faced criticism for neglecting “the dynamics of symptoms” [33], given that “variability over time and dynamic patterns of reactivity to the environment are essential features of psychopathological experiences” [38].

Self-report is not a direct pipeline into consciousness [39]. Mobile devices have enabled us to expand our inquiry to real-world contexts through ecological momentary assessment (EMA); the self-report of experience in the moment and over time [40]. However, although design research has examined mobile apps for bipolar disorder [41], depression [42], and anxiety [43], how different reporting mechanisms shape the experience of self-report and the relationship between these perspectives have largely been underexplored to date [40].

User Engagement

Designing effective self-report technologies in large part hinges upon the engagement of users, often over long periods of time, whether to collect valid data for mental health screening, behavioral change, personal health-related outcomes, or self-awareness [44,45]. Previous studies have found that longitudinal self-reporting tends to swiftly decline following “an initial burst of interest” [46,47]. Understanding users’ motivations for engagement is therefore a key step in the design of mHealth technologies, particularly in the case of those designed for self-report [47,48]. Previous research has examined

how users’ engagement with mHealth systems is shaped by the provision of feedback [47], data visualization [49], and multimodal input [50]. However, there remains a need to explore the factors that influence longitudinal user engagement in the perinatal context.

**BrightSelf**

We explore these issues in the design of BrightSelf, a mobile app and clinical interface for the self-report of psychological well-being in pregnancy. This system was developed through collaboration between public health and human-computer interaction (HCI) researchers for deployment in a multisite clinical study using a randomized controlled design to examine the capacity of mobile technologies to facilitate the longitudinal, momentary, and retrospective monitoring of antenatal mood and depression [51].

Toward these ends, the primary objective of this study is to obtain insight into the experience of pregnancy and perinatal care, motivations, anxieties and concerns of parents, aims and responsibilities of health professionals, relationships between women and public health services, and the use of technology in pregnancy. This qualitative design research allowed us to identify requirements for a mobile app for deployment within a public health service, explore concept development with users, and perform iterative prototype evaluation.

**Methods**

**Approval**

This research forms part of an interdisciplinary clinical research study reviewed and approved by the National Research Ethics Service Committee South East Coast. A research ethics submission for this design research protocol was submitted to and approved by the Head of the Department of Primary Care and Public Health and the Joint Research Compliance Office Coordinator at the same institution.

**Design Sessions**

This research involved an iterative series of design sessions. Sessions began by exploring design challenges through open discussion, including how technology shapes the self-report of well-being, how users engage and are engaged in the honest disclosure of mental health concerns, how health professionals might act upon reports of psychological well-being, and how technology might contribute to our evolving conception of perinatal well-being and its pursuit, followed by concept development and prototype feedback.

Participants were recruited through social media, the distribution of cards and posters, distant acquaintances, and contact with midwifery clinics. Individual sessions were arranged to support the inclusion of women and other individuals who were unable to attend group sessions or preferred to discuss their experiences independently. Six sessions with women were conducted over Skype at their request. Sessions were conducted by a transdisciplinary and mixed gender team of 1-3 HCI and public health researchers between April 2016 and August 2017 and lasted 1-2 hours. Colocated sessions took place in the London and Cambridge area.

**Participants**

Design sessions involved 38 participants. Five group sessions, each with 4-7 participants, were attended by 15 practice and research midwives, 1 clinical studies officer, 1 psychologist, and 4 medical researchers or clinicians in maternal health, obstetrics, and midwifery. In addition, 17 individual sessions were held with 8 pregnant women, 3 mothers, 2 general practitioners (GPs), 1 clinical psychologist, 1 child and adolescent psychiatrist, and 2 maternal and child health researchers. The health professionals who participated in these sessions were aged 25-60 years, had a variety of ethnic backgrounds, and experience working with pregnant women through practice and research.

**Table 1** illustrates the demographic characteristics of maternal participants; 7 of these 11 participants had experienced at least 1 miscarriage. Two participants (P7 and P11) had been previously diagnosed with depression, and 1 (P5) with anxiety. However, no participant had received a specific diagnosis of PND. All professed “good” to “excellent” abilities with technology, all were in stable relationships, and all held a university or college degree.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Week of pregnancy</th>
<th>Previous pregnancies</th>
<th>Children</th>
<th>Age (years)</th>
<th>Ethnicity</th>
<th>Nationality</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>27</td>
<td>0</td>
<td>0</td>
<td>28-32</td>
<td>Asian British (Indian)</td>
<td>English</td>
</tr>
<tr>
<td>P2</td>
<td>Not pregnant</td>
<td>2</td>
<td>1</td>
<td>≥38</td>
<td>Mixed Other</td>
<td>Singaporean</td>
</tr>
<tr>
<td>P3</td>
<td>22</td>
<td>0</td>
<td>0</td>
<td>28-32</td>
<td>White British</td>
<td>English</td>
</tr>
<tr>
<td>P4</td>
<td>16</td>
<td>1</td>
<td>0</td>
<td>28-32</td>
<td>White Other</td>
<td>French</td>
</tr>
<tr>
<td>P5</td>
<td>11</td>
<td>1</td>
<td>0</td>
<td>≥38</td>
<td>White Other</td>
<td>American</td>
</tr>
<tr>
<td>P6</td>
<td>35</td>
<td>1</td>
<td>0</td>
<td>33-37</td>
<td>White British</td>
<td>English</td>
</tr>
<tr>
<td>P7</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>≥38</td>
<td>White Other</td>
<td>Greek</td>
</tr>
<tr>
<td>P8</td>
<td>31</td>
<td>3</td>
<td>2</td>
<td>33-37</td>
<td>White British</td>
<td>English</td>
</tr>
<tr>
<td>P9</td>
<td>Not pregnant</td>
<td>5</td>
<td>2</td>
<td>33-37</td>
<td>White Other</td>
<td>Lebanese</td>
</tr>
<tr>
<td>P10</td>
<td>Not pregnant</td>
<td>4</td>
<td>3</td>
<td>33-37</td>
<td>Mixed Other</td>
<td>Singaporean</td>
</tr>
<tr>
<td>P11</td>
<td>39</td>
<td>2</td>
<td>1</td>
<td>33-37</td>
<td>White Irish</td>
<td>English</td>
</tr>
</tbody>
</table>
Analysis

In total, 19 hours of audio were recorded, transcribed in full, and subjected to thematic analysis. The analysis was conducted in parallel by 2 primary authors working both inductively and deductively with respect to key design challenges and issues arising within sessions related to well-being, perinatal care, self-report, technology adoption, and engagement. This paper highlights the voices of women, introducing clinical perspectives where pertinent. By complementing the directly reported experiences of women with a wide sample of health professionals, we included phronetic input from those with everyday experiences of vulnerable populations, including younger women, ethnic minorities, and women experiencing domestic abuse [52].

Results

Themes and Subthemes

Participants described pregnancy as “a bit of a journey” punctuated by both positive and negative experiences, “good days and bad days” (P3).Textbox 1 presents an overview of the themes which emerged from the analysis.

Pregnancy: A Bit of a Journey

As a pregnant woman you think in weeks, you really do. [P3]

Pregnant women described thinking about pregnancy in terms of multiple concurrent timescales, trimesters, months, and weeks. This patterning shapes parents’ reflections and provides context for descriptions of key moments: “Oh I felt my first movement at 17 weeks it was so exciting…it was amazing at 14 weeks when I stopped feeling sick” (P3).

This was described by one participant as a period of transition and expectation during which “the notion of time is essential but it’s always looking forwards” (P4). Yet, comments from other participants suggested that parents’ reflection comprises past, present, and future focus: “Is that the kind of parent I want to be later, and if not, why start now?” (P5).

Pregnancy is a time of change, frequent emotional change, but also change of a more enduring form, to self-identity, and a “shift within the couple’s life stage” (P4). Emotional changes were described as “hormonal roller-coasters” (P8), crying “and the next minute” laughing (P4), which can lead mothers to feel less “emotionally resilient” (P8). This vulnerability can be compounded by a “loss of identity,” “not at all kind of taken up or kind of considered in your normal health care” (P6).

Pregnancy, particularly in the first instance, is a significant chapter in parents’ lives, and yet, as one first-time expectant mother recounted, “I don’t want it to be the only thing going on for me” (P1).

Positive and Negative Experiences

When describing pregnancy, women recounted positive experiences, such as ultrasound scans, “really nice shared experiences” (P5) but also did not refrain from expressing feelings of pervasive worry, “when you’re pregnant you do worry about everything” (P3). In addition, health professionals expressed an awareness that “everybody is worried during pregnancy, everybody’s anxious” (Female GP).
Certain participants described particularly intense and distressing events. A mother who had experienced multiple miscarriages described these events as “shocking” and “very devastating” (P9). Her first miscarriage occurred abroad where she described the absence of a midwife “or any kind of support from family and friends.” Following the subsequent birth of her son she stated, “I know I had postnatal depression in the sense that I was always scared that I might die and who might look after him, or he might die and how would I feel?”

**Women’s Causes of Concern**

The causes of worry and, less frequently, sadness described by mothers were diverse. Women expressed concerns related to heightened awareness of their own physical health, “you are so desperate to get [any problem] sorted” (P3), while avoiding “unnecessary interventions, and extra things done” (P5). Health professionals added that “women often say that they don’t feel that they’re doing a good job” and are “very worried that something they’ve done might be a problem” (Female Midwife). These concerns can pervade everyday life.

*You have to bend, and you don’t have to bend, and you have to sleep on the right and on the left. All these are worrying because, you know, even when I sleep, I don’t know if I’m harming my baby.* [P7]

Women named past experiences, “trying for a long time and miscarriages” (P3), as well as awareness of family history “my brother died…and then my mum had a straight of late miscarriages” (P3) as causes of anxiety. In addition, women expressed future concerns, a fear of giving birth, “I’ve been really struck by others, just quite how terrified they are” (P6), and “scary stories of women not sleeping, of women not having time even to wash their hair” (P7) in the postnatal period. P9 recounted in great detail the anxiety she felt when a nuchal translucency screening revealed a risk of Down syndrome in her fifth pregnancy. Worry then can come to form a vicious cycle, following the belief that “if you worry a lot you could actually cause yourself to have problems with the baby” (P3).

Not all sources of worry and sadness recounted were related to pregnancy. P4 was going through a period of grieving and was concerned with the impact this might have, “how much the fetus can feel.” Many midwives pointed to the presence of other children in the home as a common source of stress. For one woman (P5), the concern was to avoid disconnection with her husband by keeping him involved in the pregnancy. For another (P4), her husband was eager to participate yet she found “it’s probably hormonal, it’s probably postnatal depression, the fact that I’m always worried” (P9), and subsequently upsetting women’s trust in others.

*Just being told to go and get on with it, and not to worry too much because it was completely normal, but the message that it’s completely normal when you’ve never heard about it or seen, kind of, any references to it, is not very convincing.* [P6]

Stigma was linked to a fear of particular consequences. Foremost among these is the fear that “if I told them too much they might take my baby away” (P11). Among midwives, this fear was frequently discussed.

*For them it’s a real threat that you’ll take the baby away from them and I mean I can appreciate where they’re coming from because you get it in the papers “oh they’re taking a baby away.”* [Female Midwife]

Furthermore, women expressed a fear of being placed on medication, which could cause harm to their child antenatally, “one of the biggest fears I had was that if I told the midwife about those feelings there was a chance they might…put me on a medication that might harm the fetus” (P11), or affect their ability to breastfeed, “if you’ve gotta take whatever drugs the doctor’s gonna give you, that’s gonna go in the breastmilk, and that’s gonna affect your baby’s brain” (P8).

**Times of Pronounced Concern**

Descriptions of negative experiences point to gaps in care and opportunities for effective assessment and support. Participants spontaneously described as times of particular anxiety; the planning period (P1), first discovering the pregnancy (P3 and P5), the weeks spent waiting to meet the midwife (P3, P5, P6, P9, and P11), telling others of the pregnancy (P6), the 30th week (P3), and specific weeks postnatally (P8; Figure 1).

In particular, the period between notifying a GP of the pregnancy and the first midwife appointment was described as “really difficult” (P3), “a time of high anxiety” (Female GP) and “very isolating” (P11). These feelings were exacerbated by a lack of support (P6 and P7), morning sickness (P11), bodily changes (P6), the pressure to hide pregnancy (P6), a fear of complications arising from comorbid conditions (P7), and anxiety-induced Web-based searching (P3). Miscarriage often occurs during this period, and women described this as “very difficult from a mental health point of view actually, you are just sort of told ‘Sorry, that was a miscarriage, off you go’” (P6).
of the first trimester as a medical and informational gap in line with changes to women’s needs over time mirrors previous design research findings [23,29].

Experience in Pregnancy

Striking among participants was the difference that experience in pregnancy made to their outlook. Mothers with multiple children, on the whole, spoke of pregnancy in less emotive terms. Comments made by these women reflect what they had learned and come to expect, “I know, having had two babies myself and expecting my third, that the reality is very much different” (P8).

Experience grants these women knowledge, which helps them cope with difficult circumstances, knowledge concerning “how normal those rollercoasters are and how those terrible crazy dreams are” (P11). This experience applies not only to the emotions of pregnancy but also to the health care system, its pathways, and the likelihood of undesired consequences. These women’s experience is a potential resource for first-time mothers but does not always take that form. P5, an American woman in her 11th week, found that maternity advice could be condescending “you can do pregnancy wrong or you can do it right” and that “as a first-time pregnant lady, everyone’s like ‘oh but don’t you know?’” P6 described feeling “quite rapidly that you’re less competent than you were before.”

Figure 1. Times of Pronounced Concern.

Figure 2. The antenatal care pathway. PND: perinatal depression.

The Character and Experience of Perinatal Care

The majority of NHS antenatal care is performed by midwives (Figure 2). A woman’s first meeting with her midwife, termed the booking appointment, usually takes place within the first 12 weeks of pregnancy; this appointment is typically scheduled following an initial visit to a primary care provider, such as a GP, and can last up to 2 hours. Between 8 and 12 meetings usually follow between a woman and her midwife. The number of appointments and scans provided varies depending upon the risk to the mother and child, and local resources. In certain settings, there is a discontinuity of care, with some women seeing a different midwife at each subsequent appointment. P6 commented that as a result the very notion of “your midwife” proves confusing early in pregnancy.

Midwives’ Roles

Midwives referred to their goals as ensuring the well-being of the mother and baby, monitoring the mother’s vital signs, examining the mother’s past medical history (including mental health), performing a risk assessment, and if necessary making referrals, coordinating care and covering social needs, creating a care plan, reassuring women and their families, providing information, signposting what choices and resources are available, establishing trust and forming a relationship.
Mental Health Screening

Midwives’ Views

Midwives do not see themselves as mental health professionals, as was reflected in discussion concerning the use of the EPDS in clinic; for example, “we’re not qualified to diagnose so it is then up to us to pinpoint the appropriate professional to direct them to” (Female Midwife). Midwives are also intensely aware of the treatment gap that exists with respect to PND, as illustrated by the following:

Everyone that comes through the labour ward, it’s depression, depression, depression…especially the ones that have lost their babies and I didn’t have time to speak to one of them…two days later she committed suicide…So I know there is a gap, definitely. [Female Midwife]

Women recounted a marked variance in midwives’ approach to mental health, a complex and nuanced form of interaction.

Appraising Well-Being Based on Appearance

Several women stated that their mental health and mood was rarely discussed, “I don’t know if I had a special case where the midwife generally doesn’t ask anything about your mental health or stress or worries or concerns” (P9), “I don’t think there’s been anything, anything that’s been put in front of me during my pregnancy that has focused on mental health” (P6). A female GP described how “sometimes people don’t want to pick up problems that might take more time” and employ “leading comments like ‘Well you look like you’re fine don’t you?…Things are going really well…you look great!’” This line of thought echoes the comments of a community midwife participating in previous research, “The services are not there to support women and why open a can of worms that you can do nothing about” [16].

Appraising Well-Being Indirectly

Women also described a conversational approach employed by some midwives, “they might ask you how you’re feeling but that’s a really general question isn’t it?” (P8). This light-touch approach is often motivated by midwives’ appreciation of the stigma surrounding mental health. It is therefore worth noting that women described a clear awareness of midwives’ intentions, “I know what they’re asking…. (P10), “that is the question that they were trying to ask” (P9).

Appraising Well-Being Directly

Another approach recounted by women involves direct questioning during the booking appointment, including the verbal application of the Whooley questions. Some women found this approach “so weird…I had no idea what I was doing being pregnant” (P6). Two women (P2 and P3) compared this to a routine question about domestic abuse, which also took them by surprise. Some midwives also expressed doubts whether this approach does “probe as deeply as perhaps is needed sometimes.”

The Midwife-Patient Relationship

The midwife-patient relationship is a primary feature of antenatal care and a key factor in the success of mental health screening. Several women described midwives as “very supportive and nice” (P9), “amazing” (P8), and “very lovely people” (P10) who “care really deeply” (P11). Women’s perceptions of midwives’ roles coincided for the most part with midwives’ descriptions, there “to aid you through” (P3).

In addition, 2 women expressed the sentiment that “a midwife is not a mental health professional” (P11), “it’s not that I would have wanted her to [ask me about my mental health], I never expected her to, I never thought that was something they actually covered” (P9). Instead, midwives were described as generalists, a disappointment for P9, “all the reasons for nuchal translucency…even when I spoke to the midwife, I couldn’t really talk to her about these things.”

Midwife appointments were described by some women as “very routine,” “more concerned about taking measurements” (P2), “you go in, and you do the samples, and you do the tests, and it’s like ‘see you next time.’” For P4, a woman in the 16th week of her first pregnancy, this was not a positive interaction, “after my first meeting with my midwife I was very upset about this…look into my wellbeing, I’m a mother, and I’m not just a number, I’m not just…a blood test.” Women also felt that their initial classification as low or high risk dictated subsequent interactions with their midwife. Women classified as low risk (P1 and P4) were critical of this approach, “low-risk, from a medical perspective is not the same as well-being, and you still have questions” (P4).

NHS midwives described significant time pressures in their work, and women expressed awareness of this, often in sympathetic terms (P9, P6, and P11). However, this pressure also impacted women’s willingness to disclose concerns, “they basically just kick off my appointments with ‘Oh great, you’re entirely normal, this is gonna be really quick’” (P6), “I did have questions for her but I just felt like she was in a rush” (P1).

Technology Use in Pregnancy

Women frequently described technology as playing a role in their pregnancy. All owned mobile phones and used websites related to pregnancy. Six participants owned tablet computers and only one had not used any mobile app for pregnancy (P7). Many women used email (P8 and P9) and phone (P1, P3, and P8) to contact their care providers. P9 remained in touch with her UK-based gynecologist by email while traveling abroad. A well-timed notification from an app helped P3 to identify a water infection. P6 and P1 described using app content as a way to engage their partners in their pregnancy, “a sort of third party thing that you can point at and say ‘Look, this is what might be coming up next.’” Women most frequently described using technology to seek information, particularly to overcome perceived shortcomings in care (P3 and P9), a behavior portrayed by women participating in previous research as a means to compensate for “useless” and “overwhelming” printed literature [24].

However, the use of technology was not always recounted positively. P6 found herself targeted with Web-based advertising related to her pregnancy, “Facebook notices you’re pregnant…Google also knows I’m pregnant now.” Searching for information over the Web could be overwhelming, “a pit of
anxiety,” a “terrifying free-for-all” (P6), and the removal of international barriers did not always help, “you can read things that just make you more anxious because you don’t know why you’re not getting that care” (P6).

Discussion

Design Implications

In this section, we discuss the design implications of this study for BrightSelf and apps for perinatal psychological assessment in general (Textbox 2).

In its final form, BrightSelf, a mobile app (Android and iOS) designed for deployment within a public health service, supports the self-report of well-being in pregnancy and provides a number of supplementary features, including an interactive visualization of users’ data, concise well-being and support information, and an ideas machine, which dispenses animated well-being tips (see Multimedia Appendix 1). Momentary reports are collected using visual analog scales for mood, sleep, worry, enjoyment, and energy, as well as 2 contextual questions concerning semantic location and activity, constructs chosen according to participants’ comments and prior research [53]. In compliance with existing NHS care pathways and the National Institute for Health and Care Excellence guidelines, retrospective reports take the form of the EPDS, a self-administered 10-item survey that assesses feelings of guilt, sleep disturbance, anhedonia, and suicidal ideation present during the past 7 days [31]. Users are reminded to provide reports over time using notifications.

Importance of Appropriate Framing

How do people position it? How do you want to position yourself? [P4]

These design sessions highlighted women’s intense need to understand their own well-being in pregnancy and the challenges faced by health professionals attempting to do so. Tension between these two perspectives necessitates the careful framing of any technology introduced into the perinatal context.

Aversion to Mental Health

A lot of people, as soon as you say the word mental health shut up, completely. [P4]

Women described themselves as low, anxious, and in need of support, and yet were keen to define themselves from any labels connected to mental health or illness. This intense disconnect with the term “mental health” suggests that employing this language can reduce the reach of mHealth technologies [42]. We asked women about their thoughts concerning other terms such as “psychological well-being.” While some preferred this term to mental health, others felt it possessed similar negative connotations, “psychologist, psychiatrist, mental...for me, sit in a similar category” (P8). Several women spontaneously proposed “emotional well-being” as preferable.

Introducing an App

The initial booking appointment provides an opportunity to scaffold the introduction of an app to women. Both women and professionals stressed the need for this first impression to be a normalizing experience, “same as you go to see [the] midwife for the booking appointment, it’s just something that everyone does” (Female Psychologist).

This interaction illustrates how the pathways of clinical care constrain technology design in the perinatal context. Although women highlighted the weeks before the first appointment with a midwife as a time of high anxiety, there is currently no opportunity for midwives to interact with patients in this period, and even if expectant mothers were provided with a screening tool, no pathway exists to support subsequent action.

Every Pregnancy is Unique

Pregnant women are a highly diverse demographic. Midwives also demonstrate marked variance with respect to their experience and practice. In the case of mental health screening in particular, it is important to avoid design choices that might imply pregnancy planning, the presence of a supportive partner, family relationships or history, a lack of complications in pregnancy, infant development, the presence of other children, or the occurrence of miscarriage.

Supporting Value in Self-Report

I’m not going to just use it because you ask me to use it, right. [P10]

Women emphasized that they would not comply with the burden of self-report without recognizing value in doing so. While some participants expressed reservations that engaging in self-report might reinforce negativity, lead to obsesion or a biased perception of their own well-being, others reported motivations related to understanding their subjective experience, to relationships with others and to possible actions.

Turning Inward

Women expressed value in the potential of self-report to enable and maintain self-knowledge, progress, and well-being-related change. Less anticipated were those motivations that related simply to supporting self-awareness and reflection—comparing trimesters, checking in “treating it like a game” (P5), venting “to someone or something” (P9), acknowledging emotion, and preserving experience.

Turning Outward

Other motivations for the use of self-report technologies reveal the socially situated reality of pregnancy. Women envisioned the use of data to both avoid feeling alone, “the reason why everyone Googles so much” (P3), and to feel normal, “Is this normal? Am I normal?” (P10). Health professionals often spoke of women’s need to know what’s normal, an important factor in the success and failure of mental health screening programs, “they know they’re struggling, but they’re not sure if everybody, if that’s normal” (Female Psychologist).

Taking Action

Finally, women described how the potential of self-report data to support action could also motivate its collection—inciting conversation “to ask the right questions” (P4), inspiring action “I’m suffering from something, I should do something about it” (P10), obtaining support, and enabling midwives to tailor
care “to really move away from high and low-risk pregnancy” (P4).

**Shaping a Better Self-Report Experience**

Self-reports of well-being are colored by the experience of reporting. The methodological concern of reactivity, for example, whether we are “tapping a phenomenon as it exists, or as it has been transformed by measurement” [54], translates into a design constraint for self-report systems.

Participants in these sessions expressed strikingly different reactions to the experience of retrospective (EPDS) and momentary (EMA) reporting. The medical tone of the EPDS often immediately evoked guarded reactions among women, “see, this is all the mental health stuff…” (P5), “now I’m being like ‘Ooo I’m being evaluated so I need to be careful’” (P4). Certain questions evoked particular criticism. Question 4, which asks whether a woman has been “anxious or worried for no good reason,” led participants to exclaim “what if you’re anxious for a good reason” (P5), “women hate it!” (Female Psychologist). Questions regarding “sad or miserable” feelings and crying were also described as difficult to complete when pregnant. Terms like *EMA, momentary, retrospective, and assessment* reflect medical and academic framings. We identified the terms “Check In” and “Check Back,” which were perceived more positively by users (Figure 3).

A proposed EMA reporting experience, in contrast, was described as “really easy and not intrusive” (P6), “light-hearted” (P3), and “really nice and almost a bit fun as well” (P1). In comparison to the EPDS, these momentary measures reflect a broader spectrum of well-being, including positive dimensions. This may allow women to present a more complete appraisal of their well-being and to see reporting less as “a test that you pass or fail…a box tick exercise” as one female GP described the EPDS. In addition, the use of graphics and animation can make EMA a more engaging interactive experience (Figure 4).

Women reported that they would complete EMA reports more often and with greater honesty.

**Textbox 2. Design implications.**

**Framing**
- Avoiding “mental health”
- Introducing an app
- Uniqueness of each pregnancy

**Supporting value**
- Turning inward
- Turning outward
- Taking action

**Shaping self-report experience**
- Being evaluated
- Less intrusive

**Self-awareness and self-disclosure**
- A light touch
- A safe space
- Empowerment

**Designing for Engagement**
- Interaction over time
- More than self-report

http://mental.jmir.org/2018/4/e10007/ JMIR Ment Health 2018 | vol. 5 | iss. 4 | e10007 | p.139 (page number not for citation purposes)
Figure 3. Check In and Check Back screens.

**CHECK IN**

How are you feeling? Would you like to check in?

Here, you can check in to see how you're doing right now. The questions are very quick to complete. By completing these questions as accurately as possible in the moment, some self-insight may emerge over time.

**CHECK BACK**

How have you been? Would you like to check back?

Here, you can check back to see how you've been doing over the past week. These questions are used by clinicians to provide an estimation of one's psychological wellbeing.
Focus on Self-Awareness and Disclosure

Disclosing a need for mental health support during pregnancy requires women to recognize that their symptoms are unusual, accept the possibility of illness, and trust the individuals and services they would approach for support [16].

A Light Touch

Peyton et al have encouraged designers of perinatal mHealth technologies to “use immediate needs as a hook for long-term concerns” [28]. This advice was supported by women’s observations that mental health content and assessments should be “coupled” (P9), “couched,” and “sandwiched” (P11) with other features. Women suggested that a lighter touch was key to inviting honest disclosure, “a tool to sort of mention that people often, kind of are, feel differently during pregnancy and that that’s entirely normal” (P6).

A Safe Space

Several participants made comments suggesting that technology might make it easier for women to disclose how they are feeling, “through an app I might be a bit more open” (P1), “a safe space where you can articulate some of the anxieties that you’re feeling” (P6). Transparent communication of the potential consequences of disclosure is key to the creation of a safe space [55]. As P11 states, “I think the reality is you know someone’s not going to take your baby away if you tell them that you’re feeling this way but you don’t know whether it means a midwife’s going to come to your house every other day…I’m in a very anxious moment or in a low period you can’t rationalize.” The interpretation of open-ended data presents clinical and ethical challenges. Women spoke of a desire to provide sufficient context to preserve the meaning in their reported data, “I would want to write the word ‘scan’ under that, or ‘hypo’ under the ones where I’m worried, anxious” (P5). One approach is to include multichoice questions, which allow users to provide a degree of context.

Previous design research has emphasized the need for health tracking apps to provide feedback to users [23]. However, midwives cautioned against labeling mothers’ subjective experience during feedback, “they might think ‘well hold on a minute, I don’t feel that’” (Female Midwife), echoing warnings that technologies should avoid appearing to tell people what to
feel [56]. In particular, there was a reluctance among some midwives to present the score generated by the EPDS to users, owing to a concern that it might lead women to “try to beat their score” (Female Midwife), and a sentiment that it would be more valuable to offer an action to patients “you might be feeling a bit low and you might need to speak to a friend” (Female Midwife). Furthermore, women questioned whether increased familiarity with the nature of a screening scale might lead users to “feel pressured to be in that range” (P11) or to provide scores which “they know will get results” (P5).

**Promoting Responsibility, Action, and Empowerment**

In the clinical context, asking questions creates an ethical responsibility to act upon the responses provided [52]; this requires clinical pathways to support appropriate action and can create an additional workload for midwives as well as tensions and inefficiencies in the shared responsibility of a patient’s illness [57]. One midwife indicated that self-report technologies were most likely to be adopted if responsibility was shared across the clinical team.

*If it’s a tool to elicit [women’s] true feelings, then that’s only gonna be good isn’t it…but we have to adapt and it would take a bit of planning…for one midwife I think it would be difficult, but if there were a team doing it, that might ameliorate worries.*

[Female Midwife]

Midwives were keen to stress that technology should not act to disempower patients: “it’s about empowering women to take responsibility for their mood and contacting us, rather than me going oh my god I’ve got to bring in all these women because their mood is very low.” It is often reported that mental health professionals experience “much more difficulty in interacting with participants without any progress data” [58], and “difficulty learning from their clinical experiences…when they do not receive accurate feedback” or “when their cognitive processes are inadequate (ie, when they remember information incorrectly)” [59]. Access to women’s self-report data might therefore also serve to empower midwives by providing a more accurate picture of their patients’ well-being.

**Actively Designing for Engagement**

Given the burden of reporting, studies employing self-report technologies often report high rates of attrition [48,60]. Women described a variety of features that motivated their use of technology in pregnancy—an appropriate tone, broad appeal, convenience and timeliness, a focus on women’s needs, and anonymity. Women were particularly enthusiastic about a feature of several popular apps that compares the size of the fetus each week to a fruit or vegetable. This provides a visual analogy, allows women to track their progress, and also enables women to raise the topic of their pregnancy in conversation with others.

**Interaction Over Time**

Pregnancy implies a longitudinal perspective. It is therefore essential to consider how interaction unfolds over time. Women’s perceptions of appropriate reporting patterns varied significantly according to the nature of the scale and their concurrent state. Several women felt that reporting 3 times a day for several consecutive days would often be too much, whereas others felt it would prove feasible, for example. Women’s spontaneous insights point toward strategies to support interaction over time, including positive perceptions of mobile notifications, pairing reporting with routine activities, such as Kegel exercises, and the impression that reporting could “counterintuitively” be more rewarding the more it is used.

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**Figure 5.** Supplementary features.
Designers can strive to match women’s perceptions of pregnancy, including displaying the individual week of pregnancy and providing regular updates. The timeline of perinatal care (Figure 2) and women’s coincident narratives (Figure 1) point to opportunities for maintaining engagement over time.

**Value Beyond Self-Report**

High rates of dropout and attrition indicate that it is necessary to design for value beyond the act of self-report itself to offset the burden of reporting [48,60]. BrightSelf includes an ideas machine, which dispenses microinterventions informed by previous patient-focused research [53] and women’s insights (Figure 5). This feature received highly positive comments from women and was cited as a reason to return to the app. Midwives also supported this feature, but warned against including content that made assumptions about or demanded too much of patients. Such features can serve to lighten the tone of an app, supporting honest disclosure and key clinical needs.

**Conclusions**

Appropriate design of engaging tools for the self-report of psychological well-being has the potential to enable greater understanding of well-being in pregnancy, effective mental health screening programs, and the timely identification of depression and depressive symptoms, making treatment and support available to the women who need it. Working with women, midwives, clinical psychologists, psychiatrists, GPs, and other health professionals, this study illustrates how designers can act to support these aims by appropriately framing mHealth technologies, shaping the experience of self-report, supporting self-awareness and disclosure, providing value to users through self-report and supplementary features, and actively designing for engagement over time.

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**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**

Screen flows, sketches and design rationale.

[PDF File (Adobe PDF File), 3MB - mental_v5i4e10007_app1.pdf ]

**References**


Abbreviations

EMA: ecological momentary assessment
EPDS: Edinburgh Postnatal Depression Scale
GP: general practitioner
mHealth: mobile health
NHS: National Health Service
PND: perinatal depression

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Users’ Intrinsic Goals Linked to Alcohol Dependence Risk Level and Engagement With a Health Promotion Website (Hello Sunday Morning): Observational Study

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Abstract

Background: Hello Sunday Morning (HSM) is a self-guided health promotion website with the aim to improve drinking culture. Members are encouraged to sign up for a 3-month period of alcohol abstention and record and track their progress and goals.

Objective: This study used self-determination theory (SDT) to examine the nature of goals subscribed by HSM users to test the extent to which intrinsic goal pursuit was linked to lower alcohol dependency risk and higher engagement with the HSM website.

Methods: HSM users (N=2216; 59.75%, 1324/2216, females; aged 18-79 years) completed the World Health Organization’s Alcohol Use Disorders Identification Test (WHO-AUDIT, which measures alcohol dependence risk level) at sign-up and at 4 and 6 months after sign-up. In addition, the website had a goals-subscription feature that allowed participants to share their goals. Two independent raters classified the goals according to a coding system we devised based on SDT, which proposes that intrinsic goals (eg, growth, relationships, community, and health) better promote positive outcomes than extrinsic goals (eg, wealth, fame, and image).

Results: Although there was substantial (1016/2216, 45.84%) attrition of HSM users from sign-up to 6 months, the attrition rate could not be attributed to alcohol dependency risk because people in different WHO-AUDIT risk zones were equally likely to be missing at 4 and 6 months after sign-up. The SDT-driven coding of goals yielded the following categories: wealth and image (extrinsic goals); relationships, personal growth, community engagement, and physical health (intrinsic goals); and alcohol use-related goals (which were hard to classify as either extrinsic or intrinsic). Alcohol dependence risk level correlated positively with goals related to money ($r = .16$), personal growth ($r = .17$), relationships ($r = .10$), and alcohol use ($r = .25$). Website engagement correlated negatively with alcohol dependence risk level ($r = .10$) and positively with relationship ($r = .10$) and community goals ($r = .12$).

Conclusions: HSM users with higher alcohol dependence risk tended to engage with the website less, but to the extent that they did, they tended to subscribe to goals related to alcohol use and improving their personal growth, relationships, and finances. In line with SDT, engagement with goals—particularly the intrinsic goals of connecting with close-others and the broader community—related to increased website engagement. Web-based tools intended to promote healthy behaviors in users may be effective in engaging their users if the users’ experience on the website supports the pursuit of intrinsic goals.

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KEYWORDS
alcohol dependence; aspirations; goals; self-determination theory; website engagement
Introduction

The ubiquity of the internet has led to increased interest in its utility for motivating and modifying behavior [1]. Web-based behavior change interventions are usually self-directed programs, designed to promote positive change through the provision of evidence-based materials and interactive online activities [2]. Such programs are often praised for their high reach and low cost, convenience, and the relative anonymity of users [3]. Importantly, these programs are also often effective. Web-based interventions have been useful in decreasing illicit substance use [4], smoking cessation [5], healthy weight management [6], and the promotion of mental health [7].

Web-based interventions may be particularly pertinent to the management of issues related to alcohol consumption, as drinkers tend to prefer self-directed programs such as those provided on the Web [8,9]. Comprehensive reviews indicated that the preference for Web-based programs is high and that they are useful in reducing problematic alcohol consumption [9-11]. Indeed, Web-based alcohol interventions can be as effective as face-to-face interventions [12]. However, the transient nature of Web-surfing renders Web-based programs susceptible to substantial participant dropout or attrition [13-15]. Thus, analysis of the mechanisms that potentially retain and deter users is crucial for maximizing the potential of Web-based behavior change programs.

Web-based platforms can utilize several functionalities to overcome the problem of attrition and motivate behavior change [16]. In particular, “self-monitoring” mechanisms, which facilitate the reporting and tracking of users’ goal progress, are thought to be useful for supporting behavior change goals [16]. The efficacy of these technical goal-tracking mechanisms can also be uniquely informed by psychological theory. Specifically, decades of research suggests that the types of goals to which users subscribe may also inform their program engagement.

Self-determination theory (SDT) [17,18] holds that particular goal types relate differentially to positive outcomes. Specifically, some goals are described as intrinsic, referring to goals that reflect inherent growth tendencies and engender intrinsic satisfactions, whereas others are described as extrinsic, as these are focused on outcomes associated with rewards and praise from others [18-21]. Specific intrinsic goals are those that center on personal growth, close relationships, caring for the wider community, and maintaining physical health [19-21]. Conversely, specific extrinsic goals are those for wealth, fame, and aesthetic appeal or image [20,21]. Past studies on these distinctions have shown that goal classifications are supported by factor analytic results [19,20,22]. Emphasizing intrinsic relative to extrinsic goals promotes the satisfaction of basic psychological needs (for competence, autonomy, and relatedness), which promotes intrinsic motivation and well-being [19,20,22]. Based on this evidence, a novel contribution to the internet-based intervention research would involve assessing the extent to which an emphasis on intrinsic goals in Web-based environments may encourage engagement and, therefore, strengthen the effects of Web-based interventions.

In this study, we tested the relationship of intrinsic and extrinsic goals with engagement in a sample of participants from the health promotion website Hello Sunday Morning (HSM). With the aim to improve drinking culture, HSM members are encouraged to sign up for a 3-month period of alcohol abstinence and, then, connect virtually with like-minded others, blog and post about their experiences, and record and track their goals [23]. HSM employs self-monitoring, as described above, in two main ways.

First, HSM requests that users report their alcohol consumption via weekly reminders and periodic World Health Organization’s Alcohol Use Disorders Identification Test (WHO-AUDIT) [24] completion requests. The WHO-AUDIT is designed to classify respondents into 1 of 4 alcohol consumption risk categories. Scores 0-7 are zone 1 and require simple alcohol education. Simple advice is recommended for those in zone 2 (scores 8-15), which is considered risky or hazardous [23]. Zone 3 members (scores 16-19) are considered engaging in highly risky drinking practices; the suggested intervention is advice plus brief counseling and monitoring. Those in zone 4 (scores 20-40) are thought to be at high risk for alcohol dependency and are best referred to a specialist. Preliminary research suggests that HSM is reaching its target audience, with 95% of participants reporting risky or highly risky drinking practices (meaning they are in zones 2 or 3) and 53% meeting criteria for the likely alcohol dependence (meaning they were in zone 4) [23].

Second, HSM has a goal subscription feature that allows users to specify goals they wish to accomplish. Goals are often alcohol-related, although they do not have to be, and these goals can be selected from a list of popular goals (eg, “Lose weight”), or entered manually if the member has a specific goal in mind. Carah et al [23] examined goals on the HSM platform using a subsample of 2875 participants, reporting that specific goals could be grouped into seven categories: lifestyle, bodywork (comprising fitness and mind and body goals), alcohol, travel, financial, education, relationships, and social. Bodywork and alcohol-related goals were most common, with females more likely than males to sign up for both goal types. Participants with WHO-AUDIT scores >19 (zone 4, likely alcohol dependent) were 2 times more likely to sign up for alcohol-related goals than those with scores between 0 and 7 (zone 1, for whom simple advice and alcohol education is recommended). Rather than using lay categories for goals, we suggest that analyzing intrinsic and extrinsic goals, coded according to the aforementioned principles of SDT, can lead to more specific novel hypotheses regarding website engagement and alcohol consumption, particularly given that evidence suggests that an overemphasis on extrinsic goals relates to increased alcohol consumption [25-27].

Based on the SDT research outlined above, we asked the following Research Question: Do goals (classified according to SDT principles) relate to alcohol dependence risk levels and engagement with the HSM website? Based on the evidence above, goals that center on money, fame, and image may relate to higher alcohol consumption (ie, higher WHO-AUDIT risk level), and members endorsing these goals may be less engaged with the site because of a more controlled, extrinsic orientation. In contrast, growth, relationship, community, and health goals
may relate to a lower alcohol risk level, and those endorsing these goals may have better site engagement because of the generally autonomous quality of intrinsic goals [28].

Methods

Participants

We examined ongoing WHO-AUDIT completion or noncompletion in a total sample of 2216 HSM users (749 males, 1324 females, and 143 participants did not report gender) with a reported age range of 18-88 (mean 43.59 [SD 15.3]) years at the time of sign-up (845 users did not report the date of birth, as age was not compulsorily reported). They signed up on the HSM website between November 1, 2009, and April 14, 2016. HSM members often complete multiple HSM programs, which consist of completing 3 months alcohol free, but for this study, the researchers had access to data from only those users who completed their first HSM program at sign-up.

As a key focus of this study was the examination of intrinsic and extrinsic goals, we selected only those HSM users who had pertinent goal-related data; this resulted in a sample size of 1117 (age range, 18-88, mean 43.94 [SD 15.09] years). This sample comprised 727 females and 390 males from 30 countries, including Australia (n=399), the United States (n=294), the United Kingdom (n=146), Canada (n=86), New Zealand (n=59), Ireland (n=45), and South Africa (n=12). Of participants, 42 people did not report their country of origin and the remaining 34 were spread across the other 23 countries. All data were collected by HSM and provided in a deidentified format. The website’s terms and conditions stipulate that deidentified data may be used for research purposes. Ethics clearance was obtained from the University of Sydney’s Human Research Ethics Committee (protocol 2016/218).

Measures

Alcohol Dependence Risk Level

We used the widely utilized and validated AUDIT that was developed and recommended by the WHO [24]. The test includes 10 items, 3 designed to measure alcohol consumption and 7 to assess other alcohol-related risks. Example items include “How often do you have 6 or more standard drinks on one occasion?” and “How often during the last year have you felt guilt or remorse after drinking?” each answered on a 5-item scale from 0 (Never) to 4 (Daily or almost daily). Each item is scored from 0 to 4 and then summed into a composite WHO-AUDIT score ranging from 0 to 40, with increasing scores corresponding to escalating risk levels. For those in zone 1 (scores 0-7) and zone 2 (scores 8-15), alcohol education and simple advice is recommended. Zone 3 (scores 16-19) and zone 4 (scores 20-40) suggest alcohol dependence [24,29]. HSM users are invited to complete the WHO-AUDIT when they sign up to the website (T1), 4 months after sign-up (T2), and 6 months after sign-up (T3). The website was programmed to automatically calculate the AUDIT score based on the scoring instructions provided by the WHO, and only the final score was saved in the database.

Goals

Participants subscribed to goals (both alcohol-related and nonalcohol-related) ideographically (by typing in their own unique goal) or by selecting from a list of goals prespecified on the HSM platform. The data consisted of 193,465 unique goals; however, many of these goals were similar in their semantic content. To maximize participant counts for each goal, we used title matching in R [30] to search for goals with similar content to that of the most popular goals and merged them. For example, “Get fit and healthy” is a popular goal on HSM, and title matching identified similar goals (with far fewer subscribers) such as “To be more fit and healthy” and “Feel fit and healthy.” Participants subscribing to one of the semantically similar goals, such as the two latter examples included here, were added to the list of participants subscribing to the popular goal. This process yielded 61 popular goals each with at least 100 users listing that goal. Multimedia Appendix 1 provides the list of these goals.

Engagement

Participant engagement was operationalized through the calculation of a cumulative count of every participation occasion [31]. An engagement count was earned every time a participant engaged with the site; this includes passive actions, such as simply logging into their account, and active actions, such as commenting on another user’s post, posting a comment, liking and be-friending other members.

Results

Attrition Over Time

We examined attrition on HSM over time as a function of WHO-AUDIT scores. Multimedia Appendix 2 presents individual trajectories of participants’ alcohol risk levels from sign-up up to 6 months after sign-up. Evidently, there was individual variation, as well as attrition, over time. Indeed, of the participants who were available at T1 (sign-up), 65% (1434/2216) were present at T2 (4 months after sign-up) and 54% (1200/2216) at T3 (6 months after sign-up). Table 1 reports the mean and median scores for each alcohol dependence risk zone at sign-up and at 4 and 6 months after sign-up. While WHO-AUDIT scores at T1 were normally distributed, the distributions of the scores at all subsequent waves were skewed such that those in zones 1 and 2 (the lower-risk categories) appeared most frequently (see Multimedia Appendix 3 for WHO-AUDIT frequency distribution plots at each time-point).

We did not conduct any longitudinal statistical models of these data (eg, to test the change in WHO-AUDIT scores over time) because the results would yield biased estimates because of the high attrition observed in the data, but we did examine the extent to which attrition was systematically linked to WHO-AUDIT scores. For instance, we assessed whether people in higher-than lower-risk zones would be more likely to be absent than present at later waves of data. Table 2 depicts the percentage of available and absent participants in each WHO-AUDIT zone at 4 and 6 months after sign-up.
Table 1. World Health Organization’s Alcohol Use Disorders Identification Test (WHO-AUDIT) means, SDs, and medians for each alcohol dependence risk zone at sign-up (T1) and 4 (T2) and 6 months (T3) after sign-up.

<table>
<thead>
<tr>
<th>Zonesa</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Zone 1</td>
<td>4.10 (2.10)</td>
<td>4</td>
<td>1.87 (2.44)</td>
</tr>
<tr>
<td>Zone 2</td>
<td>11.92 (2.25)</td>
<td>12</td>
<td>5.19 (5.59)</td>
</tr>
<tr>
<td>Zone 3</td>
<td>17.52 (1.08)</td>
<td>17.5</td>
<td>6.93 (6.78)</td>
</tr>
<tr>
<td>Zone 4</td>
<td>25.39 (4.23)</td>
<td>25</td>
<td>10.12 (10.02)</td>
</tr>
</tbody>
</table>

aZone 1 (low risk), AUDIT scores 0-7; Zone 2 (moderate risk of harm), AUDIT scores 8-15; Zone 3 (high risk), AUDIT scores 16-19; and Zone 4 (almost certainly dependent), AUDIT scores 20-40.

Table 2. The percentage of participants present and missing in each alcohol risk zone 1 month (Time 2) and 3 months (Time 3) after sign-up.

<table>
<thead>
<tr>
<th>Time-point</th>
<th>Zone #</th>
<th>Zone #</th>
<th>Zone #</th>
<th>Zone #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Time 2</td>
<td>Present</td>
<td>70.97</td>
<td>65.38</td>
<td>66.75</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>29.03</td>
<td>34.62</td>
<td>33.25</td>
</tr>
<tr>
<td>Time 3</td>
<td>Present</td>
<td>54.30</td>
<td>55.47</td>
<td>52.96</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>45.70</td>
<td>44.53</td>
<td>47.04</td>
</tr>
</tbody>
</table>

A nonparametric test of the differences in missing and nonmissing participants in each risk zone at different waves was not significant ($\chi^2=0.6$, $P=.90$), indicating that attrition was not linked to the alcohol risk level because members of the 4 alcohol risk zones were equally likely to be present (or missing) in any given wave.

Self-Determination Theory-Informed Analysis of Goals

The 61 most popular goals were categorized according to SDT [18] principles as implemented in the Aspiration Index [20], which distinguishes extrinsic goals (wealth, fame, and image or attractiveness) from intrinsic goals (personal growth, close relationships, community service, and physical health). Accordingly, we classified the goals into one of the 7 aspirations categories. Five goals were coded as money-related (285 counts), examples included “Get out of debt” and “Save money” (notably, the finance-related goals did not center on the acquisition of abundant wealth as specified in the Aspiration Index, as such these goals have been relabeled “money” goals as opposed to wealth). As no fame goals were identified, this category was omitted from the analysis. Two image goals (614 counts) emerged, including “Lose weight” and “Get my body mass index under 25,” which were both double-coded with physical health. In addition, there were 15 personal growth goals (893 counts) such as “Find a new hobby,” as well as 11 relationship goals (550 counts), including “Treat my partner better,” 3 community goals (19 counts), including “Volunteer in a cause greater than myself, even for one day,” and 13 physical health goals (1869 counts), for example, “Get fit and healthy” and “Stop smoking.” A separate category of alcohol-related goals was created to encapsulate the popular goals for which an intrinsic or extrinsic orientation could not be inferred. Furthermore, 29 goals were coded as alcohol-related (1907 counts), for example, “Dance sober” and “Have a sober new year’s.”

Two raters independently coded the 61 goals into the seven goal categories. An interrater reliability analysis using Cohen kappa was performed to determine the interrater consistency. Cohen kappa was .78 for relationships; .86 for personal growth; .97 for alcohol; and 1 for money, image, community, and physical health, suggesting substantial to perfect agreement [32]. These goal-level analyses provided initial evidence that a theory-driven approach to categorizing goals was informative—participants’ goals can be meaningfully categorized in this manner with independent raters showing a sufficiently high degree of agreement. To conduct participant-level analyses of the goals, the goals codes were summed to create a per-participant count for each of the seven goal categories. For instance, a participant could potentially get a count of 0 for money but 5 for physical health and so on. The seven goal variables, therefore, represented count data.

Intercorrelations

Table 3 provides Spearman correlations, means, and SDs of the goals count variables with the count data of engagement and the initial WHO-AUDIT scores at sign-up. The Spearman method uses ranks and is more conservative than Pearson’s $r$, which is appropriate, given our use of count data and the large sample size.
Higher alcohol dependence risk tended to engage with the HSM platform. This result indicates that HSM users with a statistically significant, weak negative correlation with alcohol community-related goals, and, interestingly, engagement had moreover, engagement related positively to relationship- and growth and relationships are unexpected. Alcohol dependence goals relate to increased alcohol consumption [25], though links goals; this result aligns with evidence suggesting that extrinsic within the intrinsic domain, all goals were positively correlated, image goals may have a more these data. Indeed, image goals related only to alcohol goals and health goals, suggesting that image goals may have a more intrinsic quality on the HSM platform, thus explaining their link and health goals, suggesting that image goals may have a more alcohol-related goals correlated positively with all other goals, except those related to the community (for which goal counts were low), indicating that reducing consumption is a common thread through HSM users’ goal activity. While the intrinsic goals for money and image are positively correlated in the aspirations literature [20], these goals were not correlated in these data. Indeed, image goals related only to alcohol goals and health goals, suggesting that image goals may have a more intrinsic quality on the HSM platform, thus explaining their link to physical health and absence of such a link to money goals. Within the intrinsic domain, all goals were positively correlated, again except for community goals, which is largely congruent with the existing literature [19,20,22]. Money, growth, relationships, and—intuitively—alcohol goals related positively with alcohol dependence risk level, meaning that as alcohol dependence risk level increased so did subscription to these goals; this result aligns with evidence suggesting that extrinsic goals relate to increased alcohol consumption [25], though links to growth and relationships are unexpected. Alcohol dependence risk level did not relate to image, community, or health goals. Moreover, engagement related positively to relationship- and community-related goals, and, interestingly, engagement had a statistically significant, weak negative correlation with alcohol dependence risk level. This result indicates that HSM users with higher alcohol dependence risk tended to engage with the website less.

### Discussion

To inform research on potential mechanisms of participant engagement in Web-based interventions, in this study, we used an SDT-driven approach to analyze participants’ goals on the HSM platform. Based on the theory [18,20], we predicted that intrinsic goals (goals related to personal growth, relationships, community, and health) would relate to increased website engagement and that the endorsement of extrinsic goals (goals related to money and image) would relate negatively to engagement and predict alcohol dependence risk level (WHO-AUDIT scores). The engagement hypotheses were partly supported by the positive correlation between relationship and community goals and engagement, although engagement was not related to either extrinsic goal. WHO-AUDIT scores related positively to extrinsic goals related to money, though not to image goals, also partly supporting our alcohol risk level hypothesis. Counter to our expectations, WHO-AUDIT scores also positively correlated with personal growth and relationship goals, both of which are intrinsic.

Our initial analysis also identified some participant attrition (noncompletion of WHO-AUDIT assessments) from the sign-up time-point through the two follow-ups, which is consistent with past evidence suggesting that hazardous alcohol consumption predicts dropout in Web-based interventions [12]. Of the initial 2216 users, 35.29% (782/2216) were missing at T2 and 45.85% (1016/2216) were missing at T3; these participation rates are respectable given that dropouts for Web-based social network
Health behavior interventions more generally tend to be in excess of 80% [33]. Rates of attrition were not different across alcohol dependence risk zones, which indicates that dropout (or retention) was equally likely in each of the 4 risk zone groups; this result was unexpected, given that heavy drinkers are often the least amenable to intervention and are prone to program noncompletion [8,12]. While higher risk participants were no less likely to report alcohol dependence risk level over time (as indicated by the WHO-AUDIT reporting results discussed above), they were engaging with the site less, as evident from the negative correlation between engagement and alcohol dependence. Notably, the correlation, while statistically significant, was weak ($r=-.10$), accounting for 1% of the shared variance between engagement and the WHO-AUDIT.

Consistent with SDT, relationship- and community-related goals related positively to engagement; this may suggest that engagement with more intrinsic, socially oriented goals promotes platform engagement. Arguably, this is because intrinsic aspirations are thought to demonstrate more of an other-orientation than a self-orientation [34], and interactive Web-based environments such as HSM present opportunities to connect and interact with other members.

The correlations with the seven goal count variables indicate that high endorsement of alcohol-, money-, growth-, and relationships-related goals may predict a higher risk of alcohol dependency (eg, higher WHO-AUDIT scores). The relationship of alcohol-related goals to alcohol dependence risk level is intuitive; the more at risk one is, the more their goals might center on reducing that risk. With regards to the correlation between the WHO-AUDIT and money-related goals, an extrinsic asparagus focus has been found to relate to increased alcohol consumption [25]; in addition, and more pragmatically, the more one drinks, the more one is likely to spend on alcohol, so this relationship is evidentially and practically founded. However, the positive correlation between the WHO-AUDIT and growth and relationship goals is unexpected. Growth goals included, for example, “Find a new hobby,” and an example relationship goal is to “Treat my partner better”; the theoretical link between goals of this nature and alcohol dependence risk level is unclear and may simply be a function of the fact that this sample is, on average, at high alcohol dependence risk level relative to the general population.

The strengths of this study lay in its large sample size and the combination of qualitative and quantitative methodologies. However, the analysis was limited by several factors. We were not able to model the data longitudinally because of the attrition rate. Furthermore, we were not able to test the internal consistency of the WHO-AUDIT in this sample because of the inability to access the individual item responses. However, the fact that WHO-AUDIT scores correlate meaningfully with other relevant variables is some evidence of its construct validity. In addition, this study is, of course, not an efficacy study. The systematic examination of alcohol risk level and participant engagement using a randomized controlled trial is a logical next step for future research.

Despite these limitations, this study illustrates that an SDT-driven approach can lead to new insights and a better understanding of users’ experiences in Web-based behavior change environments such as HSM. The theory-congruent and novel results presented here set the scene for future replication and expansion using longitudinal datasets. Hence, subscription to intrinsic, more socially oriented goals may help users remain engaged with such health promotion platforms.

Acknowledgments
We thank Dr David Milne for his assistance in preliminary data processing and Ms Brooke Van Zanden for her assistance in the coding of the goals data.

Conflicts of Interest
The fourth author, AM, is an employee of Hello Sunday Morning. However, this working relationship in no way affected the analysis of the data or interpretation of the results.

Multimedia Appendix 1
List of the top 61 goals.

[PDF File (Adobe PDF File), 277KB - mental_v5i4e10022_app1.pdf ]

Multimedia Appendix 2
Individual trajectories of alcohol risk over time measured by the World Health Organization’s Alcohol Use Disorders Identification Test (WHO-AUDIT).

[PDF File (Adobe PDF File), 211KB - mental_v5i4e10022_app2.pdf ]

Multimedia Appendix 3
Distribution of alcohol risk level as measured by the World Health Organization’s Alcohol Use Disorders Identification Test (WHO-AUDIT).


Abbreviations

HSM: Hello Sunday Morning
SDT: self-determination theory
WHO-AUDIT: World Health Organization’s Alcohol Use Disorders Identification Test
A Smartphone App to Foster Power in the Everyday Management of Living With Schizophrenia: Qualitative Analysis of Young Adults’ Perspectives

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Abstract

Background: Literature indicates that using smartphone technology is a feasible way of empowering young adults recently diagnosed with schizophrenia to manage everyday living with their illness. The perspective of young adults on this matter, however, is unexplored.

Objective: This study aimed at exploring how young adults recently diagnosed with schizophrenia used and perceived a smartphone app (MindFrame) as a tool to foster power in the everyday management of living with their illness.

Methods: Using participatory design thinking and methods, MindFrame was iteratively developed. MindFrame consists of a smartphone app that allows young adults to access resources to aid their self-management. The app is affiliated with a website to support collaboration with their health care providers (HCPs). From January to December 2016, community-dwelling young adults with a recent diagnosis of schizophrenia were invited to use MindFrame as part of their care. They customized the resources while assessing their health on a daily basis. Then, they were invited to evaluate the use and provide their perspective on the app. The evaluation was qualitative, and data were generated from in-depth interviews. Data were analyzed using a hermeneutical approach.

Results: A total of 98 individuals were eligible for the study (mean age 24.8, range 18-36). Of these, 27 used MindFrame and 13 participated in the evaluation. The analysis showed that to the young adults, MindFrame served to foster power in their everyday management of living with schizophrenia. When MindFrame was used with the HCPs consistently for more than a month, it could provide them with the power to keep up their medication, to keep a step ahead of their illness, and to get appropriate help based on their needs. This empowered them to stay on track with their illness, thus in control of it. It was also reported that MindFrame could fuel the fear of restraint and illness exacerbation, thereby disempowering some from feeling certain and secure.

Conclusions: The findings demonstrate that young adults diagnosed with schizophrenia are amenable to use a smartphone app to monitor their health, manage their medication, and stay alert of the early signs of illness exacerbation. This may empower them to stay on track with their illness, thus in control of it. This indicates the potential of smartphone-based care being capable of aiding this specific population to more confidently manage their new life situation. The potentially disempowering aspect of MindFrame accentuates a need for further research to understand the best uptake and the limitations of smartphone-based schizophrenia care of young adults.

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KEYWORDS
mental health; mHealth; mobile app; participatory design; patient empowerment; patient involvement; patient participation; schizophrenia; smartphone; young adults

Introduction

Background
It is well established that self-management knowledge and skills are the cornerstones of preventing exacerbations and relapse of psychotic illness [1-4]. However, many young adults recently diagnosed with schizophrenia skip their clinical visits [5,6], leaving them with only little knowledge and skill power to manage everyday living with the illness efficiently. This causes a serious threat to their current and future health and quality of life [7,8]. This proves the need to find new and innovative approaches to build competencies to empower them to manage the illness in the context of their daily lives. An approach could be smartphone-based care. The pervasive nature of the smartphone and smartphone apps allows to monitor health and for customized information and self-management tools to be disseminated in real time and in real-life settings [1,9-14], where and when it is needed [15-16].

Smartphone Apps for Schizophrenia Care
Smartphone apps have been developed for schizophrenia care [17-25], yet only limited attention has been paid to mobile health (mHealth) apps to provide illness management support to individuals with schizophrenia outside the confines of the mental health clinic [26]. A review of smartphone apps for schizophrenia identified only 1 app providing this kind of support [27,28]. This app offered prescheduled and on-demand resources to facilitate symptom management, mood regulation, medication adherence, social functioning, and improved sleep. Evaluation of the app in 33 individuals with schizophrenia or schizoaffective disorder showed that the participants were willing and capable of using the app independently in their own environment [28].

Although sparse, the existing literature indicates that a smartphone app is a promising way to empower young adults recently diagnosed with schizophrenia to manage everyday living with their illness. The viewpoint of this matter from the perspective of those living with the illness as part of their daily lives, however, is unknown. As interests in smartphone apps in schizophrenia care grow [14,17,20,24,25,29], this seems increasingly important to explore.

Qualitative research is a systematic inquiry seeking to explore, and eventually understand, the experiences of a particular group of people [30,31]. A qualitative inquiry may provide insider perspectives to aid the understanding of the viability of apps to make those recently diagnosed with schizophrenia more capable and confident in managing their lives. Using a qualitative inquiry, the objective of this study was, therefore, to explore how young adults recently diagnosed with schizophrenia used and perceived a smartphone app (MindFrame) as a tool to foster power in the everyday management of living with their illness.

Methods

MindFrame
Using participatory design thinking [32-35] and methods [36-38], MindFrame was iteratively developed to run on the Monsenso mHealth platform powered by Monsenso ApS. The platform has been technically and clinically validated in various clinical evaluation studies and randomized clinical trials (RCTs) [39]. First, interviews were conducted with young adults recently diagnosed with schizophrenia to explore their perspective of needs to be supported in the everyday management of living with the illness and to generate ideas of using the smartphone to accommodate the needs [40]. Then, young adults recently diagnosed with schizophrenia, health care providers (HCPs), a researcher, and software designers collaboratively designed resources to accommodate the needs [41]. Figure 1 shows MindFrame, which consists of a smartphone app that allows young adults diagnosed with schizophrenia to access resources to aid their self-management. The app is affiliated with a website to support collaboration with their HCPs. A comprehensive description of the resources in MindFrame, including its aims, capabilities, and intended use, is provided in Table 1.

Figure 1. Screenshots of the MindFrame app and the affiliated website.
Table 1. MindFrame app resources.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Aim of resource</th>
<th>Capabilities of resource</th>
<th>Intended use of resource</th>
</tr>
</thead>
</table>
| Self-assessment      | Monitor health               | Data input to report the mental health state, for example, mood, activity, sleep, stress, medication, alcohol, hallucinations, hash, isolation, exercise, hygiene, paranoia, self-harm, sensitivity, and drugs. A note function allows explaining the assessment scores. | • The young adult and the health care provider (HCP) customize the assessment list together.  
• The young adult enters data every day using the app. A reminder is provided given the mental health state has not been reported at 8 pm.  
• Data are stored by the smartphone and transmitted automatically to a study server when internet connectivity is available. At this point, data are visible to the HCPs through the affiliated website. |
| Visualization        | Psychoeducation              | Data display of the reported mental health state.                                         | • The young adult uses the displayed data to explore relations between symptoms, wellness, and behaviors alone or with the HCP. The HCP has an iPad with wireless internet connection and an external keyboard to access data on home visits. |
| Early warnings signs | Awareness on changes in health | Display of early signs of exacerbation of illness and suggestions of how to tackle changes to stay well. | • The young adult and the HCP identify the relapse signature and drill together and create customized feedback to stay alert to early signs of change in the mental health state. |
| Triggers and alerts  | Notifications of changes in health | Data survey to notify signs of exacerbation of illness and to provide feedback on actions to take to stay well. | • The young adult and the HCP set up threshold values together to survey the self-assessment scores, for example, stress level higher than 2 (pretty stressed) on more than 2 consecutive days. When the threshold values are triggered, feedback on actions to take is provided. |
| Action plan          | Strategies to stay in good health | Display of 3 levels of relapse prevention strategies: (1) stay well, (2) what can help, and (3) get help. | • The young adult and the HCP customize the action plan together. |
| Medication overview  | Medication management        | Reminders and tracking of medication adherence.                                           | • The young adult and the HCP produce and update the medication overview together.  
• The young adult reports adherence to medication and changes in medication management.  
• The young adult is indirectly reminded about medication management as part of the self-assessment procedure. |
| Settings             | Customization of resources   | Customization of reminders and change of pin code. Access to user guide and a film introducing MindFrame. | • The young adult makes changes because of needs and preferences. |

**Research Design**

The study design was qualitative and constituted the third phase of a participatory design process. The phases of the overall study are available elsewhere [40]. MindFrame was tested as an intervention during the period of January 1 to December 31, 2016. Subsequently, the intervention was evaluated.

**Setting**

The setting of the research was OPUS. OPUS is a bio, psycho, and social course of intensive outpatient care in Denmark available to young adults, aged 18 to 36 years, for the first 2 years following diagnosis [7]. The course of care is publicly funded. Effects of the OPUS program have been extensively researched and documented [42-44].

**Intervention**

MindFrame was implemented as an add-on tool to regular OPUS care in 1 OPUS clinic in Denmark. The criteria for participation in the intervention were the ability to read Danish and willingness to download and use the smartphone app.

The HCPs provided the young adults the invitations to use MindFrame. The invitation informed that (1) MindFrame had been developed in close collaboration with individuals with schizophrenia and HCPs from OPUS as a collaborative tool to support the everyday management of living with the illness, (2) they could use the app for free and for an unlimited period during the intervention period, (3) it was voluntary to use the app, (4) they could terminate use of the app at all times, (5) early termination of the app would not influence their course of care, and (6) they would be invited to share their views on
the usefulness and impact of MindFrame at the end of the intervention period. Invitations to use MindFrame were provided throughout the intervention period. Thus, the length of the intervention and the time when the intervention was applied in the course of care differed from person to person.

When a young adult consented to use MindFrame, they were registered on the MindFrame website, and the smartphone app was downloaded from Google Play or App Store. An install guide was provided for this purpose. A secretary at OPUS made the registrations and handled any install problems. The registration procedure automatically generated an email that was sent to the young adult’s private inbox with a secure log-in code (see Ethics section). The log-in code was used to open the app. Individuals who did not own their own smartphone were offered one to use during the intervention period.

**Training**

The HCPs in OPUS were responsible for teaching and guiding the young adults in using and customizing the resources in MindFrame. Therefore, HCPs received training ahead of the intervention period. The first author and a MindFrame software designer conducted the training. The training was group-based and held as a 2-hour hands-on session, where the app and the website were carefully explained and then put into their hands to play around. The HCPs who were unable to partake in the group training were offered a one-on-one session by the first author. After the training session, the HCPs were provided a hard copy of a user guide describing each resource in MindFrame in depth, customization of the MindFrame resources, and how to receive first-level support. The first author was available for questions and supervision throughout the intervention period.

**Evaluation**

Following the intervention period, MindFrame was evaluated qualitatively. The evaluation process used for this study was inspired by interpretative hermeneutics. As such, it strove to bring out and manifest what is normally hidden in human experiences and human relations [45]. Data were collected through telephone interviews, which have shown to be productive in qualitative research [46].

All the young adults who had used MindFrame at some point during the intervention period were invited to participate in the evaluation. Thus, the recruitment strategy for the interviews was pragmatic and convenient [30]. The only criterion for participation in the evaluation was willingness to share experiences of MindFrame use by virtue of knowledge. The HCPs in OPUS distributed the invitation, and the first author phoned those consented to be contacted explaining more about the purpose of the evaluation and their rights as study participants. The young adults were encouraged to ask questions and were given time to make a decision on participation. All made their decision immediately and provided written consent. Characteristics of the evaluation sample are outlined in Table 2.

The interviews lasted between 35 and 66 min. They were conducted in Danish and recorded using the TapeACall app from Epic Enterprises. To guide and direct the interviews, a semistructured thematic interview guide [47] regarding personal power, knowledge power, and skills power [48] was used. To encourage the participants to speak freely about their views on how MindFrame contributed in the management of their lives with the illness, interview questions were open-ended. However, at the end of each interview, 15 close-ended questions were posed to work around the concept of empowerment and to prompt more direct answers. Examples of the close-ended questions are “When I use MindFrame I feel more in control” and “When I use MindFrame I become more uncertain of what is right and wrong.” Answering could by default be “yes,” “no,” or “I don’t know,” yet most answered in sentences. Given the questions had not been touched upon in the first part of the interview, the participants were invited to unfold their answers.

**Analysis**

An interpretative hermeneutical approach, grounded in the work of the German philosopher Hans-Georg Gadamer, guided the data analysis. A hermeneutic interpretative approach goes beyond mere descriptions to look for meaning embedded in common life practices. These meanings are not always apparent to the participants but can be gleaned from the narratives produced by them [45].

In Gadamer’s perspective, interpretation of meaning is not a stepwise approach. He emphasizes the canon principle that meaning comes from the hermeneutical circle of iteratively moving between part and the whole of the text [49]. Consequently, Gadamer does not provide a method for analyzing text, for example, interview transcripts, audio recordings, observations, and notes [50]. Nevertheless, he states that to obtain understanding, methodological direction through a systematic approach is needed [49].

To provide structure in the process of analysis, 4 tasks grounded in the hermeneutical circle served as a guide. The tasks that were derived from Gadamer’s work and proposed by Fleming et al [50] were as follows: (1) finding fundamental meaning of the text as a whole, (2) exploring parts for meaning, (3) comparing the meaning of the whole with the parts, (4) and identifying passages representative of the interpreted meaning.

Guided by hermeneutical thinking, the analysis began with listening to the tapes multiple times and obtaining a fundamental meaning of the interviews from an empowerment perspective. Then, the fundamental meaning was split into smaller parts that were explored by listening to smaller sections and individual sentences. Using the analytical question “what is said in relation to power,” sections and individual sentences were selected. To obtain meaning from the sections and sentences, they were deconstructed through interpretation, and the interpretations were constantly compared and contrasted with the meaning of the whole. According to Gadamer, there is no understanding without the activity of questioning [49]. Hence, explorative questions were constantly posed to the text in the process of interpretation. To ensure a rigorous analysis, questioning continued until an inner unity, which was free from logical contradictions, had been reached. At this point, categories of synthesized meaning were constructed.

Table 2. Characteristics of the evaluation sample.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (69)</td>
</tr>
<tr>
<td>Age in years, mean (range)</td>
<td>24.8 (18-36)</td>
</tr>
<tr>
<td>Education in years, n (%)</td>
<td></td>
</tr>
<tr>
<td>Low: ≤9</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Middle: 10-12</td>
<td>6 (46)</td>
</tr>
<tr>
<td>High: ≥13</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>7 (54)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6 (46)</td>
</tr>
<tr>
<td>Living conditions, n (%)</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>8 (61)</td>
</tr>
<tr>
<td>Living with spouse or partner</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Living with family</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Has children, n (%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10 (77)</td>
</tr>
<tr>
<td>Yes</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Support worker, n (%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5 (39)</td>
</tr>
<tr>
<td>Yes</td>
<td>8 (61)</td>
</tr>
<tr>
<td>Weekly</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Biweekly</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Medication for mental health issues, n (%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (69)</td>
</tr>
</tbody>
</table>

Ethics

In accordance with the Danish law, a formal ethics approval of the study was not required. Authorization by the Danish Data Protection Agency (Datatilsynet) was obtained (2008-58-0028).

The study was consistent with the Declaration of Helsinki [51], meaning that the participants were fully informed about the purpose of the research. The informed consent was obtained verbally and in writing before the enrollment, and information about the right to withdraw from the study was provided. The participants were carefully explained that any withdrawal from the study would not influence their course of care.

MindFrame was established under the standard security approval and procedures of the information and technology department in the specific region in Denmark where it was applied.

Results

Use of MindFrame

As evidenced in Figure 2, a total of 98 individuals were eligible to use MindFrame during the intervention period and 27 used it. One of the individuals was excluded from using it as a result of not being able to speak Danish and 50 refused to use it. In 20 cases, individuals were not invited by their HCPs to use MindFrame. On being asked why, the HCPs owed the opt-out decision for exclusions to concerns that these individuals were too ill to use and engage with the app. Out of the 27 young adults who used the app, 13 participated in the evaluation.

The participants in the evaluation described MindFrame as easy and intuitive to use. In accordance with needs and preferences, the period of use of MindFrame differed among the participants. Some participants terminated use within 1 month (n=5), others terminated use within 2 to 3 months (n=4), and others used MindFrame for 6 to 12 months, terminating their use when the intervention period stopped (n=4). Reasons given for...
self-initiated termination of MindFrame included boredom, lack of motivation and energy, fatigue, and problems quantifying their mental health.

**Perceived Use of MindFrame**

On the basis of the participants’ descriptions of use, 2 main and very different categories were generated about the usefulness and impact of MindFrame. When MindFrame was used with HCPs consistently for more than a month, it could provide the participants with the power to keep up their medication, to keep a step ahead of their illness, and to get appropriate help based on their needs. This empowered them to stay on track with the illness, thus in control of it. Furthermore, MindFrame could fuel the fear of restraint and illness exacerbation, thereby disempowering some from feeling certain and secure. This was observed when MindFrame was applied early in the course of care when the participants barely knew their HCP.

Five subcategories led to the 2 main categories. These are outlined in Table 3 and presented in the following section.

**MindFrame Can Provide the Participants With the Power to Keep Up Their Medication**

A total of 9 participants received psychotropic drugs for their mental illness during the study. They explained how their memory had been disabled by the illness, yet emphasized how MindFrame had helped them take the medication more regularly. As health tracking covered whether the medication had been taken, not taken, or taken with changes, the self-assessment procedure worked as a daily medication reminder, making it easier to comply with the medication regime. This was a comforting way of staying in control of the medication:

> Every day I was reminded to take my medication through the app. That worked really, really well. When I was reminded about it I asked myself, “have you remembered to take your medication today.” If not, I ran out to take it straight away.

Some participants explained how they forgot to take the medication deliberately although they knew by heart that they needed it to stay well. One participant who had used MindFrame for 9 months explained how the self-assessment scores had helped her discover that irregular consumption of medication impacted her mental health state. Insight into this pattern of behavior helped her to make the decision to resume her medication regime:

> Sometimes the scores made me realize that I needed to take my medication. It is easier to make decisions on [...] resuming taking the pills when I can see that my symptoms are progressing when I don’t take them.

**Figure 2.** Flowchart of participants in the study.
Thus, MindFrame seemed to provide the participants receiving psychotropic drugs the power to keep up with their medication so as to stay well. This was the case when the self-assessment procedure was used passively as a reminder to take medication or when the self-assessment scores were used actively to make the decision that medication should be resumed to stay on track.

**MindFrame Can Provide the Participants With the Power to Keep a Step Ahead of Their Illness**

The participants stressed how they had to react quickly to early signs of exacerbation of illness to prevent symptoms from progressing into full psychosis. The participants who had set up threshold values for triggers emphasized how MindFrame was a powerful resource to this end. They explained how their scores had prompted a trigger, which alerted them to be aware of the early signs of change, causing them to act upon these signs to stay in good health:

> The trigger and alert function was really smart. It showed when things changed, and made one aware to do something in order to stay well.

Awareness was brought to mind automatically through the visualization feature in MindFrame even when threshold values had not been set. Most of the participants made self-assessments on a daily basis for a period of time during the intervention period and emphasized how the display of their scores helped them to see when they should behave differently to stay well. This encouraged the belief that the illness would remain within their control:

> It is so comforting that I know that the system shows me if the illness is getting worse. Then I know when I should act to prevent it from getting out of control.

To stay in control of the illness, it was not enough to know when action should be taken. Knowing *which* action should be taken and *how* to stay on track were equally important. A few of the participants had customized their action plan with their HCPs, and they explained how the plan of action had provided them with strategies to stay well, saying, “The action plan tells me what to do to stay well.” Other few participants had used the action plan without customization, which some found useful.

Thus, MindFrame seemed to provide the participants with the power to keep a step ahead of their illness rather than at the rare end of it by making them aware of when to act and how. This was the case when self-assessments had been conducted for more than a month and especially the case when the self-assessments were used with triggers and a customized action plan.

**MindFrame Can Assist the Participants With the Power to Get Appropriate Help Based on Their Needs**

All the participants described how cognitive difficulties challenged them when trying to remember how their health had been over time. In this respect, they stressed how MindFrame had empowered their memory to keep track of their state and progress:

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<table>
<thead>
<tr>
<th>Words on tapes (quotations)</th>
<th>Immediate answers: what is said in relation to power?</th>
<th>Decontextualization through interpretation: empowering aspects of MindFrame</th>
<th>Categories</th>
<th>Result and major categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>When I first started in OPUS I had problems with compliance. MindFrame helped me to remember to take my pills.</td>
<td>Helped me to remember to take my pills.</td>
<td>Power to maintain medication</td>
<td>MindFrame can provide the participants with the power to keep up their medication</td>
<td>MindFrame can empower the participants to stay on track with the illness</td>
</tr>
<tr>
<td>Triggers and alerts made me conscious about signs I had to pay attention to, and act upon to stay well [...]. I believe that has helped me to stay on track.</td>
<td>Made me conscious; pay attention; act [...] to stay well; stay on track.</td>
<td>Power to act timely to stay on the track of health</td>
<td>MindFrame can provide the participants with the power to keep a step ahead of their illness</td>
<td>MindFrame can empower the participants to stay on track with the illness</td>
</tr>
<tr>
<td>MindFrame helped me to get anti-depressants pretty fast, when I needed it. I don’t believe that would have happened if my psychiatrist had not had the chance to look at my scores.</td>
<td>Helped me [...] fast; when I needed it.</td>
<td>Ability for health care providers (HCPs) to be more responsive to needs</td>
<td>MindFrame can assist the participants with the power to get appropriate help based on their needs</td>
<td>MindFrame can empower the participants to stay on track with the illness</td>
</tr>
<tr>
<td>If my scores were really bad, then, could they [HCPs] use my scores to put me under restraint? I was really uncertain of that in the beginning.</td>
<td>Could they put me under restraint?; really uncertain.</td>
<td>Lack of power to feel secure</td>
<td>MindFrame can increase participant fears and worries of restraint</td>
<td>MindFrame can also fuel the fear of restraint and illness exacerbation, thereby disempowering some participants from feeling certain and secure</td>
</tr>
<tr>
<td>Triggers and alerts gave attention to any early signs of change. What is this? Am I getting worse? That made me worried at some point.</td>
<td>What is this?; Am I getting worse?; made me worried.</td>
<td>Lack of power to feel certain</td>
<td>MindFrame can increase uncertainties in the participants about their mental health state</td>
<td>MindFrame can also fuel the fear of restraint and illness exacerbation, thereby disempowering some participants from feeling certain and secure</td>
</tr>
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Table 3. The hermeneutical-inspired process of analysis governing the findings.
It [MindFrame] helps me a great deal when remembering how I was last week or a couple of weeks ago. I cannot find back to how things were. MindFrame has helped me to keep track of this: how it was.

The ability to keep track of their mental health state and progress was strongly emphasized by the participants, as it provided a solid basis for discussing their health and needs of care with the HCPs. To this end, most underlined how mental health tracking assisted their HCPs to ask more direct questions about the fluctuations in their mental health and relations between the mental health state and their behaviors and actions:

It has been easier for [name of HCP] to ask questions since she could see my scores: “I can see that you have had a bad day what happened that day?” She knew how my week had been and could ask more direct questions.

Ultimately, this contextualized dialogue enabled the HCPs to be more responsive to the needs of the participants, which empowered them to receive the help they needed when they needed it:

I was in a period where my thoughts were getting darker and darker and [name of HCP] said to me: “I can see from your scores that your mood and sleep is not good at the moment. I don’t think your antidepressants help you enough.” She was right. Then the dose was increased, and after some time I started to get better.

As such, MindFrame seemed to provide the participants with the power to get appropriate help based on their needs. This was the case when they reported their mental health state and the scores were used by the HCPs as a basis for assessing and adjusting care to their needs.

Several of the participants emphasized how they wanted their HCPs to take even more advantage of using their scores in their course of care. They explained how looking at the scores with the HCPs and getting expert help to add meaning to the score enabled them to better understand the causations of fluctuations in the mental health state and allowed the effectiveness of behavior change to be evaluated. They believed that learning generated from their own data could equip them to more confidently and independently navigate the everyday management of the illness in the long run.

MindFrame Can Increase Participant Fears and Worries of Restraint

As evidenced in the previous section, it seems that MindFrame could provide the participants with the power to stay on track of their illness. However, it also seemed that MindFrame could increase fears and worries in some of the participants, thereby disempowering them from feeling certain and secure. This was observed in 3 participants who had just been enrolled in OPUS and had only known their HCP for a short period. Shared for these participants were concerns of using MindFrame even before beginning its use. They stressed how they were worried that their HCPs could survey their mental health state on a day-to-day basis or keep them under surveillance in the time between consultations. They feared that surveillance could lead to situations where they were unwillingly put under restraint and committed to hospital:

My biggest concern about starting using MindFrame was that my nurse would observe my condition every day. Then, would there be consequences? Could she use my scores to admit me to the hospital?

The fear of surveillance seems to fade with use. Two of the 3 participants stressed how concerns and fears had become less dominant over time as they had become more familiar with MindFrame and certain about the fact that their HCPs were only interested in their scores to provide the best possible care:

At first I was a bit worried that [name of HCP] could see all my scores, but when I found out that she was only interested in my scores to help me my worries disappeared.

In 1 of the 3 participants, fears and concerns of restraint remained. Consequently, this participant did not report his true state of mind on his bad days. Rather, he touched up the scores making his mental health seem better than it was. This participant stopped using MindFrame within 1 month. The rest of the sample did not address fears and worries of restraint in relation to their mental health state being observed by their HCPs. Rather, they talked about surveillance of their mental health as a way of careful watching, helping them to get timely and appropriate help based on their needs.

Thus, for some participants, MindFrame seemed to increase fears and worries of restraint, which prevented them from feeling confident and safe. Worries and fears seemed to fade with use of the app but remained with 1 participant who embellished his data to stay in control.

MindFrame Can Increase Uncertainties in the Participants About Their Mental Health State

MindFrame seemed to provide the participants with the power to keep a step ahead of their illness, thus staying on track. Being a step ahead of the illness, however, was not always perceived positively. Two participants who had conducted self-assessments continuously for several months addressed this. Both participants felt that the notifications felt comforting and allowed them to act timely; however, occasionally it was stressful to be alerted about all the changes in their mental health state, as it left them wondering if their condition was worsening:

Being notified of all the changes sometimes made me anxious. It made me wonder if the illness was maybe about to get out of control.

The 2 participants explained that doubt and hesitation about their mental health state was something they dealt with on a daily basis, thus it was not something new. However, they stressed how the notifications in some ways increased their uncertainty. They experienced this when there were incongruences between their perception of their mental health state and the state communicated by MindFrame. When their personal interpretation of the information gained from their senses did not match the notifications from MindFrame, they were left in doubt of what to think and whether or not to act:
When the notifications tell me to take care and I feel fine, it makes me question myself even more. Is it ok now, or should I do something?

Thus, for some participants, MindFrame seemed to increase uncertainties regarding their mental health state and thereby disempowered them from feeling self-confident and on track with their illness. It was only observed in 2 participants, and they stressed that their uncertainty often disappeared when the notifications were shared and discussed with their HCPs.

Discussion

Principal Findings

This study explored how young adults recently diagnosed with schizophrenia used and perceived the smartphone app MindFrame as a tool to foster power in the everyday management of living with their illness. Findings from the interviews showed that when MindFrame was used continuously for more than a month and with the HCPs, the participants were provided with the power to keep up their medication, to keep a step ahead of their illness, and to get appropriate help based on their needs. This empowered them to stay on track with the illness, thus in control of it.

The findings showed that prolonged and continuous self-assessments were main components responsible for the efficiency of MindFrame. When data were collected consistently over a period of time, a picture of the mental health state of the participant was generated, and this picture worked as a tool to inform decisions about medication and as a tool to alert timely actions to stay in good health. In addition, prolonged and continuous self-assessments worked as a tool to inform the HCPs about the mental health state of the participant, which enabled them to deliver timely care more responsive to their needs. The findings highlight that as a tool to foster power in the everyday management of living with schizophrenia, MindFrame is mostly viable in young adults with schizophrenia who are willing, able, and capable of assessing their health over the course of time. Tenacious use of smartphone apps in the care for persons with schizophrenia may be difficult to obtain [52-55], which was also evident in our study where 5 out of 13 participants terminated use of MindFrame within the first month. This was true, although the resources in MindFrame were closely aligned with the needs and preferences of the intended user group, which is suggested to foster engagement [53,56-58]. This shows that MindFrame—despite being codesigned—was neither applicable nor appealing to all. The fact that only approximately 35% (27/77) of those invited to use the app accepted to use it further underlines this and indicates that MindFrame may not generalize to the broader population of young adults recently diagnosed with schizophrenia. Further research is needed to establish this.

The findings showed that collaborative use of MindFrame was another main component of its efficacy. When the self-assessment scores of the participants were shared with their HCPs, the HCPs were enabled to deliver care more responsive to their needs, which empowered them to stay on track. The participants stressed how they wanted their HCPs to take even more advantage of using their scores in their course of care. They believed that learning generated from their own data could equip them with the knowledge and skills to more confidently and independently navigate the everyday management of the illness in the long run. In line with previous research, the findings indicate that HCPs are responsive to integrating smartphone technology into young adult schizophrenia care [25], yet, that HCPs uptake could be better [59]. Successful implementation and dissemination of smartphone apps as part of schizophrenia care for young adult population will rely on provider uptake as well as client use [25]. Future research will need to address how to increase provider uptake and evaluate the impact of provider engagement on the ability to navigate the everyday management both in the short and long run.

As evidenced, the findings suggest that MindFrame can be used as a tool to foster power in the everyday management of living with schizophrenia. However, we identified 2 key aspects of use to take into account.

First, we identified that MindFrame could increase fears and worries of restraint, thereby disempowering some participants from feeling certain and secure. The fears and worries were related to data sharing when participants did not know their HCP very well. Ben-Zeev et al [14] investigated passive monitoring through sensors in a smartphone app. Using a sample of 11 inpatients and 9 outpatients with schizophrenia, for 1- or 2-week periods, respectively, they observed that approximately 20% of the sample felt upset by monitoring. This substantiates that worries related to health monitoring are rather common in individuals with schizophrenia even when data are generated automatically. We found that the feeling of uncertainty blurred when the participants got more familiar with the monitoring aspect of the app and their HCPs. This suggests that certainty may develop with use over time. However, we found that 1 participant embellished his data to stay in control, which accentuates that this might not always be the case. This advocates that health monitoring may have its limitations and highlights the paramount importance of carefully assessing the most appropriate time in the course of care to introduce and use an app for empowering purposes. Future research will need to look closer into the characteristics of those feeling upset from monitoring to fully understand its limitations.

Second, we identified that MindFrame could increase uncertainties about participants’ own mental health state, thereby disempowering some from feeling certain and secure. The uncertainty was related to notifications of exacerbations of illness and arose when the app indicated worsening, but the participant was fine. The findings show that being notified may lead to an emotional response of disturbance when the notification does not correspond to the participant’s sense of health. The same was identified in individuals with severe and very severe chronic obstructive pulmonary disease. Hunicke et al found that disturbance arose when individuals felt better or worse than what the technology indicated [60]. The former is in line with our findings and highlights how monitoring may increase uncertainty even in individuals who have been living and managing their illness for a long time. The finding highlights the paramount importance of using an app as part of a collaborative partnership with the HCP to increase certainty. HCPs have clinical knowledge and insights of importance that equip them with the knowledge and skills to more confidently and independently navigate the everyday management of the illness in the long run. In line with previous research, the findings indicate that HCPs are responsive to integrating smartphone technology into young adult schizophrenia care [25], yet, that HCPs uptake could be better [59]. Successful implementation and dissemination of smartphone apps as part of schizophrenia care for young adult population will rely on provider uptake as well as client use [25]. Future research will need to address how to increase provider uptake and evaluate the impact of provider engagement on the ability to navigate the everyday management both in the short and long run.
would help young adults diagnosed with schizophrenia set up the right threshold values to notify changes in their mental health state and to adjust the values as the illness stabilizes or exacerbates. Given the young adult is left alone to do this, it is likely that the amount of false-negative or false-positive notifications may increase. Ben-Zeev et al stress that in the future, evidence-based mHealth apps will be downloaded directly onto the smartphone and used by individuals with little or no contact to mental health care facilities [28]. Our findings suggest that in the case of young adults recently diagnosed with schizophrenia, this may leave some worried and uncertain.

Schermor has sketched 2 possible future scenarios of the use of smartphone technologies in mental health care. One scenario is the Big Brother scenario, where monitoring technology will reproduce the old paternalistic paradigm of patient-HCP interaction in which compliance and monitoring are the aims. The other scenario is that it will create a new situation that centers on shared decision making and self-management, adding to the autonomy of the service user [61]. Our findings suggest for the latter scenario to be feasible.

Limitations
A number of key limitations must be acknowledged. The recruitment strategy restricted 20 individuals from choosing for themselves whether or not to engage in the intervention. Opt-out decisions where HCPs set up their own criteria for excluding individuals with mental health issues from participation in interventions appear rather common [62-64]. In our study, this may have contributed to an evaluation sample nonrepresentative of the population and the impression that MindFrame may not generalize to the broader population of young adults with a recent diagnosis of schizophrenia.

The evaluation sample was small, and most of the participants had positive attitudes toward MindFrame. The poor retention of study participants may have overvalued the positive effects of the technology. A replication of the study with a larger sample size and maximum variation sampling in the interviews could help clarify this. Contrary to convenience sampling, maximum variation sampling and extreme case sampling allow the researcher to purposefully select participants to learn from the most extreme and unusual cases [30].

The evaluation sample was one of convenience and consisted of 9 women and 4 men. Research has established that first episode schizophrenia incident rates are approximately 2 times higher in men than in women [65,66]. This suggests that our findings are gender biased and potentially in favor of women. A replicative study with a sample more representative of the population would be interesting to see whether these study findings are gender consistent. This might not be the case, as previous research has provided findings that male gender is a specific predictor of nonadherence to mHealth interventions [53].

The sample was interviewed post intervention. For the participants who had terminated using MindFrame after a short period, the evaluation was conducted several months after they had stopped using it. Given the cognitive deficits addressed in the analysis and broadly in the scientific literature [67,68], it is possible that our study design has contributed to recall bias, which may have prevented some complexities from unfolding. The research process, however, does not indicate this. When interview questions were posed, the participants easily shared their views and experiences.

Conclusions
Our findings demonstrate that young adults recently diagnosed with schizophrenia are amenable of using a smartphone app as part of their everyday life to monitor their health, to manage medication, and to stay alert of early signs of exacerbation of illness. Given the app is used consistently for more than a month and in close collaboration with HCPs, it may empower them to keep the illness within their control.

The findings encourage the application of smartphone-based care to aid this population to better help themselves in the time following the diagnosis. The disempowering aspect of MindFrame accentuates that a smartphone app should be used in a reflected manner at the right time in the course of care and with the right amount of support. Further research is required to understand the best uptake and limitations of smartphone-based young adult schizophrenia care.

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Conflicts of Interest
None declared.

References


**Abbreviations**

HCPs: health care providers
Abstract

**Background:** Digital technology has the potential to improve outcomes for people with psychosis. However, to date, research has largely ignored service user views on digital health interventions (DHIs).

**Objective:** The objective of our study was to explore early psychosis service users’ subjective views on DHIs.

**Methods:** Framework analysis was undertaken with data obtained from 21 semistructured interviews with people registered with early intervention for psychosis services. Robust measures were used to develop a stable framework, including member checking, triangulation, independent verification of themes, and consensus meetings.

**Results:** The following 4 themes were established *a priori*: acceptability of technology in psychosis and mental health; technology increasing access to and augmenting mental health support; barriers to adopting DHIs; and concerns about management of data protection, privacy, risk, and security of information. The following 2 themes were generated *a posteriori*: blending DHIs with face-to-face treatment and empowerment, control, and choice. DHIs were also viewed as potentially destigmatizing, overcoming barriers faced in traditional service settings, facilitating communication, and empowering service users to take active control of their health care.

**Conclusions:** In the first study of its kind, early psychosis service users’ were largely positive about the potential use of DHIs supporting and managing mental health. Overall, service users felt that DHIs were a progressive, modern, and relevant platform for health care delivery. Concerns were expressed around privacy and data security and practical barriers inherent within DHIs, all of which require further attention. Future research should explore whether findings transfer to other service user groups, other technology delivery formats, and across a range of treatment modalities.

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**KEYWORDS** qualitative; psychosis; framework analysis; digital health; mHealth; mobile phone
Introduction

Integration of technology into health services is becoming commonplace, primarily owing to recent developments in hardware and connectivity. Along with facilitating direct contact between service users and clinicians [1,2] digital monitoring and health intervention tools have been recently applied in the treatment of psychosis with promising effects [3-8]. Given the inverse relationship between the age and use of digital health technology [9], computer literacy [10,11], and mobile phone ownership or use [12-14], mobile health (mHealth) systems may be particularly advantageous when applied to an early psychosis population vulnerable to relapse [15]. Levels of technology use in psychosis are similar to that in the general population [12,3], and people with psychosis express favorable attitudes toward digital health interventions (DHIs) and self-management systems [3].

Despite potential advantages of technology integration into mental health care [16], few investigations have focused on service users’ subjective views of digital systems [17]. Palmier-Claus et al [18] explored the views of 24 people with psychosis about ClinTouch self-monitoring of symptoms with a smartphone app. The following 3 key themes were identified: usability and familiarity with the technology, acceptability and integration of technology into daily life, and perceived impact of technology on health care. Another qualitative study with individuals experiencing psychosis reported that using Web-based resources to access mental health-related information was commonplace with many participants expressing positive attitudes toward the potential of mental health apps for self-care [19]. An in-depth understanding of the views of early psychosis service users, however, is yet to be reported.

Key United Kingdom (UK) policies have set clear recommendations regarding a closer involvement of service users in the development of digital innovations and enabling stakeholders’ engagement with digitally enabled services (eg, National Health Service, NHS, Five Year Forward View [20]). Evidence suggests that involving service users in intervention development is associated with high levels of engagement with DHIs more generally [21], highlighting the need to examine service users’ perspectives on DHIs.

This study aimed to engage with early psychosis service users to gain an in-depth understanding of their perspectives and attitudes toward DHIs. The study is part of a larger program of work to codevelop and test a DHI for early psychosis [22]. To our knowledge, this is the first study to examine qualitatively early psychosis service users’ views about a DHI delivered via a smartphone app.

Methods

Overview

The study was a collaborative partnership involving clinical academics, clinicians, and early psychosis service users who were all involved in the study design, topic guide development, and analysis and interpretation of data.

Study Design

This was a qualitative investigation nested within a broader research program concerned with development, feasibility, and acceptability of a theory-informed smartphone app for early psychosis, Actissist [22]. Data were gathered from semistructured interviews (N=21). The study was funded by the Medical Research Council, UK, and received ethical approval from the National Research Ethics Committee West Midlands–South Birmingham (14/WM/0118).

Participants

The purpose of recruitment was to identify participants who could provide insight into the phenomenon being studied rather than achieving a random or representative sample of the population. Therefore, we used a systematic, nonprobabilistic sampling approach to recruit a purposive sample of service users registered with early intervention for psychosis services (EISs) across the North West of England. EISs are multidisciplinary community mental health services that provide psychosocial and pharmacological treatment and support to people aged 14-65 years in the first 3 years of their initial episode of psychosis. Recruitment was over a 22-week period. Study exclusion criteria were kept to a minimum to include a diverse range of views and experiences. Eligibility criteria were as follows: ability to provide informed consent; registration with EISs; English speaking; and consent to record interviews digitally and publication of deidentified data.

Procedures

A researcher contacted team managers and gave presentations about the study at service meetings. Subsequently, clinicians identified potential participants and gained consent to contact. A researcher met with participants either in their own homes or at convenient locations. Following consent, semistructured interviews were conducted using a topic guide (available on request) developed for the study based on review of the literature and Smith’s [23] guidelines for constructing the semistructured interview schedule. The topic guide was refined in collaboration with an expert reference group convened for the broader Actissist trial [22]. Open-ended questions were designed to explore the following broad areas: participants’ use of technology generally; views about receiving health care and psychological support via smartphone technology; whether mental health apps make sense in the context of service users’ daily lives; incentives and barriers to use; equity and ethics; privacy concerns; and participants’ recommendations and requirements for a mental health app. All interviews were conducted by RM who was trained by an experienced clinician and academic (SB) and qualitative methodologist (DE). The order in which topics emerged was influenced by the topic guide but was not exclusively driven by it. Interviews were conducted as part of an iterative and inductive process of data collection and analysis [24], that is, as understanding of relevant issues developed, the topic guide was altered to focus interviews on emerging themes, thus allowing the data to drive development of relevant questions; for example, participants spontaneously spoke about the importance of personification of a mental health app, resulting in the inclusion of a related question in the topic guide. With each additional issue raised, we recontacted participants.

interviewed prior to the addition of new items to elicit their views regarding such issues. Interviews were digitally recorded and transcribed verbatim.

Data Analysis and Framework Development

Data were analyzed using a framework analysis approach [25]. While sharing common features with other qualitative approaches (eg, thematic analysis), framework methodology makes explicit a visible, systematic process that allows for the inclusion of both a priori and emergent concepts. With the help of a service user expert group, we developed a list of important topics we wished to seek views about prior to developing the framework. With these topics in mind, questions for the topic guide were developed and subsequently informed the framework’s a priori themes. Specifically, we explored people’s previous and current satisfaction with using mental health services; perceptions of DHIs and the ability of technology to facilitate symptom monitoring and support self-management; incentives and barriers to use and implementation of mHealth tools; experiences of using technology to support mental health; and the impact of DHIs on disclosure of risk and governance issues. Therefore, the following 4 themes were established a priori: acceptability of technology in mental health; technology’s ability to increase access to, and augment, mental health support; barriers to adopting digital solutions; and data protection, privacy, and security of information. At the same time a priori topics were being explored, other themes, which participants’ spontaneously described, emerged from the data. The following 2 themes emerged from the data a posteriori: blending DHIs with face-to-face treatment and empowerment, control, and choice.

Although nonlinear and often condensed, data analysis involved the following key stages: (1) familiarization with the data: listening to recordings, reading and rereading transcripts and making analytical notes; (2) coding the data: combination of deductive (using predefined codes based on specific research questions) and inductive approaches (using “open coding” to identify any emergent, possibly relevant information); and (3) developing a thematic framework: we developed an initial framework by comparing codes assigned to the data after independently coding several transcripts before agreeing on the set of codes to be assigned to subsequent transcripts. Subsequent framework iterations were shared with the members of the wider research team and participants themselves (“member checking”). We then coded remaining transcripts into the framework and constantly compared new data with the framework. Data were then interpreted and summarized, new codes generated, redundant codes deleted, and overlapping codes merged; (4) indexing: the framework was applied to the dataset; (5) charting: a framework matrix for each emergent category across the whole dataset using illustrative quotations was developed using QSR International’s NVivo 10 Software data management software; and (6) mapping and interpretation: emergent (a posteriori) and a priori characteristics of the data were identified and connections between categories “mapped,” facilitating exploration of relationships (similarities and differences) and theoretical concepts and generation of typologies.

We took a number of additional steps to enhance the study’s methodological rigor and to minimize researcher bias. Specifically, SB and DE scrutinized interviews and provided feedback and training to the interviewer to minimize any tendency to lead participants: a selection of transcripts was coded independently by authors GH and KB (who were independent of framework development), providing triangulation of analysis and independent verification; framework refinement and development of the analytical matrix was undertaken by all authors. Regular consensus meetings were held until a stable framework emerged. Participant feedback on the framework and subsequent findings (participant verification) were sought from study participants. Data collection ceased when no further themes were advanced (ie, data saturation [26]).

Results

Participant Characteristics

Interviews lasted from 39 to 78 minutes. Uptake of study participation was high; 88% of service users that we approached consented to take part in the study. Participants had a mean age of 26 years (SD 5.14, range 16-34) and a mean length of 22 months of EIS involvement. Just over half of participants were female (11/21, 52%), were in full-time employment, education, or training (11/21, 52%), and living with family members, partners, or others (13/21, 62%).

Table 1 summarizes the use of technology and potential barriers of using DHIs across the sample. All participants (21/21, 100%) used the internet primarily for social networking (12/21, 57%), followed by video and audio streaming (9/21, 43%) and research or studying (9/21, 43%). All except one participant owned a mobile phone (20/21, 95%) with the majority owning smartphones (18/21, 90%). All participants (21/21, 100%) had previously used smartphone apps. Two-thirds (12/18, 67%) of the sample reported using apps for health purposes, half (9/18, 50%) for social networking, and one-third (7/18, 39%) for gaming purposes. A third (n=7/21, 33%) of participants reported literacy difficulties. However, these participants reported finding information accessible on a smartphone more accessible than paper-based approaches.

The framework is summarized in Figure 1 and elaborated below, as evidenced by key quotations embedded within the text.

Theme 1: Acceptability of Technology in Psychosis and Mental Health

There was a complete agreement across participants (n=21) that mobile technology is an acceptable and relevant way to gather information about, and access support for, mental health problems. Generally speaking, the idea of using smartphones to seek help was viewed as just as acceptable as traditional methods:

I do think that [technology] is really good cause it’s going to be accessible to people that will need the help. Some people don’t always want to speak outwards. It would be much easier on an app where I could take it with me anywhere at anytime and open it up and record how I am doing…. [Participant 15]
Technology was viewed as a good way of accessing help and support when needed because participants reported often feeling restricted by traditional face-to-face service provision:

*It’s not like a GP [general practitioner] where you’ve gotta go up the road and then speak to him. [using technology] You can easily sit in your own home and read through the app...when I’m going to a GP...I’m silent.* [Participant 14

Nearly half of the participants (10/21, 48%) held the view that technology is progressive, modern, and relevant and that mental health apps reflect a good way of “moving with the times,” which is more in keeping with how young people communicate on a daily basis. Making this link between day-to-day communication styles and engaging with health services that reflects current methods young people use to interact with each other was viewed as positive and progressive development of mental health care:

*I’m very good on computers so it’s easier for me to type than it is for me to speak to someone. People these days are quite up on apps and stuff...* [Participant 10

Participants expressed the view that technology has the capacity to be destigmatizing. Smartphones, as opposed to mental health settings, were viewed as inherently normalizing because majority of people use and carry this technology:

*You’ve got these people turning up at your front door and they’ve got their health things on round their necks...you might as well be wearing a sign really. One woman took me to [retail store] and told me she goes there with a lot of other service users. That made me incredibly anxious because I thought other people that work here are gonna know what her job is, whereas everyone uses an app these days innit? It’s normal now.* [Participant 3

However, not all participants shared this view; others described feeling embarrassed or uncomfortable while using a mental health app in front of other people:

*If the app is asking you to pull it out every time you’re in a social situation, it gets embarrassing and that can add to the anxiety you feel in a social situation.* [Participant 13

---

**Table 1. Reasons for using the internet and smartphones.**

<table>
<thead>
<tr>
<th>Type of use reported</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internet use</strong></td>
<td></td>
</tr>
<tr>
<td>Social networking, blogging</td>
<td>12 (57)</td>
</tr>
<tr>
<td>Video, audio streaming</td>
<td>9 (43)</td>
</tr>
<tr>
<td>Research, studying</td>
<td>9 (43)</td>
</tr>
<tr>
<td>Email</td>
<td>6 (29)</td>
</tr>
<tr>
<td>Gaming</td>
<td>5 (24)</td>
</tr>
<tr>
<td>News</td>
<td>5 (24)</td>
</tr>
<tr>
<td>Web-based banking</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Self-help websites</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Art tools (browser-based app)</td>
<td>1 (5)</td>
</tr>
<tr>
<td><strong>Smartphone apps use</strong></td>
<td></td>
</tr>
<tr>
<td>Health purposes (physical &amp; mental)</td>
<td>12 (67)</td>
</tr>
<tr>
<td>Social networking</td>
<td>9 (50)</td>
</tr>
<tr>
<td>Gaming</td>
<td>7 (39)</td>
</tr>
<tr>
<td>Art (including photography)</td>
<td>4 (22)</td>
</tr>
<tr>
<td>News</td>
<td>4 (22)</td>
</tr>
<tr>
<td>Appointment reminders or calendar</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Shopping</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Banking</td>
<td>2 (11)</td>
</tr>
<tr>
<td>E-books</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Global positioning system</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Television guide</td>
<td>1 (6)</td>
</tr>
</tbody>
</table>

*a n=21.

*b n=18.*
Theme 2: Technology Can Increase Access to and Augment Mental Health Support

In many instances, participants expressed the view that apps could overcome barriers to traditional service set-up and, in particular, increase access to treatment and services because the use of technology does not depend on workers being available at specific times. Support could be accessed in one’s naturalistic environment at the point of need and was therefore viewed as having high ecological validity:

“I’ve already had CBT [cognitive behavior therapy]...I think I would have been more successful with it if I had something like this because there’s lots of elements of it [CBT] where you’re supposed to be keeping diaries of your moods and if you’re low...If there’s nothing to prompt you other than yourself, it’s very hard to motivate yourself and then you might find yourself coming to your weekly appointment realizing you haven’t bothered to fill in any of this stuff out for the last 4 days and just trying to make it up on the spot.” [Participant 16]

Participants’ accounts suggested that technology could extend the reach of service delivery, circumventing resource limitations and reducing waiting times:

“I think it would cut down on time that people will have to wait to see a health professional...some people wouldn’t need to see a professional face-to-face, they might just be able to deal with their issues via the app.” [Participant 11]

Furthermore, a few participants (n=6) commented on the fact that secondary or related symptoms of psychosis (eg, sleep problems and social withdrawal) or negative beliefs about technology itself causing harm can make it difficult to attend traditional clinics:

“If you are someone that’s awake all night and you sleep all day or you struggle to leave the house then you’re going to struggle with face-to-face [contact].” [Participant 8]

Theme 3: Blending Digital Health Interventions With Face-to-Face Treatment

There were mixed views on whether mental health apps could be used as a stand-alone intervention or whether it should be clinician supported. In general, participants felt that DHIs offered more benefits compared with face-to-face contact. Participants were positive about the ability of smartphone technology to keep a track of their symptoms and experiences. Many thought that this ability would actually enhance their understanding of psychotic experiences.

“I think it would be a great help because people would be able to see the warning signs very early on and go ‘hang on a second, this isn’t right, what do I need to do to help myself’.” [Participant 16]
Additionally, DHIs seemed to give people space to understand their experiences for themselves:

Sometimes it’s better when you’re on your own and you get to create your own opinions on how you’re feeling and understanding how you feel instead of being told how you feel. [Participant 17]

Participants who had used symptom-monitoring apps in the past felt that the ability to track symptoms using smartphone technology facilitated feelings of empowerment and enhanced motivation in a way traditional health care face-to-face delivery could not:

You learn a bit more about yourself and how you’re actually feeling at that moment...it helped motivate me to improve. [Participant 11]

Some younger participants identified that because they have grown up with technology, they find digital means of communication easier than face-to-face methods:

For me personally, I’d rather talk online. You know, if people aren’t going to talk to someone [face-to-face] then with an app they can still deal with their problems. [Participant 9]

It’s easier for me to type than speak cos I was brought up with computers. [Participant 16]

The fact that an app is anonymous appealed to some because direct clinician contact can reinforce people’s sense of guilt or failure if they have not completed therapy tasks or complied with medication:

You don’t feel guilty if you haven’t done your homework. [Participant 6]

In addition, although many participants described the perceived value of talking to a clinician face-to-face, others did not share this opinion; for example, some participants said that they would feel much more comfortable using an app to support their mental health problems rather than talking to a member of their care team:

I think there’s one side of it that could really work which is kind of like the exercises...it could talk you through them, and actually not being in front of a person, you might do them more truthfully. [Participant 7]

A few participants, however, felt that apps should be used as an adjunct to, rather than a replacement for, direct clinician contact so that DHIs complement rather than replace clinician-supported care:

I think it would not replace one-to-one talking therapy but I think there are aspects of [an intervention] which could be put into an app, which you could access in-between sessions of talking one-to-one with someone. [Participant 7]

Some participants noted using an app, rather than seeing a clinician, might feel dismissive as though they are not worthy of a clinician or therapist. There was cynicism among some participants, albeit the minority, that technology adoption across health services was a cost-cutting exercise, which would ultimately be detrimental to the health care people receive. If used in conjunction with traditional clinician-delivered care, participants thought that apps could be helpful. However, they wanted control over how they use the app and with whom the information is shared.

There’s some things I don’t share with my [clinician] that I don’t want him to know yet and for him to be able to find it in a diary, I wanna be able to say‘actuallycan we skip that day? It’s a really personal day’ [Participant 9]

Of note, other participants said that if they knew that their information was shared with their care team, they might interact differently with the app, for example, by being a “little less honest,” as evidenced by Participant 21:

I would describe my symptoms as not as bad because I wouldn’t want my [clinician] worrying or thinking that the treatment wasn’t working. [Participant 21]

Although some people thought that sharing risk information would compromise trust and might affect the way they interact with digital technology (“I would be more careful and less experimental,” Participant 8), many participants thought that their mental health was something private. On the whole, participants thought that reporting risk to their care teams would be advantageous and potentially life-saving, leading to better focused care.

**Theme 4: Empowerment, Control, and Choice**

The majority of interviewees believed that smartphone technology could facilitate a sense of personal ownership and control over their health care:

If I had an app I would have kept on top of [my mental health] a lot better. I don’t like scenarios where I feel my mental health is dictating my life and that is all that my life is, and that’s how it feels when you’re going to appointments all the time...an app would be just kind of enabling people to be empowered themselves, to take their care into their own hands. I think there’s a habit for people to be quite passive in their care. They think ‘the Dr. knows best’ [Participant 2]

A common belief among interviewees was that people should be given options about the health care they receive and treatment choice, which may differ at times; for example, some interviewees highlighted a stepped-care pathway, wherein an individual might choose to use an app exclusively at a specific point in time in the course of their recovery but incorporate human contact at other times:

If you’re at an all-time low then you might think ‘right, I need to actually speak to someone’. If it’s sort of like creeping on and you’re just feeling a bit, just crying, then the app would be handy. [Participant 5]
Theme 5: Barriers to Adopting Digital Health Interventions

A number of barriers to using technology-related mental health tools were identified. Some interviewees described the absence of a human quality and lack of emotional reassurance and feedback offered by apps problematic because DHIs provide limited opportunities to connect and interact at an emotional and interpersonal level:

Talking to somebody is very personal. You can get their instant reaction, their emotions and everything. When you're opening up it's crucial that you have somebody there to reassure you. [Participant 20]

If you are talking to a machine, you know you're talking to a machine, so if it tries to pretend it's a human, even if you're allowing yourself to go along...you are being degraded in a way. [Participant 12]

Practical barriers, such as forgetting to turn on or charge the phone and losing or breaking the phone, could impact engagement with digital tools. Furthermore, the concept of the “digital divide” (inequalities with regard to access to, use of, or provision for information and communication technologies) was noted by some participants who highlighted that some people do not have access to smartphones, thus limiting their ability to access DHIs. Indeed, even participants with access to smartphones stated that poor data allowance would prevent them from using the technology:

On my phone I only get like 1 GB out of it which runs out quick. [Participant 5]

Theme 6: Data Protection, Privacy, and Security of Information

About two-thirds (16/21, 76%) of participants expressed concerns about data protection and information governance. However, participants stated that their fears about information safety could be allayed if services reassured them about data safety. Many participants said that endorsement of a DHI by a valid institution (eg, university, health service, or respected, well known mental health charity) would be sufficiently reassuring and would increase DHI uptake. However, a minority of interviewees said they would prefer endorsement by individuals (eg, care co-ordinator and doctor) rather than by organizations because “organizations have hidden agendas” (Participant 13). Alternatively, a strong relationship between a service user and staff member working in a service would be sufficiently reassuring for some interviewees.

I trust the early intervention team and people associated with it, so I would be fairly confident that it would be secure, if they said so. [Participant 7]

Some participants identified that data stored locally on the smartphone and on a server needs to be safe, secure, and private and that, ideally, data should be “locked” on the phone. On the whole, participants did not report concerns about clinical services gaining access to their data per se. Rather, concerns were expressed about data being linked to outside agencies (eg, commercial search engines, iCloud, and social networking sites):

Storing it in iCloud wouldn’t be acceptable, storing it by email, sending it in email that is unencrypted isn’t the greatest way to share data. Those kinds of things should be addressed particularly as it is mental health and mental health has a strong taboo in society...If it was leaked, it would be disastrous for the people involved. [Participant 15]

Discussion

Overview

In light of the inevitable adoption of a worldwide digital health service, it is surprising that this is the first qualitative study to examine early psychosis service users’ perspectives on digital technology use for health care needs. We found that in an early psychosis sample, DHIs were just as acceptable as traditional methods and preferable in some instances for seeking information about, and support for, mental health problems.

Principal Findings

Despite concerns around privacy and data security and some practical barriers inherent within digital platform systems, early psychosis participants’ views were largely positive about the potential use of DHIs in supporting and managing mental health difficulties. These findings are largely consistent with the broader literature across a range of mental health problems [27-29] and reflect some views of carers for early service users [30]. Overall, 6 themes were evident. First, participants felt that apps could enhance services’ accessibility by providing a platform for service users to be open and honest in a way they might not be able to be in traditional clinic-based appointments. These findings support previous assertions by clinicians that the faceless and anonymous nature of DHIs may allow service users to be more open and honest about their experiences [31] and provide more access to Web-based information rather than face-to-face meetings with a clinician [19]. These findings also echo views from a Spanish sample of outpatients with established schizophrenia, who also felt that digital health technology could improve contact with clinicians, affording the chance to have greater contact with health professionals [32]. Technology was not only viewed as a progressive, modern, and relevant platform for health care but also inherently destigmatizing. Perceived stigma is a key barrier to engagement with mental health care services [33]; provision of intervention delivery options that are destigmatizing is therefore warranted. Second, participants reported that DHIs could increase access to, and augment, support by extending the reach of services to one’s naturalistic environment, at the point of need, potentially circumventing lengthy waiting times. Although the national (UK) guidelines recommend the provision of psychological therapies for early psychosis [34], factors such as a limited number of trained clinicians, service cost, and resource pressures mean that many people who could benefit are often unable to receive timely access to evidence-based treatment [35]. Our findings suggest that service users find implementation of DHIs in early psychosis services an acceptable avenue for health care provision. This echoes the findings of the study conducted by Aref-Adib and colleagues (2016), in which semistructured interviews with 22 people with psychosis accessing secondary
Participants reported finding Web-based information more accessible across space and time compared with receiving information and support from clinicians. In the context of bipolar disorder, people have also reported that apps facilitate clinician understanding of the user’s experiences of symptoms, encourage shared decision making about treatment, improve service user-clinician communication [27], and enhance clinical care, making time spent with clinicians more efficient.

People with more established psychosis have also emphasized how DHIs can help clinicians gain insights into service users’ mental states, potentially leading to earlier and more effective intervention because service users do not need to rely on retrospectively recollecting symptoms when using DHIs capable of capturing experiences in the moment [18]. These views are similarly highlighted by carers for early psychosis service users, who see the value in DHIs facilitating communication with service providers, particularly during times of social withdrawal [30].

Views about whether DHIs could replace face-to-face contact were mixed. Some participants, particularly those who find the clinic environment threatening, indicated that DHIs could indeed replace clinician contact. Creating a safe distance from a clinician facilitates openness and honesty about distressing experiences and facilitates empowerment. Indeed, recent interviews with individuals who had received the Actissist app [22] revealed that some participants felt more comfortable in being open and honest compared with face-to-face support options. Previous studies have also highlighted that both clinicians and service users view DHIs for people with severe mental health problems as empowering owing to the transfer of control and power from the clinician to the service user and the opportunity for service users to take meaningful and active control over their health care needs [13,36]; for example, in an established psychosis sample, Aref-Abid and colleagues (2016) found that the act of independently seeking information related to one’s health online and the understanding and knowledge gained as a result of seeking information online was closely linked to feelings of control and empowerment. This finding was also supported in a meta-synthesis review of experiences of computer-delivered therapy for people with depression and anxiety, whereby participants referred to the empowering nature of computerized therapy [36]. In contrast, traditional service settings have been viewed by some service users as disempowering owing to lack of shared decision making and involvement in developing and monitoring treatment and care plans [37,38]. Findings highlight the potential utilization of DHIs for providing early psychosis service users the control and choice over treatment options and support such policy documents as the NHS Constitution Pledge and Five Year Forward View to improve the provision of shared decision making and promotion of service user choice.

Despite the acceptability of DHIs highlighted in this study, some participants viewed apps as potentially invalidating. Digital tools should complement, rather than replace, clinician contact. These findings support conclusions drawn by previous qualitative interviews with psychosis service users who used a symptom-monitoring app; they described the need for clinician involvement and the potential benefits of mental health apps for facilitating service user-clinician communication [18]. Additionally, views expressed in this study mirror those expressed by secondary mental health care staff who believed that an app should never be offered as a stand-alone replacement for face-to-face support options [31]. Participants argued for choice about how DHIs could be used in the health care setting.

Furthermore, data security, safety, and risk require careful consideration and management. This concern is not limited to early psychosis. Similar concerns have been raised in the general population; for example, participants drawn from a large community sample in Australia expressed concerns around privacy issues related to mHealth programs and described the importance of Web-based security, anonymity, and privacy [28]. Privacy and security concerns have also been raised among people with bipolar disorder [27] with particular concerns reported around handset access and secure storage of data in apps. Carers for early psychosis service users have also expressed the importance of safeguard measures, specifically in terms of the professional’s role in how DHI platforms are used [30]. We found that participant concerns around this issue could be allayed if a trusted source endorsed the system. However, recent reviews of publically available smartphone apps revealed that less than a quarter of those available for bipolar disorder included a privacy policy [39] and less than 10% of those available for social anxiety provided organization information [40]. This contrast between current information provided on publically available mental health smartphone apps and the preference of service users for DHIs from trusted sources suggests that content information currently available may not be sufficient to alleviate service user privacy concerns, thus potentially negatively impacting engagement. Future developers must ensure that clear and explicit statements regarding privacy and organizational sources are made available.

On the whole, DHIs were viewed as destigmatizing. The potential of DHIs to enhance service user power, control, and choice over the pathway of care reflected the desire for service user-centered approaches to mental health care, incorporating DHIs that are truly coproduced from the outset [41].

Strengths and Limitations
This is the first study to explore early psychosis service users’ views on use of digital solutions for health care. Service users have highlighted important factors that researchers and technical developers need to consider when designing and building digital systems in mental health. Our methodological and analytical approaches were rigorous. We allowed the interview schedule to drive development of relevant interview questions by regularly reviewing it and the data gathered, allowing in-depth examination of participant-driven relevant issues. Formal processes to ensure credibility of our findings, including independent peer verification and member checking processes, were exhaustive, ensuring that all participants’ views were thoroughly considered as new themes emerged.

Findings need to be considered in light of the study limitations. Interviews were with an early psychosis group, who, based on the mean age of our sample and smartphone ownership rates, are considered “digital natives,” rendering the sample inherently familiar with smartphone technology [42]. Nevertheless, the
sample was a mix of relatively young men and women who were reflective of the early intervention sample we sought to examine. Because most participants were in some form of employment or training, this might be less reflective of other early intervention samples. Participants were recruited in the context of a larger DHI trial and may have already held favorable views toward technology use. However, examination of our findings suggests that service users were well versed in the pros and cons of DHIs for mental health. Previous experience with mental health apps and related products, negative experiences with traditional mental health services, and socially desirable responses during interviews might have influenced participants’ expressed views.

Implications and Recommendations

Until now, early psychosis service users’ views on DHIs for mental health care have not been considered. This may be, in part, owing to the fast-paced rate of digital technology adoption and the sense of urgency evident in development of DHIs. This study provides a timely exploration of service user views and highlights the potential facilitators and barriers to adoption that must be considered during DHI development. First, the study highlighted that DHIs were acceptable to service users with early psychosis owing to access via an app being destigmatizing, normalizing, progressive, modern, and relevant. These findings highlight the potential for health care apps to mirror how people currently communicate in their routine day-to-day lives. Nevertheless, DHIs require regular updating to remain relevant. Further consideration must be given to smartphone access and data allowance prior to DHI implementation to minimize digital exclusion. A smartphone loan scheme, supported funding, or discounts for medical use warrant further consideration for DHI service adoption.

Participants placed a significant emphasis on the importance of choice, particularly in relation to whether DHI would be used in conjunction with, or as a replacement for, clinician-delivered care. However, further consideration should also be given to what point in the service user’s recovery journey a DHI might be most useful and when clinician contact might be needed (if at all). Furthermore, the process of shared decision making is important to consider. According to these data, service users would like to be given choices regarding information they share with health professionals. Service user choice around, but not limited to, these issues should remain at the forefront of DHI development and implementation.

These findings also highlight the need for focused consideration of secure data collection and storage and reassurance about this, ensuring that service users are fully informed about governance issues. Finally, future research should explore whether our findings transfer to other service user groups, in a broad context of technology delivery formats, across a range of treatment modalities.

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Conflicts of Interest

SB and SL are directors of Affigo CIC, a not-for-profit social enterprise company, spun out of the University of Manchester in December 2015, to enable access to social enterprise funding and to promote ClinTouch, a symptom-monitoring app, to the NHS and public sector.

References


Abbreviations

- **CBT**: cognitive behavior therapy
- **DHI**: digital health intervention
- **EIS**: early intervention for psychosis service
- **GP**: general practitioner
- **mHealth**: mobile health
- **UK**: United Kingdom
- **NHS**: National Health Service
How Inclusive, User-Centered Design Research Can Improve Psychological Therapies for Psychosis: Development of SlowMo

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Abstract

Background: Real-world implementation of psychological interventions for psychosis is poor. Barriers include therapy being insufficiently usable and useful for a diverse range of people. User-centered, inclusive design approaches could improve the usability of therapy, which may increase uptake, adherence, and effectiveness.

Objective: This study aimed to optimize the usability of an existing psychological intervention, Thinking Well, which targets reasoning processes in paranoia using a basic digital interface.

Methods: We conducted inclusive, user-centered design research characterized by purposive sampling of extreme users from the margins of groups, ethnographic investigation of the problem context, and iterative prototyping of solutions. The UK Design Council's double diamond method was used. This consisted of 4 phases: discover, including a case series of Thinking Well, stakeholder interviews, desk research, user profiling, system mapping, and a mood board; define, consisting of workshops to synthesize findings and generate the design brief; develop, involving concept workshops and prototype testing; and deliver, in which the final minimal viable product was storyboarded and iteratively coded.

Results: Consistent with our previous work, the Thinking Well case series showed medium to large effects on paranoia and well-being and small effects on reasoning. These were maintained at follow-up despite some participants reporting difficulties with the therapy interface. Insights from the discover phase confirmed that usability was challenged by information complexity...
and poor accessibility. Participants were generally positive about the potential of technology to be enjoyable, help manage paranoia, and provide tailored interpersonal support from therapists and peers, although they reported privacy and security concerns. The define phase highlighted that the therapy redesign should support monitoring, simplify information processing, enhance enjoyment and trust, promote personalization and normalization, and offer flexible interpersonal support. During the develop phase over 60 concepts were created, with 2 key concepts of thoughts visualized as bubbles and therapy as a journey selected for storyboarding. The output of the deliver phase was a minimal viable product of an innovative digital therapy, SlowMo. SlowMo works by helping people to notice their worries and fast thinking habits, and encourages them to slow down for a moment to find ways of feeling safer. A Web app supports the delivery of 8 face-to-face sessions, which are synchronized to a native mobile app.

Conclusions: SlowMo makes use of personalization, ambient information, and visual metaphors to tailor the appeal, engagement, and memorability of therapy to a diversity of needs. Feasibility testing has been promising, and the efficacy of SlowMo therapy is now being tested in a multicentered randomized controlled trial. The study demonstrates that developments in psychological theory and techniques can be enhanced by improving the usability of the therapy interface to optimize its impact in daily life.

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KEYWORDS
inclusive design; user-centered design; participatory design; design thinking; mHealth; eHealth; digital therapy; schizophrenia; paranoia; psychosis

Introduction

Background to SlowMo Therapy
The development of psychological interventions for psychosis has accelerated in the last 2 decades, particularly with the second- and third-wave cognitive behavioral therapies (CBT) [1]. Although these show promise in reducing distress and improving people’s quality of life, significant barriers to real-world effectiveness remain [2,3]. Effect sizes are in the small to medium range, and psychological interventions are only accessed by 15 to 30% of eligible service users [4-8]. Some people are not motivated to try therapy and those that do may struggle to understand it and to apply new insights to everyday situations [9-11]. Efforts to improve effectiveness have focused so far on identifying causal mechanisms linked to specific outcomes and developing therapy techniques that target these mechanisms [12]. For example, interventions for sleep, worry, self-esteem, and reasoning styles have demonstrated larger effect sizes on paranoia compared with generic CBT for psychosis [13-15]. However, there is continuing concern about barriers to therapy access, uptake, and adherence [5,12,16], and strategies for improving implementation are urgently needed.

We propose that enhancing the usability (or ease-of-use) of therapy will address implementation barriers and thereby improve effectiveness. To the best of our knowledge, this study is the first to focus on optimizing the usability of an existing therapy (Thinking Well) by conducting inclusive, user-centered design (UCD) research. Thinking Well is a brief protocol-based therapy that targets jumping-to-conclusions and belief inflexibility, the reasoning styles that contribute to paranoia [17]. We have already shown that this therapy improved reasoning and reduced paranoia in a case series, a randomized experimental study, and 2 feasibility randomized controlled trials [10,18-20]. However, its effects declined following the end of therapy, and some people reported that the intervention was insufficiently personalized, enjoyable, or applicable to daily life. Moreover, people with working memory problems and negative symptoms tended to benefit less from the therapy [10]. This may, in part, be because of the use of thought records, a widely used tool for the identification and evaluation of distressing cognitions in CBT. Thought records can be cognitively demanding to complete, and their pen-and-paper verbal format limits their usefulness in supporting real-world behavior change [21,22]. Before proceeding to a multicenter randomized controlled trial, we therefore sought to optimize the usability of the intervention to address these concerns. The output of this study, SlowMo, is an innovative blended digital therapy for people who fear harm from others. A Web app supports the delivery of 8 face-to-face sessions, which are synchronized to a native mobile app for use in daily life. SlowMo works by helping people to notice their worries and fast thinking habits, and encourages them to slow down for a moment to find ways of feeling safer. SlowMo is currently being tested in a multicenter randomized controlled trial [23].

Designing Digital Interventions for Psychosis
SlowMo reflects the rapid growth of digital technology in mental health care, given its potential to improve access, outcomes, and costs [24-26]. In psychosis, findings indicate promising rates of acceptability, usability, and safety for interventions delivered via the Web, short message service (SMS) text messaging, mobile phone apps, and virtual reality. However, research is in its infancy and further development and testing are required [27-31]. In addition, gender, age, ethnicity, severity of difficulties, digital literacy, and social support may moderate adherence. This suggests interventions need to be tailored to the needs of a range of potential users [32-36]. Indeed, concerns about uptake and adherence are common in digital health interventions, given the marked overrepresentation among users of highly educated women. This highlights the need to ensure technology interfaces are more compelling and appealing across all groups in society [37].

Design thinking is a process whereby challenges to therapy access, uptake, and adherence can be addressed. It involves developing a rich understanding of the problem area and its context to identify valued outcomes. From this, themes are derived to develop possible new ways of framing the problem.
by highlighting its paradoxes, and solutions are then generated to resolve them [38,39]. For example, paradoxes that design thinking may help to resolve include a person’s desire to be healthier while continuing to engage in unhealthy behaviors or government attempts to promote a sense of safety through authoritarian controls that actually exacerbate public perceptions that society is dangerous. However, design thinking alone is insufficient to lead to meaningful change, as professional designers often operate outside problem contexts, and this may limit their ability to understand the problem and develop effective solutions.

UCD methods address this limitation as they privilege the empathic understanding of end users and their contexts, thereby ensuring solutions are relevant to the diverse needs of people involved [39-41]. Participatory design, or codeign, is a UCD technique that emphasizes direct user involvement and has its roots in activism and shared decision making. It is increasingly used in digital mental health research, based on ethnographic and qualitative methods [42-44]. To date, participatory design methods used in the development of digital therapies for psychosis have included investigation of stakeholder attitudes through observation, surveys, interviews and focus groups, workshops to develop and test prototype ideas, and laboratory-based think aloud usability tests [45-53]. However, these studies have not tended to incorporate design thinking methodology, which can constrain innovation, so that new designs are variations of the status quo. In addition, a risk inherent in participatory design is that the most willing, able, and vocal users are more likely to be involved so that the needs of marginalized people are neglected.

Research Objectives

Our multidisciplinary collaboration of people with lived experience, clinicians, researchers, industrial designers, and software developers aimed to integrate the best practice principles of design thinking and participatory design. This involved using the Design Council’s [54] double diamond method and adopting an inclusive UCD approach. The double diamond consists of ethnographic investigation of the problem context (the discover phase) and using insights from this phase to reframe the problem and generate a design brief (the define phase). From this, solutions are generated and iteratively tested with users (the develop phase), with feedback determining the optimal design for development (the deliver phase). Our strategy for involving people in the design process, inclusive UCD, is different from conventional participatory design. It involves purposive sampling of people at the margins of a normal distribution (extreme users) to ensure the design solution is suitable for the widest range of people. This purposive sampling of extreme users can help to ensure the needs of marginalized groups are considered [55]. On the basis of previous findings, we assumed demographics, cognitive abilities, use of technology, and attitudes to therapy were of particular relevance to the therapy design. We therefore aimed to ensure our sample of people with lived experience of psychosis reflected the extremes of these dimensions.

In summary, we anticipated that the inclusive, UCD research methods employed would support the development of an improved version of the Thinking Well intervention tailored to meet a diversity of needs. Our intention was that the design thinking approach would result in a redesign of the therapy that was more accessible, appealing, memorable, and easy to use, both within sessions and in daily life.

Methods

Study Design

We conducted our design research alongside a case series of the previous version of the Thinking Well therapy. This was done to support the discovery phase of the double diamond. The case series will first be described, followed by an overview of the double diamond method. The design research was conducted from October 2014 to May 2017.

Thinking Well Case Series

Participants

Fourteen participants were recruited from community mental health teams in a National Health Service (NHS) Trust between March 2014 and May 2015 (see Table 1 in the Results section). Inclusion criteria were a diagnosis of nonaffective psychosis, aged 18 to 65 years at study entry, with relatively stable symptoms and no major crisis in the 3 months before participation, a sufficient level of English to complete measures and participate in the intervention, and a score of 33 or above on the Green Paranoid Thoughts Scale (GPTS) [56]. Exclusion criteria were lack of capacity to provide informed consent, primary diagnosis of substance dependency, and a primary diagnosis of organic syndrome or learning disability.

Design

A case series design was used. Assessments were conducted at baseline, post therapy (8 weeks), and at follow-up (12 weeks).

Intervention

The case series used the fourth version of Thinking Well, which built on earlier iterations and aimed to incorporate the participant feedback from our previous trial (see Waller et al’s study [20] for a description of the preceding version of the therapy). This new version was developed before starting the inclusive UCD research. The changes included presentation of therapy session materials in PowerPoint, on a laptop, to allow for more multimedia, interactive content; Web pages hosted on a NHS website to support the use of therapy strategies outside of sessions; and use of everyday accessible terminology for key psychological concepts. For example, the terms fast and slow thinking were introduced as a heuristic for capturing the ideas of jumping to conclusions and belief inflexibility, and analytical and reflective thinking, together with the focus on slowing down for a moment as a means of managing worries [57]. Other changes, based on feedback from therapists in the previous trial, included extending the therapy content from 4 to 6 meetings and adding sessions on the impact of past experiences and confirmatory bias in paranoia. Although this version of Thinking Well was more digitized than previous versions, the software was not fully interactive. Pen and paper materials were still used during therapy sessions and offered for out-of-session use if people were unwilling or unable to use the Web pages.

Screenshots providing an example of the therapy materials, taken from session 1, are shown in Multimedia Appendix 1 (including PowerPoint slides used in the session with images of the paper thought record and practice card and the out-of-session Web pages). Therapy was delivered by clinical psychologists with at least 5 years of experience in delivering cognitive behavioral therapy for psychosis (CBTp) or therapists who had completed a postgraduate CBTp diploma and had a minimum of 1 year of postqualification experience.

**Measures**

**Positive and Negative Symptoms**
The Scale for the Assessment of Positive Symptoms (SAPS) [58] is a 34-item semistructured interview used to assess the severity of hallucinations, delusions, bizarre behavior, and positive formal thought disorder. Each item is rated over the past month from 0 (absent) to 5 (severe) with global ratings for each section. Negative symptoms over the past week were assessed using the Brief Negative Symptom Scale (BNSS), a 13-item semistructured interview measuring blunted affect, asociality, anhedonia, and avolition, on a 7-point scale from 0 (absent) to 6 (severe) [59]. The SAPS and BNSS were only completed at baseline to assess the clinical characteristics of the sample.

**State Paranoia**
The GPTS [56] is a 32-item measure of state paranoia with sections on ideas of reference and persecution. Each item is rated over the past month from 1 (not at all) to 5 (totally) and a total score is derived.

**Paranoia Distress and Preoccupation**
Participants were asked to rate their current distress and preoccupation regarding their main paranoia belief using a 100-point Visual Analog Scale (VAS) ranging from 0 (not at all) to 100 (totally).

**Paranoia Conviction**
Using a VAS, participants were asked to provide a rating between 0 (believe not at all) and 100 (believe absolutely) of their current conviction in their main paranoia belief.

**Belief Flexibility**
Two items were employed to assess belief flexibility. Possibility of being mistaken was assessed using an item from the Maudsley Assessment of Delusions Scale [60], with participants providing a rating from 0 to 100 to indicate if it was at all possible that they may be mistaken in their belief. The Explanation of Experiences assessment [61] was then used to explore whether participants had any alternative explanations for the experiences contributing to their main paranoia belief.

**Well-Being**
The Warwick-Edinburgh Mental Well-Being Scale [62] was used to measure participants’ sense of well-being. This consists of 14 items, rated from 1 (none of the time) to 5 (all of the time), measuring the degree of positive emotions, fulfilling personal relationships, and sense of agency experienced by participants. A total score is derived, with higher scores indicating more well-being.

**Therapy Feedback**
A semistructured interview schedule was used after each therapy session and at the end of therapy to elicit feedback regarding acceptability, usefulness, and usability.

**Analysis**
Feedback interviews are summarized descriptively. As this case series was primarily conducted to support the design research and not powered to detect significant effects, the focus of the results is not on significance testing. However, to support comparison with our previous work, we report Cohen’s $d$ standardized effect sizes for continuous outcomes, calculated as the difference in the mean between 2 time points divided by the SD of the change.

**Inclusive, User-Centered Design Research**
An overview of the design research methods used at each phase of the double diamond is shown in Figure 1 and will be further described below.

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**Figure 1.** The design research methods used at each phase of the double diamond to develop SlowMo therapy.
Discover

The aim of this phase was to develop a shared understanding of psychological therapy, behavior change, psychosis, and technology use from the perspective of service users, carers, therapists, and clinicians. This phase is divergent in its approach as it explores the subject matter from a variety of viewpoints. It started with desk research covering empirical studies, self-help books, therapy manuals, lived experience narratives, computer games, and gamification. The lead designer (AW) did live and taped observations of the Thinking Well case series and, for comparison, taped observations of 2 cases of a therapy targeting anxiety processes in paranoia. In total, 6 service users were interviewed about topics, including their daily habits, therapy experiences, attitudes toward therapy, and technology preferences. Therapists were shadowed in their service contexts to gain insight into their roles and service user journeys through the system. Following these tasks, user profiles of prototypical service users and therapists were created, together with mapping of the contexts in which therapy is delivered. Methods for illustrating and visualizing thoughts and emotions were also explored to identify the most intuitive ways of communicating them. This included research into areas such as art, visual communication, symbolism, music, movement, and dyslexia.

Define

The define phase is convergent in its approach, aiming to refine and reframe the breadth of insights emerging from the discover phase. This consisted of workshops to synthesize the research insights into themes and identify the most salient areas for improving mental health care in psychosis. A matrix of service users’ and clinicians’ needs in relation to the therapy was developed, with each need rated according to potential impact and ease of implementation. On the basis of these insights, a design brief was developed, specifying the desired area of impact and aims for the redesign.

Develop

The develop phase resumed a divergent process, which focused on creating a wide range of ideas for addressing the design brief. At the beginning of the develop phase, concepts to address the design brief were generated, developed, evaluated, and refined by the project designers, technologists, and psychologists. Prototypes of the selected concepts were then made and validated with service users. Prototypes for different modalities of monitoring worries were also explored.

Deliver

The convergent deliver phase consisted of refining the breadth of concepts generated in the develop phase. The selected concepts for therapy redesign were finalized and storyboards were developed. The new version of the design was iteratively produced through rapid prototyping in software code, with user testing of a low fidelity version of the therapy redesign. This resulted in the final minimal viable product.

Results

Thinking Well Case Series

Forty-five service users were referred: 12 were unsuitable before screening, 4 declined to meet, 5 did not meet the cut-off score for paranoia, and 24 were suitable. Four service users disengaged between screening and consent, and 20 service users consented to participate. Of those consented, 6 disengaged during the baseline assessment. Fourteen participants were included in the case series, 2 dropped out, and 12 completed the intervention. One of the participants who dropped out experienced a relapse in mental state that was assessed as unrelated to participation in the study and the other disengaged from therapy. No other adverse events were reported. All participants who completed the intervention did the posttherapy assessment and 10 completed the 12-week follow-up assessment. One participant was not contactable as they had moved out of the area and the other was not able to attend because of new personal commitments.

The case series sample demographics are presented in Table 1 and the outcome data and summary statistics in Table 2. Inspection of the descriptive statistics and effect sizes indicates there were improvements in all measures post therapy and at follow-up, relative to baseline. These were in the medium to large range for paranoia and well-being, with small effects on reasoning variables. The results were maintained at follow-up, in contrast to our previous findings [23] where effects reduced at follow-up on all key outcomes. This suggests the extension of the therapy from 4 to 6 sessions was useful, together with an increased focus on multimedia content and normalizing accessible language. Table 3 shows themes arising from the therapy feedback, including experience of the therapy, strategies for feeling safer, and suggestions for improvement, with illustrative quotes. Participants indicated the therapy was helpful in supporting the learning of slow-thinking strategies, and they valued the digital presentation of materials in sessions. They also wanted less verbal information and more interactive and accessible content.

All participants were offered the opportunity to register to the website, which hosted the therapy Web pages. Of the 12 participants in the case series, all expressed an initial interest and 4 completed registration. Of these, 3 never accessed the Web pages and 1 person logged on once, with support from their therapist. Participants were asked about their reasons for not accessing the Web pages at the posttherapy assessment (see Table 4). Responses indicated that the website was too difficult to access because of it only being available on a computer, involving complex log-in instructions, and having an unappealing user interface. This suggested that although people were positive about the use of technology, the basic Web pages were not helpful in improving the therapy experience.

Table 1: Case series sample demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>N</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>85.71%</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>28.57%</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100%</td>
</tr>
<tr>
<td>Age range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under 20</td>
<td>1</td>
<td>6.25%</td>
</tr>
<tr>
<td>20-30</td>
<td>12</td>
<td>75%</td>
</tr>
<tr>
<td>30-40</td>
<td>3</td>
<td>18.75%</td>
</tr>
<tr>
<td>40+</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100%</td>
</tr>
<tr>
<td>Clinical diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosis</td>
<td>1</td>
<td>6.25%</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>75%</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>81.25%</td>
</tr>
<tr>
<td>Therapy type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive</td>
<td>12</td>
<td>75%</td>
</tr>
<tr>
<td>Dynamic</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>75%</td>
</tr>
</tbody>
</table>

Table 2: Outcome data and summary statistics

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pretherapy</th>
<th>Posttherapy</th>
<th>Follow-up</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paranoia</td>
<td>25.2</td>
<td>19.3</td>
<td>18.3</td>
<td>0.32</td>
</tr>
<tr>
<td>Well-being</td>
<td>10.2</td>
<td>13.3</td>
<td>12.3</td>
<td>0.53</td>
</tr>
<tr>
<td>Reasoning</td>
<td>1.2</td>
<td>1.1</td>
<td>1.0</td>
<td>0.01</td>
</tr>
<tr>
<td>Total</td>
<td>36.2</td>
<td>22.3</td>
<td>20.3</td>
<td>0.62</td>
</tr>
</tbody>
</table>

Table 3: Themes arising from the therapy feedback

<table>
<thead>
<tr>
<th>Theme</th>
<th>Illustrative quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience of therapy</td>
<td></td>
</tr>
<tr>
<td>Strategies for feeling</td>
<td></td>
</tr>
<tr>
<td>Safer</td>
<td></td>
</tr>
<tr>
<td>Suggestions for improvement</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Reasons for not accessing the Web pages

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty</td>
<td>3</td>
</tr>
<tr>
<td>computer</td>
<td>3</td>
</tr>
<tr>
<td>Log-in</td>
<td>1</td>
</tr>
<tr>
<td>Unappealing</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 1. Thinking Well case series sample demographics (N=12).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Statistics</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>43.83 (11.40)</td>
<td>N/A&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (42)</td>
<td>N/A</td>
</tr>
<tr>
<td>Female</td>
<td>7 (58)</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>7 (58)</td>
<td>N/A</td>
</tr>
<tr>
<td>Black British</td>
<td>2 (17)</td>
<td>N/A</td>
</tr>
<tr>
<td>Black African</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Afro-Caribbean</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Black Caribbean and white</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>9 (75)</td>
<td>N/A</td>
</tr>
<tr>
<td>Married</td>
<td>3 (25)</td>
<td>N/A</td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>8 (68)</td>
<td>N/A</td>
</tr>
<tr>
<td>Carer or housewife</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Employed</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Volunteer</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Student</td>
<td>1 (8)</td>
<td>N/A</td>
</tr>
<tr>
<td>SAPS&lt;sup&gt;b&lt;/sup&gt; positive symptoms, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hallucinations</td>
<td>2.23 (2.20)</td>
<td>0-5</td>
</tr>
<tr>
<td>Delusions</td>
<td>4.00 (0.58)</td>
<td>3-5</td>
</tr>
<tr>
<td>Bizarre behavior</td>
<td>0.08 (0.28)</td>
<td>0-1</td>
</tr>
<tr>
<td>Formal thought disorder</td>
<td>1.00 (1.16)</td>
<td>0-3</td>
</tr>
<tr>
<td>BNSS&lt;sup&gt;c&lt;/sup&gt; negative symptoms, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anhedonia</td>
<td>1.18 (1.20)</td>
<td>0-4</td>
</tr>
<tr>
<td>Lack of normal distress</td>
<td>0.31 (0.75)</td>
<td>0-2</td>
</tr>
<tr>
<td>Asociality</td>
<td>1.42 (1.66)</td>
<td>0-6</td>
</tr>
<tr>
<td>Avolition</td>
<td>1.23 (1.28)</td>
<td>0-4</td>
</tr>
<tr>
<td>Blunted affect</td>
<td>1.21 (1.23)</td>
<td>0-5</td>
</tr>
<tr>
<td>Alogia</td>
<td>0.65 (1.11)</td>
<td>0-4</td>
</tr>
</tbody>
</table>

<sup>a</sup>N/A: Not applicable.
<sup>b</sup>SAPS: Scale for the Assessment of Positive Symptoms.
<sup>c</sup>BNSS: Brief Negative Symptom Scale.
Table 2. Case series paranoia, well-being, and thinking habit outcomes.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n=12)</th>
<th>Post therapy (8 weeks; n=12)</th>
<th>Follow-up (12 weeks; n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistics</td>
<td>Cohen d</td>
<td>Statistics</td>
</tr>
<tr>
<td>GPTS\textsuperscript{a}, mean (SD)</td>
<td>105.50 (17.40)</td>
<td>91.33 (28.49)</td>
<td>0.59</td>
</tr>
<tr>
<td>VAS\textsuperscript{b} distress, mean (SD)</td>
<td>79.58 (16.16)</td>
<td>61.67 (34.00)</td>
<td>0.61</td>
</tr>
<tr>
<td>VAS preoccupation, mean (SD)</td>
<td>70.58 (25.46)</td>
<td>62.92 (30.56)</td>
<td>0.50</td>
</tr>
<tr>
<td>WEMWBS\textsuperscript{c}, mean (SD)</td>
<td>39.13 (2.80)</td>
<td>42.55 (7.84)</td>
<td>0.71</td>
</tr>
<tr>
<td>VAS conviction, mean (SD)</td>
<td>75.42 (29.65)</td>
<td>56.83 (32.91)</td>
<td>0.67</td>
</tr>
<tr>
<td>VAS possibility of being mistaken\textsuperscript{d}, mean (SD)</td>
<td>36.36 (37.69)</td>
<td>41.75 (35.78)</td>
<td>0.12</td>
</tr>
<tr>
<td>Number with ≥1 alternative explanations, n (%)</td>
<td>4 (33)</td>
<td>6 (50)</td>
<td>N/A\textsuperscript{e}</td>
</tr>
</tbody>
</table>

\textsuperscript{a}GPTS: Green Paranoid Thoughts Scale.
\textsuperscript{b}VAS: Visual Analog Scale.
\textsuperscript{c}WEMWBS: Warwick-Edinburgh Mental Well-Being Scale; baseline: n=8, post: n=11, follow-up: n=9.
\textsuperscript{d}Baseline: n=11.
\textsuperscript{e}N/A: not applicable.

Table 3. Case series therapy feedback.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience of therapy interface</td>
<td>“More helpful than talking therapy because it had the computer programme. I felt comfortable rather than worried I wouldn’t know what to say.”</td>
</tr>
<tr>
<td></td>
<td>“Videos, liked the visual representation of how events can change mood and thinking.”</td>
</tr>
<tr>
<td></td>
<td>“Comfortable. I’m not too good at talking but with someone who knows what they’re talking about it helps bring it out.”</td>
</tr>
<tr>
<td></td>
<td>“Don’t like the writing—I prefer the therapist to write.”</td>
</tr>
<tr>
<td></td>
<td>“I found it quite hard because I had to think more.”</td>
</tr>
<tr>
<td>Strategies for feeling safer</td>
<td>“Using the coping cards, photographing them so I have them on my phone. Trying to practise to keep it in mind.”</td>
</tr>
<tr>
<td></td>
<td>“Looking for evidence, trying to think outside the box and looking for alternatives.”</td>
</tr>
<tr>
<td></td>
<td>“Slowing down and thinking that it could be something else.”</td>
</tr>
<tr>
<td></td>
<td>“Dwelling less, doing more with friends and family, slowing down, and looking for more information.”</td>
</tr>
<tr>
<td></td>
<td>“The suspicions come up, but they don’t escalate cause I’ve got tools I can reach for.”</td>
</tr>
<tr>
<td>Suggestions for improvement</td>
<td>“More videos—they are a good visual aid and more relatable.”</td>
</tr>
<tr>
<td></td>
<td>“Getting people together to say what they’ve learnt, even just at the end.”</td>
</tr>
<tr>
<td></td>
<td>“Oyster card wallet that contains the cards to help people remember the coping strategies.”</td>
</tr>
<tr>
<td></td>
<td>“More interactive things and more interactive scenarios to help practise other explanations.”</td>
</tr>
<tr>
<td></td>
<td>“Examples of other people’s past experiences and how they affect them.”</td>
</tr>
</tbody>
</table>

Table 4. Case series Web pages feedback.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware accessibility</td>
<td>“They were too difficult to access, the website was only available on a computer and I don’t have one.”</td>
</tr>
<tr>
<td></td>
<td>“It was too much effort to go to the drop-in sessions that the trust hosted to use the website.”</td>
</tr>
<tr>
<td>Software accessibility</td>
<td>“It meant finding the handouts, getting to a computer, and writing in the address to access the website, as well as a number of instructions just with the welcome pack, it’s asking a lot of effort.”</td>
</tr>
<tr>
<td></td>
<td>“The password got sent separately by post, I lost it.”</td>
</tr>
<tr>
<td></td>
<td>“It was difficult to remember how to use.”</td>
</tr>
<tr>
<td>User interface</td>
<td>“Interface was not user friendly or self-explanatory. Finding things on the page was difficult even once I’d managed to login.”</td>
</tr>
</tbody>
</table>
Design Research

The key insights and outputs from each phase of the double diamond will be described below. There were 18 participants in the design research sample. The sample included all the participants who completed the case series, the participants who disengaged from the case series, and 5 participants who were purposively recruited to improve the extent to which the sample represented the extremes of our target sampling characteristics (ie, demographics, digital literacy, cognitive abilities, and relationship to therapy). The sample included 9 (9/18, 50%) men and 9 (9/18, 50%) women (age range 23-62 years). Seven (7/18, 39%) participants were white British, 3 were black Caribbean (3/18, 17%), 2 were black African (2/18, 11%), 2 were black British (2/18, 11%), 2 were white British and black Caribbean (2/18, 11%), 1 was white British and black African (1/18, 6%), and 1 was white British and black Caribbean (1/18, 6%). On the basis of their self-report and presentation during the design research tasks, 2 (2/18, 11%) participants appeared to have above-average cognitive abilities, 7 (7/18, 39%) participants had average cognitive abilities, 5 (5/18, 28%) participants had mild difficulties with attention, reasoning, and memory (often because of psychotic experiences), and 4 (4/18, 22%) participants had moderate to severe difficulties in these areas. In relation to digital literacy, 2 (2/18, 11%) participants had minimal experience of using technology, of whom 1 was interested in developing their skills and 1 was not. Seven (7/18, 39%) participants used a basic mobile phone, of whom 3 were not confident in using. Nine (9/18, 50%) participants had experience with smartphones and laptops, including 7 frequent and competent users and 2 who were not confident in using and wished to improve their skills. With regard to attitudes to therapy, 11 (11/18, 61%) participants viewed therapy as both supportive and useful. In addition, 4 of these reported no difficulty in applying insights to daily life and 7 reported struggling to generalize strategies outside of therapy because of the intensity of their distress, memory problems, motivation, social stressors, and physical health problems. The remaining 7 (7/18, 39%) participants were ambivalent about therapy usefulness either because they were unsure of its relevance to their problems or struggled with its reliance on verbal material and paper tools. Involvement in the design research tasks varied across participants, 6 participants were interviewed, 15 had either live or taped observations of their therapy sessions, and 4 participants were involved in prototype testing.

Discover

Multimedia Appendix 2 contains the processes and outputs during the discover phase, including process map of therapy sessions, mapping of the broader multidisciplinary service context, service user journeys, user profiles, a mood board reflecting the communication of thoughts and emotions, and a table summarizing the 5 salient themes arising from this phase, illustrated by comments from the participant interviews. These 5 themes were validated against the insights arising from the therapy observations, service shadowing, and context mapping.

The first theme concerned challenges to the usability of therapy. Service users and therapists struggled to manage information processing and communication demands, given the amount and complexity of the therapy materials. This limited the potential impact of therapy on people’s lives. As a result, adaptations were made to make the materials more concise and accessible, such as personalizing the content and using mobile phones to record therapy strategies. The second theme related to technology use. Concerns about digital literacy and privacy were frequent, although these often occurred alongside a desire to integrate technology into therapy and improve digital skills. A wish to progress and to document achievements using technology was also highlighted. Enjoyment was the focus of the third theme, with a consensus that interactive, gamified tasks and visual materials were the most enjoyable aspects of therapy. The next theme related to the therapy relationship. Feedback in this area reflected some people valuing the support from their therapist, with others being less committed to or avoidant within the relationship. The final theme was about interpersonal support from others experiencing similar difficulties. Service users varied as to what level of support they would find useful, ranging from accessing previously recorded stories and suggestions to more active involvement in digital or face-to-face support groups.

Define

The define phase involved defining the design brief based on the insights from the discover work. A number of possibilities for the therapy redesign were identified, including family and carer involvement, social inclusion, peer support, and self-help. The areas of impact that appeared most relevant to improving usability were optimizing therapists’ and service users’ time within and between sessions and improving self-monitoring and self-management in daily life. The design brief was then generated by identifying the factors that could limit how useful the therapy was during and outside of therapy sessions (ie, the problem paradox). The design brief, therefore, specified that we aimed to develop a digital platform to support the therapy process by:

1. Supporting people to notice their thoughts and thinking habits
2. Presenting information in a simple and memorable way
3. Being enjoyable and trustworthy
4. Promoting personalization and normalization
5. Helping people feel more supported and independent

Develop

Multimedia Appendix 3 illustrates the key processes and outputs during the develop phase, including concept generation, concept development, concept evaluation, narrative prototypes, modality prototypes, and participants’ feedback on the prototype testing. The develop phase commenced with creative workshops involving clinicians, industrial designers, and game developers. On the basis of the design brief, we generated concepts for optimizing each therapy session and the time between sessions. Sixty concepts were suggested, which were grouped by theme by:

- Rating each concept according to its potential impact on the therapy process
- Selecting concepts based on participant feedback and expert feedback
- Refining concepts based on user feedback and expert feedback

The developed concepts were then rated according to ease of implementation, likely impact, and appeal. On the basis of these ratings, 3 concepts were selected for narrative prototype testing.
These concepts were bubbles, where thoughts are visualized as bubbles that can be influenced by our actions; journey, where therapy is framed as an incremental process with challenges and achievements; and interaction, which focused on providing simple and habitual tools for dealing with worries.

The selected concepts were prototyped digitally and validated by presenting them to participants on a tablet. The validation process focused on both participants’ verbal reports and their behavior in relation to the prototypes. The concept of illustrating thoughts as bubbles resonated strongly. Participants displayed positive affect and approach behavior responses. Importantly, with regard to the aims of psychological therapy, the metaphor helped them see their thoughts as transient and separate from the self. They noted that bubbles could have different sizes depending on their intensity and that their movement, speed, and color could reflect different thinking patterns and styles. Participants also liked the idea of therapy represented as a journey, where each session is characterized by new experiences guided by their digital avatar who interacts with other characters along the way. The interaction prototype was less appealing to users who had a neutral or confused affective response and commented that it felt too abstract and oversimplified their problems. Bubbles and journey were therefore selected as the design concepts for framing the therapy redesign.

The second prototype testing explored the uptake and usability of different modalities for monitoring thoughts (text questions, camera, voice recorder, and counter) using a design probe. Participants were given a basic smartphone with the prototype installed for them to use over a week. They were told to use the prototype as they wished to explore if and how they engaged in using the smartphone to monitor their worries. At the end of the testing period, daily data indicated 87% (24/28) usage for the text questions, 50% usage for the voice recorder and counter (14/28), and 34% (10/28) for the camera. This suggested a preference for simple text as the main monitoring modality, although it was notable that the voice recorder and counter were also used, despite being considerably harder to access on the phone’s interface. In addition, participants reported a mean rating of 73% for enjoyment, 61% for usability, and 85% for acceptability on a 10-item User Experience Survey (adapted from [49]) designed specifically for the testing. Participants’ feedback showed that monitoring was viewed as valuable, enjoyable, and easier in digital modality than using pen and paper materials. Unsurprisingly, given the basic and unintuitive handset, participants noted the prototype was quite difficult to use. There were further concerns about privacy and impact on paranoia. All participants wanted more support from the phone to manage their worries.

**Deliver**

**Wireframe Storyboard Development**

In the deliver phase, wireframe storyboards of the session and out-of-session content were developed based on the selected concepts and then iteratively coded alongside user testing. All the session content from Thinking Well was incorporated, with a redesigned interface and functionality. An analogue aesthetic (ie, life-like illustration) was used throughout to provide an accessible and friendly design for people less willing and able to use technology. The use of written text was significantly reduced and replaced with short audio files or simple visual displays. Haptic interactions were used, where possible, to promote engagement, enjoyment, and memorability. The mobile app was designed so that people could use it without the keyboard if they wished, improving accessibility for those less digitally literate. The flow through the interface was designed to increase the likelihood of sustained engagement and completion of therapeutic tasks. For example, next buttons were made more visually salient than back or exit buttons so that users were more likely to tap them and sustain their engagement.

Rapid prototyping and testing also explored the aesthetic of the bubbles used to visualize thoughts and thinking habits, given that they represented a unifying visual language in the therapy. On the basis of the design research insights, a balance was sought between an appealing appearance that increased the likelihood of people wanting to use it and a wish not to invalidate their concerns. It was anticipated this would help people to see their thoughts as less threatening and separate from themselves. Visual attributes (eg, size, movement, and color) and ways of interacting with the bubbles (eg, scaling, tapping, moving, and popping) were investigated as a way of communicating information about the nature of thoughts and how we can relate to them. It was decided that the size of the bubble would reflect the intensity of the thought, whereas the speed at which it spins would illustrate the associated thinking habit. Worries are shown as gray bubbles, safer thoughts or other strategies for feeling safer are displayed as colored bubbles, and worries that the person has slowed down are given a colored halo. A finger tap was chosen for selecting a thought and its color, with scaling used to alter the bubble size or spinning speed.

The therapy name, SlowMo, was the product of a brainstorming workshop with designers, psychologists, and software developers. Workshop participants were given the aim of finding a name that would appeal to both service users and therapists, that communicated the essence of the therapy, that was phonetically engaging and memorable, and that could function within the clinical context (eg, when clinicians were referring service users or in therapy discharge reports). Popular digital brand names were reviewed for inspiration, and name concepts were generated based on the themes of care and compassion, feeling safe and calm, and tools and superpowers. Over 200 concepts were developed; each participant selected their favorites, which were then reviewed. SlowMo was selected, supported by the tagline slow down for a moment.

**SlowMo: Minimal Viable Product**

The main screens from the SlowMo Web app and mobile app are shown in Figures 2 and 3, respectively, with further details provided in Multimedia Appendices 4 and 5. The wiredframe storyboards were iteratively coded alongside user testing to produce the minimal viable product. SlowMo consists of 8 individual, face-to-face sessions, lasting 60 to 90 min, which are supported by a Web app delivered on a laptop or tablet. When a person starts therapy, a unique user profile is set up, which is linked to an identification code. No personally identifiable information is required by the system. The
identification code allows the user-entered data to be stored on the Web app, which are then synchronized during sessions to a native, android app for use in daily life. It was decided to use the identification code and native app as a way of minimizing concerns about privacy and security. People may also choose to not link the app to their user profile so that no data are transferred. Another advantage of the native app is that it minimizes financial costs as no internet connection is required, ensuring it has minimal provider costs and is thus accessible to low-income users.

**Figure 2.** Main screens from the SlowMo Web app (from left to right, top to bottom): journey screen for navigating the sessions, aims screen, worries formulation, safer thoughts formulation, animated screen providing psychoeducation, avatar screen providing normalizing stories, example task for slowing down thoughts, and prompt screen for in-session practice of the app.
Figure 3. Main screens from the SlowMo mobile app: A) The home screen displays worries and safer thoughts; B) When experiencing a worry, the app encourages the user to slow down for a moment and provides tips to support finding safer, alternative thoughts; C) The app provides easy access to users’ personalized safer thoughts and helpful tips.

SlowMo Web App: Minimal Viable Product

The Web app has a fixed structure to support fidelity and adherence, although content can be skipped to allow tailoring of the material to the person’s cognitive needs. The journey concept is used to anchor the therapy. During set-up, people select an avatar to represent them on their therapy journey and input a chosen name. The home screen then displays the person’s
journey through therapy from which individual sessions can be accessed. The journey home screen also contains a destination signpost where people enter their personal valued goal for the therapy. As with previous versions of the therapy, initial sessions involve building the meta-cognitive skill of noticing thoughts and thinking habits. People learn that although fast thinking is common and can be useful, slow thinking can be helpful in dealing with stress and worries about other people. This principle is expanded in subsequent sessions by covering a new topic area and a related slow down for a moment tip. The topics from sessions 1 to 8 are notice your thoughts; notice your thinking habits; slow down for a moment; slow down: what is your safer thought; use a safety strategy; slow down: past experiences; slow down: pop the worry; and making a habit of slowing down. With some exceptions in sessions 1 and 8 for initial and final tasks, sessions follow a consistent format of monitoring progress, reviewing the formulation (ie, an overview of triggers, worries, impact of worries, and alternative safer thoughts), collaborative agreement of session aims, psychoeducation, normalization, experiential tasks to personalize learning, recording of key learning, practice with the SlowMo native app, and documenting a goal for the week.

The interface for these tasks was developed in line with the design brief. Progress is monitored through scaling the visual appearance of bubbles (size for intensity, spinning speed for thinking habit, and transparency for conviction) to be more appealing and reduce the reliance on numerical rating and graphs. A formulation of people’s difficulties detailing triggers, worries, impact on life, and helpful thoughts and strategies is developed in session 1 using the visual language of bubbles. This is pulled through to remaining sessions and can be easily updated as new insights, difficulties, and ways of coping emerge. The potential aims are communicated through interactive boxes that are tapped to reveal their content to be more engaging and memorable and provide a shared understanding of the session structure. Psychoeducation information is presented with brief audio messages paired with illustrative animations. Three characters with prototypical experiences of paranoia share their stories as the therapy progresses. Their function is to provide normalizing messages about fears of harm from others (eg, that they are common in the general population) and to model how the SlowMo tips can be used to make sense of worries and feel safer. Experiential learning tasks are designed to optimize personalization and implementation in daily life, for example, by exploring the impact of fast thinking on daily life or by practicing the application of the SlowMo tips to worries selected from the formulation. Text or audio recordings are then made of the most important learning points from the session and of a note outlining a goal or key message for the week to support the person in making use of the therapy strategies. The learning messages are pulled through to the final session to support a personalized review of the therapy, from which the individual can choose a customized selection of the SlowMo tips for use after the end of therapy.

**SlowMo Native App: Minimal Viable Product**

There is an emphasis throughout the intervention on practicing skills inside and outside sessions, with the SlowMo native app providing a bridge between the therapy meetings and everyday life. The app works by unlocking new content toward the end of each session, based on the learning topic covered in the Web app. This new content is reviewed in session, and where possible, the therapist supports the person to practice the use of the app outside the consulting room. The home screen has 2 viewing modes, one displaying worries and the other feeling safer thoughts and strategies. In the first session, the home screens automatically populate from the data inputted to the Web app formulation, which consists of the person’s worry bubbles. People are then encouraged to use the app to identify their worries over the next week. When they experience a worry, they tap the associated bubble to record its occurrence and then size the bubble to indicate how distressing it is. An additional screen is unlocked on the app during session 2, where the thinking habit associated with the worry is rated by spinning the bubble faster or slower. From session 3, a slow down screen is added to the process, which displays a spinning bubble. This slows down when tapped, to act as a cue to slow down for a moment to manage worries. From session 4 onward, additional strategy prompts or tips are provided on this screen based on the topic covered in the session. When a user selects a tip, a halo corresponding to the tip color appears around the gray worry bubble, providing visual feedback that a helpful slowing down idea has been identified. Following the slow down screen, there is an option to record useful new information by way of audio or text and then select an alternative safer thought or strategy. The user finally rerates the distress associated with the worry to evaluate the impact of slowing down.

Data are stored in a format whereby, when experiencing recurrent concerns, people can readily access what was previously helpful. When a worry is tapped on the home screen, this will initially access a thought profile page from which users can either enter the slowing down process or see a summary of previous occasions when they have slowed the thought down (ie, the selected tip, information recording, safer thoughts, and pre- and postdistress rating). Another option is to access a list of all the tips that have been liked in relation to the thought. In addition, the burger menu of the app sequentially unlocks a brief summary of each session (under a My journey option) to act as an aide memoir for session content (ie, the slowing down tip, the message to self, the most important learning point, and monitoring ratings). The burger menu also consists of settings, where the offline mode can be selected, and at the end of therapy, an option is unlocked to allow the selection of slowing down tips. The burger menu also contains an About SlowMo section that briefly details the background to the development of SlowMo and privacy and security information. A My safety plan section advises users what to do in a crisis and provides an option to insert crisis contact numbers. Finally, optional notifications are available if people wish the app to provide prompts to encourage slowing down.

**Technology Platform**

The software development work was done by Evolyst Ltd, a user-centered and evidence-based health care software development company, informed by the British Standards Institute quality criteria and code of practice for health care apps [63]. SlowMo uses a proprietary software platform developed using an Azure-based Windows Communication Foundation.
Web Service, acting as an Application Programming Interface to a Model View Controller Asp.Net Web app, and a Xamarin.Android-based mobile app, allowing for use of the full Microsoft Stack and negating interoperability issues. SlowMo has currently been developed as a standalone product, given the lack of consensus on operating systems across the NHS trusts and current interoperability issues.

Discussion

Principal Findings

This study is the first to employ inclusive UCD methods within a design thinking approach to optimize the usability of an existing therapy for psychosis, Thinking Well. In the case series of a newly extended version of Thinking Well, we found indications of sustained medium to large effects on paranoia and well-being and small effects on reasoning post therapy and at 12-week follow-up. However, obstacles to the intervention interface were noted, underscoring the need for the design research. The inclusive UCD research identified the importance of therapy being usable, memorable, trustworthy, enjoyable, personalized, and normalizing, and of it offering flexible interpersonal support [27,37-39,42-44]. This led us to develop SlowMo, a blended digital therapy consisting of an intuitive Web app to augment the experience of face-to-face therapy sessions, which is synchronized with a native mobile app for use in daily life. By adding an app to the therapy, we hope to optimize its reach beyond the consulting room. SlowMo therapy is presented as a journey that supports people to notice the large, fast spinning, and gray worry bubbles that fuel distress and makes use of slow spinning and colored bubbles to shrink fears and feel safer. The use of personalization, ambient information, and visual metaphors provided a step change in therapy delivery to assist learning, monitoring, and management [36-37]. The application of inclusive UCD to the therapy interface may improve adherence, thereby increasing the likelihood of delivering benefit in real-world settings [64]. However, SlowMo requires further testing of its usability and usefulness. A feasibility study of the native app has been completed, with promising findings, while SlowMo’s overall effectiveness and the adherence and usage of both the Web app therapy sessions and the mobile app are currently being investigated in a multicenter, randomized controlled trial [23].

Limitations and Future Directions

An important limitation of the study is the lack of integration of an implementation strategy within the therapy design. This is critical, given that most health technologies fail to be adopted, scaled-up, spread, and sustained, even where they are efficacious in randomized controlled trials [65]. The tailoring of the SlowMo design to its specific target problem, a range of intended users, and the delivery context may support initial adoption, together with the progress made in establishing its value proposition to stakeholders and technological requirements. However, even if SlowMo is found to be sufficiently usable and useful in our trial, there are significant challenges to it being embedded in health service care pathways across organizations, which will need to be tackled for successful implementation.

We therefore do not consider SlowMo to be a finished product, but rather a nascent behavioral intervention technology [66] or technology-enabled service [67]. The fundamental cognitive and behavioral principles of SlowMo will not change, given the theoretical underpinning and the robust findings from our previous empirical work [17]. However, we are developing the therapy interface iteratively, in the context of this trial, with the aim of moving toward a sustainable service. At this stage, we have funding for relatively minor and incremental changes. However, dependent on the trial outcomes, there are several target areas for further innovation, which may involve additional behavior change methods and technologies (eg, embodied conversational agents, online support groups, instant messaging, wearable biofeedback, and gamification) [68-71]. From an agile science perspective, SlowMo could be implemented as a module within a broader digital therapy platform for psychosis [42,72] or adapted for a range of other difficulties and settings. Its innovative redesign of a thought record, a widely used CBT tool, could be repurposed for other mental health difficulties. We are currently testing the feasibility of a stand-alone version of the app, Mo, to support stress management and well-being in the general population.

Conclusions

In conclusion, this study is the first to demonstrate how an inclusive UCD method (which privileges the involvement of a wider range of service users than in conventional participatory design) can enhance the usability of therapy and augment developments in psychological theory and interventions. We hope that our study may serve as a prototypical example of how design thinking can challenge skeuomorphism in digital health, whereby therapy features made redundant by technology are unnecessarily replicated (eg, digitally replicating pen and paper tools such as thought records) instead of facilitating psychological mechanisms of change through innovative digital means. Notwithstanding the hugely valuable progress made over the past 2 decades in psychological therapy for psychosis [1], we echo recent calls to shift the frame of therapy radically to address the fundamental paradox that evidence-based psychological interventions are often not sufficiently helpful to bring about meaningful change [39,64,66,73]. We recommend the adoption of inclusive, UCD methods to develop novel digital solutions that embed psychological principles into daily life.

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Conflicts of Interest
None declared.

Multimedia Appendix 1
Screenshots of the Thinking Well therapy.

[PDF File (Adobe PDF File), 3MB - mental_v5i4e11222_app1.pdf ]

Multimedia Appendix 2
Design research processes and outputs from the discover phase.

[PDF File (Adobe PDF File), 5MB - mental_v5i4e11222_app2.pdf ]

Multimedia Appendix 3
Design research processes and outputs from the develop phase.

[PDF File (Adobe PDF File), 3MB - mental_v5i4e11222_app3.pdf ]

Multimedia Appendix 4
Screenshots of the SlowMo webapp from the deliver phase.

[PDF File (Adobe PDF File), 2MB - mental_v5i4e11222_app4.pdf ]

Multimedia Appendix 5
Screenshots of the SlowMo app from the deliver phase.

[PDF File (Adobe PDF File), 11MB - mental_v5i4e11222_app5.pdf ]

References


Abbreviations

BNSS: Brief Negative Symptom Scale

CBT: cognitive behavioral therapy

CBT-p: cognitive behavioral therapy for psychosis
GPTS: Green Paranoid Thoughts Scale
NHS: National Health Service
SAPS: Scale for the Assessment of Positive Symptoms
UCD: user-centered design
VAS: Visual Analog Scale
A Web-Based Intervention for Relatives of People Experiencing Psychosis or Bipolar Disorder: Design Study Using a User-Centered Approach

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Abstract

Background: Relatives of people experiencing bipolar mood episodes or psychosis face a multitude of challenges (eg, social isolation, limited coping strategies, and issues with maintaining relationships). Despite this, there is limited informational and emotional support for people who find themselves in supporting or caring roles. Digital technologies provide us with an opportunity to offer accessible tools, which can be used flexibly to provide evidence-based information and support, allowing relatives to build their understanding of mental health problems and learn from others who have similar experiences. However, to design tools that are useful to relatives, we first need to understand their needs.

Objective: The aim of this study was to use a user-centered design approach to develop an accessible Web-based intervention, based on the Relatives Education And Coping Toolkit (REACT) booklet, to support the informational and emotional needs of relatives of people experiencing psychosis or bipolar disorder.

Methods: We engaged relatives of people with experiences of bipolar disorder or psychosis in workshops to identify their needs and design requirements for developing a Web-based version of a paper-based toolkit. We used a 2-phase qualitative approach to explore relatives’ views on content, design, and functionalities, which are considered to be engaging and useful in a Web-based intervention. In phase 1, we consulted 24 relatives in 2 workshops to better understand their existing support infrastructure, their barriers for accessing support, unmet needs, and relatives’ views on online support. On the basis of the results of these workshops, we developed a set of design considerations to be explored in a smaller workshop. Workshop 3 then involved working with 2 digitally literate relatives to design a usable and acceptable interface for our Web-based toolkit. Finally, in phase 2, we conducted a heuristic evaluation to assess the usability of the toolkit.

Results: Our findings indicated that relatives require technologies that (1) they can place their trust in, particularly when discussing a highly sensitive topic, (2) enable learning from the lived experiences of others while retaining confidentiality, and (3) they can work through at their own pace in a personalized manner.

Conclusions: Our study highlights the need for providing a trustworthy, supportive tool where relatives can engage with people who have similar experiences to their own. Our heuristic evaluation showed promise in terms of perceived usability of the REACT Web-based intervention. Through this work, we emphasize the need to involve stakeholders with various characteristics, including users with limited computer literacy or experience in online support.

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Introduction

Background

Psychosis is an umbrella term that covers many different conditions, the common feature of which is a loss of touch with reality. The most common way this manifests is being believing things that are generally accepted to be untrue by other people (often called delusions); not being able to think straight, thus sounding very muddled and confused (often called thought disorder); experiencing things that are not actually happening, for example, hearing or seeing things that other people cannot (often called hallucinations).

Along with the presence of these unusual experiences, many people with psychosis also report a loss of valued experiences, most notably, pleasure in everyday activities (anhedonia) and loss of motivation (apathy). These losses are sometimes referred to as negative symptoms and are particularly challenging for relatives: not least because they are hard to differentiate from normal teenage angst, side effects of medication, or depression. It is difficult to report exact figures on the number of people who will experience psychosis as many may never have contact with mental health services. However, most recent estimates include worldwide incidence at approximately 1 in 13 people (7.7%; [1]) and up to 10% in the United Kingdom [2]. Only a fraction of these people will come into contact with mental health services and receive a diagnosis of a mental health condition. In general, these are likely to be people for whom these experiences are particularly distressing or cause significant changes in behavior.

Bipolar disorder (BD) is the third most common mental health cause of disability globally [3], affecting 1% to 4.5% of adults [4] and costing the English economy £5.2 billion annually, largely because of inadequate treatment [5]. BD is characterized by episodes of extreme low mood (depression) and extreme high or irritable mood (mania or hypomania in its milder form). Challenging behaviors such as increased self-harm and suicidal behavior, excessive financial spending, sexual disinhibition, and heightened irritability can all escalate during mood episodes, and psychotic symptoms are also more likely to occur. Between episodes, functioning may return to normal levels, although many people do report problematic subsyndromal levels of depression, which impact on their functioning and relationships [6].

Both psychosis and BD present significant challenges to relatives, particularly in recognizing and understanding what is happening, living with the elevated risk of suicide, the impact on relationships within the family, and having to balance commitments such as caring and work.

First episodes usually appear in adolescents, at which point the individuals are still living with families [7]. In this study, we refer to the wider community of partners, friends, family, and caregivers as relatives, as this was deemed to be the most inclusive term without assuming the nature of the relationship.

Relatives play a significant role at all stages of recovery; however, this unrecognized caregiving role can have adverse effects on relative’s psychological well-being, relationships, finances, employment, and quality of life [8-13]. Due to societal stigma related to mental health, relatives may struggle to seek help or to share their feelings and lived experiences with others [14]. This can result in isolation and loneliness and can influence their capacity to cope as well as to affect their own mental health [15].

The family unit affected by BD and psychosis-like experiences can benefit from information and educational support on how to support their relative [16]. Family intervention is used to involve all members of the family to discuss how such experiences affect the family unit and individual relationships. The aim of family interventions is to identify changes and strategies that could improve coping strategies of family members and establish a better family relationship. Family interventions require a trained member of staff to meet with family members face-to-face on a regular basis and have shown to be effective in reducing relapse rates for people with mental health problems [17,18] and improving the relative’s well-being [19]. However, delivering a family intervention through health and social care services can be challenging because of the (1) practical difficulties in gathering all family members in 1 room during working hours because of work and family commitments, (2) costly nature of face-to-face model, and (3) lack of resources in services [20]. The rates of implementation for family interventions in the United Kingdom vary from 0% to 53% [20], is up to 15% in Western Europe, and only about 10% of families receive family intervention in the United States [21].

Relatives Education And Coping Toolkit Booklet (REACT)

To improve delivery of family intervention, we consulted relatives about the key challenges they faced and what kinds of support they most needed [22]. The outcomes of the consultation process informed the design of the Relatives Education And Coping Toolkit (REACT) booklet. The REACT booklet is an informative modular toolkit, which draws on key elements of family intervention, and can be used by relatives directly without the involvement of other family members or extensive service support. The REACT modules include information on managing symptoms, managing difficult behavior, coping with their own stress, information about medication, and understanding mental health services. The REACT booklet has shown to be effective during a randomized controlled trial (RCT; N=103) [23]. Those who had access to the REACT booklet in addition to usual treatment showed reduced distress, increased perceived support, and increased perceived ability to cope compared with controls with access to usual treatment only [24].

Digital as a Vehicle for Providing Support

Despite the success of the printed REACT booklet, there are several limitations that the use of digital tools can address: (1) scalability both in terms of cost and access; (2) updating the information while health and social care services are constantly
changing; and (3) booklets tend to be more generic and limited in scope. As we have progressed into the digital age, the provision of health and social care services has moved toward online models, which has, in turn, improved access for a wide variety of patient and caregiver groups [25-27]. Digital platforms that provide support for mental health have also proven to be successful and cost-effective [28-31] as they offer flexibility, accessibility, inclusivity, and anonymity, which can be appreciated in a stigmatized mental health context [32]. Therefore, we aimed to develop a Web-based version of the REACT booklet. In this paper, we describe a qualitative study that used a user-centered approach to design a widely accessible REACT Web-based intervention.

**User-Centered Approaches in the Design of Digital Health Interventions**

Research suggests that effectiveness of Web-based health interventions correlates with users’ level of engagement [33-35]. However, attrition is a common problem across digital health technologies [36-38]. The importance of investigating approaches to improve user engagement has been highlighted in the literature [39], with the use of incentives [40] and prompts [41] identified as being methods of increasing engagement. The importance of taking users’ perception into account in the design of the content of Web-based interventions is needed to ensure (1) relevancy of content to their lived experiences, (2) consistency with their values, and (3) that the content provides additional benefit [42]. As such, the employment of user-centered methods, which aim to understand end users’ needs and values throughout the lifecycle of design, development, and evaluation, intended to improve user engagement [43]. Although the literature highlights the importance of user-centered design [44-49], using this approach in a mental health context can be challenging in terms of recruiting participants and understanding the lived experiences of those affected by mental health conditions [50,51].

In this paper, we present the results of our qualitative study. First, we conducted 2 workshop sessions with 24 relatives. These workshops aimed to understand (1) the current infrastructure (eg, the lived experiences of relatives and what support is currently available for them), (2) the barriers (eg, the main challenges for accessing existing support), and (3) the gap (eg, the support currently missing from the care system). This was followed by a workshop involving 2 relatives. This workshop aimed to verify and expand on the findings from the first 2 workshops and further explore the features that needed to be considered in the design of a supportive Web-based toolkit for relatives. Second, we conducted a small heuristic evaluation of a design prototype to better inform our final set of requirements. However, we focus the majority of our study on reporting the experience-driven needs and values that participants shared during our design process. The specific challenges faced by our participants, who were mainly older parental relatives of people with mental health problems, can be used as a starting point toward understanding how we might design inclusive and accessible digital interventions to support this complex user group. In this paper, the term participants is used when discussing relatives who took part in our study.

Through this study, we contribute (1) insight into the needs of relatives and their concerns about Web-based interventions intended to provide information and support, (2) a pragmatic example of a user-centered approach in designing a Web-based intervention, including the complexities of engaging a representative sample of full-time relatives in the discussion of highly sensitive topics, and (3) a set of design considerations for the development of a Web-based toolkit to support the informational and emotional needs of relatives.

**Methods**

**Phase 1 Method: User-Centered Approach**

In accordance with our ethics approval from Lancaster National Research Ethics Service Committee (15/NW/0732), participants were invited to take part in our study if they identified as a relative or close friend involved in supporting someone with BD or psychosis-like experiences. Our recruitment strategy involved advertising locally to obtain a convenience sample who would be able to attend face-to-face workshops. An email advertisement was circulated through the Lancaster University’s Spectrum Centre, which specializes in conducting research in BD and psychosis. Once participants indicated interest in taking part, an information sheet was sent by an email or post before attending the workshop to allow them to make an informed decision about attending and ask any questions in advance. Participants were offered a £20 Amazon voucher as an appreciation for their time and input. Each workshop was audio-recorded with participants’ permission and transcribed verbatim for later analysis (approach described below in the section Data Analysis). A total of 25 participants took part in this qualitative study. Although we aimed to recruit participants from a diverse demographic background in terms of age, gender, and relationship with the person with a mental health problem, the length of time being a relative, and computer literacy, the participants were predominantly female (18 females), over the age of 65 years (age range 21-75 years), parents (n=20), and infrequent computer users. Most participants had many years of experience of caring for their relatives (on average, approximately 10 years).

**Phase 1 Design Workshops**

**Workshops 1 and 2**

We conducted 2 workshops with 13 participants in workshop 1 and 11 participants in workshop 2 (total n=24), which lasted for 2 hours each. Two researchers facilitated the workshops using a semistructured topic guide to lead the discussions and asking open questions to elicit a range of views. Our aim was to better understand the relatives’ needs, their context of use, and how they may, or may not, engage with online support in their caring role. First, the participants were encouraged to reflect and share their lived experiences as relatives of someone with a mental health problem, including how their relative was first diagnosed, how they became involved as relatives, the impact of mental health problems on their family unit and daily life, their current support-seeking practices, and any specific type of support or strategies they find most useful. Second, they were asked about the gaps in the support system for relatives,
their views on how to overcome this gap, and their views on the role of online support. We then looked at the REACT booklets together and discussed the best ways in which these could be redesigned as a Web-based intervention and the types of support relatives would need to use this intervention.

**Workshop 3**

We conducted a third workshop with 2 participants to allow for an in-depth discussion around scoping the types of features that could be implemented on the REACT Web-based intervention. For this workshop, we aimed to bring together participants who were comfortable using computers. We also wanted to have an older and a younger representative to identify any possible age-related challenges relatives might have. The first participant (older adult, aged 61 years) had taken part in workshop 1 and so acted as a representative for the initial discussions, and the second participant (younger adult, aged 21 years) was new to the study.

Before the workshop, participants were given access to a website containing PDF information taken directly from the REACT booklet, which both the participants spent a considerable amount of time reading. During the workshop, participants were given brief information about the REACT project. First, participants were asked to highlight mental health–related and nonrelated webpages they liked or disliked, then we looked into their aesthetics and functionalities together. This was followed by visual demonstration of a series of prototypes, which represented design choices for the REACT Web-based intervention based on data from workshops 1 and 2. The prototypes were designed in conjunction with a Web design company and mainly focused on aesthetic aspects of the Web interface, that is, logo, font style and size, navigation menu, color scheme, and multimedia choices.

We wanted to know how to translate the values and needs participants highlighted in workshops 1 and 2 into functionalities that can be implemented in the REACT Web-based intervention. In particular, we wanted to know how to provide a positive user experience and, therefore, asked the participants to discuss (1) how to design the REACT Web-based intervention to be more engaging, (2) what features could motivate relatives to revisit the intervention, and (3) the types of support features, which can only be offered online. These design decisions were explored in depth in workshop 3, which focused on attempting to make clear design decisions to bring forward to the development phase for the REACT Web-based intervention.

**Data Analysis: Phase 1**

The qualitative data collected from all 3 workshops were coded in NVivo 11 software (QSR International) [52] by 2 researchers using the Braun and Clarke [53] thematic analysis to identify key ideas to inform the design of the REACT Web-based intervention. The analysis was inductive and, therefore, data driven. Coders then worked together and discussed any discrepancies before agreeing on a final set of themes. Identified themes were discussed and refined with input from another researcher to ensure the themes were representative of the data and could inform the design of the Web-based version of REACT.

**Phase 2 Method: Heuristic Evaluation**

The clinical effectiveness and cost-effectiveness of the REACT Web-based intervention is currently undergoing a national RCT [54]. We wanted to run a preliminary, surface-level usability evaluation of the REACT Web-based intervention with a small group of participants in preparation for the RCT. Our intention with this heuristic evaluation was not to evaluate the clinical effectiveness of the REACT Web-based intervention but to identify any inconsistencies, which could be addressed before the start of the RCT. We were looking for any inconsistencies in relation to language, functionalities, content, and structure of the intervention as well as whether the registration process is easy to follow and would make sense to the relatives. Using a similar approach to van der Krieke et al [55], we created a table of the questions that we were looking to address in this evaluation stage (see Table 1; questions adapted from the study by van der Krieke et al [55]). The questions were designed based on the 10 usability principles of Neilsen’s heuristic evaluation guideline [56]. All participants were informed about the aim of the evaluation and were instructed to think about our questions during their evaluation. To gain a better perspective of the typical users, we conducted this evaluation in 2 different settings of controlled and uncontrolled environments.

**Controlled Setting Testing**

This session was conducted in a controlled setting in a computing laboratory at Lancaster University. Overall, 3 participants took part; all were relatives and had mixed computer abilities. Two participants were new to the study. The one-to-one sessions were planned as *think-aloud* activities where participants were asked to walk through the intervention starting with the registration process, then using and testing functionalities, and documenting their experiences as they went through. The participants were asked to talk about their experience as they were using the intervention and report any incidents related to the questions in Table 1. Each session was audio-recorded and was used as a feedback to evaluate and refine the system requirements. Participants were provided with the opportunity to get in touch via email after the session to provide any further thoughts or ideas they wished to be included in the final development stage.

**Uncontrolled Field-Testing**

Because relatives are more likely to access the intervention from their own personal environment and without any assistance, it is important to review the intervention in an uncontrolled setting. A total of 8 participants were given access to the REACT Web-based intervention for 2 weeks, were asked to use it from their preferred environment (eg, their home), and provide feedback via email. Participants were recruited from our service user researcher group, which is a group comprising people with mental health problems and their relatives.
Table 1. Questions adapted from the study by van der Krieke et al to examine the usability of the Relatives Education And Coping Toolkit (REACT) Web-based intervention.

<table>
<thead>
<tr>
<th>Usability principle</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visibility of system status</td>
<td>Are the steps in the registration process clear to relatives?</td>
</tr>
<tr>
<td></td>
<td>Is the intervention unresponsive or slow at any point?</td>
</tr>
<tr>
<td>Match between system and the real world</td>
<td>Does this intervention represent real-world experiences of relatives’ population and whether or not speaks in a language or uses terminologies that are familiar to this group?</td>
</tr>
<tr>
<td>User control and freedom</td>
<td>Is it clear for relatives which actions or activities are private and public?</td>
</tr>
<tr>
<td></td>
<td>Is it clear that user can make the decision on how to engage with the intervention (unrestrictive model)?</td>
</tr>
<tr>
<td>Consistency and standards</td>
<td>Are the content, terminologies, and features of the intervention consistent throughout the intervention?</td>
</tr>
<tr>
<td>Error prevention</td>
<td>What mistakes are likely to occur during the registration process and completion of the eligibility questionnaires?</td>
</tr>
<tr>
<td></td>
<td>Does the intervention have capacity to prevent or act on these mistakes?</td>
</tr>
<tr>
<td>Recognition rather than recall</td>
<td>Are the list of available functionalities, icons, and structure of the intervention clearly explained to the relative at all time?</td>
</tr>
<tr>
<td>Flexibility and efficiency of use</td>
<td>Does the relative have control over how they wish to use the intervention (personalized manner)?</td>
</tr>
<tr>
<td>Aesthetic and minimalist design</td>
<td>Are features of the intervention easy to understand, distinguish, and use?</td>
</tr>
<tr>
<td>Help users recognize, diagnose, and recover from errors</td>
<td>Is there enough clear instruction on how to get in touch and report any issues to the team?</td>
</tr>
<tr>
<td>Help and documentation</td>
<td>Is there enough guidance on how to use the intervention?</td>
</tr>
</tbody>
</table>

Data Analysis: Phase 2

The qualitative data collected from the controlled setting testing were analyzed by 1 researcher using content analysis [57] to identify the improvements suggested by our participants. Participants who took part in the uncontrolled field testing provided their feedback by email, which consisted of mainly bullet points of recommended changes. The list of all identified changes from both settings was collated by 1 researcher, which was then passed to our internal software team to be addressed.

Results

Phase 1 Findings

Although the themes and subthemes are described as discrete, themes are to a large extent intertwined, building, or expanding on previous themes. A total of 9 themes emerged from all 3 workshops’ data, which were then synthesized into the 3 wider theme headings that we used to illustrate our findings. The 3 main identified overarching themes are (1) caring as an invisible role, (2) support needed for relatives, and (3) concerns about online support. Although relatives’ experiences as caregivers have been widely researched and described elsewhere [58-60], it is important to provide a context for the experiences of those involved in our study. We first report these broad themes to provide an insight into the themes of discussion. We then move to discuss the design requirements for the REACT Web-based intervention, which was generated from workshop 3. We append the quotes along with both workshop and participant number to distinguish sources of data (eg, a quote from workshop 1 participant 9 would be [WS1, P9]). In workshop 3, P2 represents the younger adult participant.

Caring as an Invisible Role

A Change in Identity

Participants reflected on their personal experiences around the process of becoming a relative of someone with a mental health problem. Participants talked about feeling a loss of sense of self in their journey of becoming a carer. They felt they had been pushed into a carer role and found it hard to maintain their identity as a mother, brother, and so on. The role of the carer was particularly unappealing as there was no formal training or guidance for this role; so, as well as being enforced, it was also very challenging:

*I don’t want to be a carer, I don’t like the word. I’m a Mother.* [WS1, P9]

Many participants described how it took years for them to learn strategies to cope with the impact of mental health problems on the rest of the family, including (1) how to cope with new responsibilities and burden of care, (2) the changes the caregiving role brings to relative’s personal and professional life, (3) coping with emotional side effects, and (4) societal stigma surrounding mental health.

Impact on the Whole Family

Participants described the very broad impact of mental health on the wider family and the need for support for all family members:

*Our youngest son didn’t understand what his brother was going through. He may have known about his brother thinking that people were after him, but it must have been terrible for him and in fact not long ago he actually left the family.* [WS1, P1]
In addition, participants discussed requiring support not just as relatives but also as individuals in their own right, with other responsibilities in their lives:

*I might have had a right morning with my son; threatening suicide or wrestling for my own. And I’d have to go in work...change into my uniform and drive to work and I’ve got a lump in my throat.* [WS2, P3]

**Social Isolation**

Social interaction is challenging for relatives of those with physical illness as they may have little respite because of the need for constant caring. However, with mental health, social isolation can be further exacerbated by the result of stigma and lack of public awareness about mental health. Participants talked about having found it difficult to open up and discuss their mental health–related experiences with others. Finding other people with similar lived experiences had been initially challenging, but once accessed, became invaluable, not only for emotional support but also for signposting to important information and guidance elsewhere. Many were part of charity-run face-to-face peer support groups facilitated by an expert relative:

*The person who runs our small group is a God send, what’s worrying is if she couldn’t do that job what would we do with it? That’s what I always think about because there’s got to be a system there that does what she does...* [WS1, P4]

Although valuable, these groups were considered to be scarce and almost invisible to newly adopted relatives.

**Support Needed for Relatives**

**Informational Support**

Participants acknowledged that it can take years for relatives to learn about the mental health problems and, on reflection, identified 3 types of educational information sources that could be useful for other relatives:

1. All available sources of support (eg, local support groups and national charity organizations):

   *This exists. That exists. You can read this. You can read that. You can go here. You’ve got a right to this—this is practical help—not the general pat you on the back and say everything’s alright and happy clappy, and let’s be friends. But actual hard practical, meaningful.* [WS1, P6]

2. Information about medication, including types, side effects, and how to manage doses:

   *We’re never given sort of like a comparative—information about the various anti-psychotics. They had awful side effects.* [WS2, P5]

3. Legal rights:

   *I think actually what carers are entitled to under the law is very different from what they get in real life. And you’ve got to know.* [WS1, P1]

Overall, participants agreed that knowledge is power and that relatives of those who have been newly diagnosed would benefit from guidance on how to get help and to be signposted to trusted and up-to-date resources.

One of the challenges of a self-management toolkit is that there are often no right or wrong answers. Participants highlighted the importance of vicarious learning in addition to didactic instruction. One participant felt that a limitation of many of online support they had reviewed was that they tried to provide checklists of what to do:

*like a lot of websites will say, oh why don’t you try meditation, going for a walk.* [WS3, P2]

Instead, it was suggested that online support needs to be thought provoking: it needs to facilitate thinking and reflecting exercises that enable relatives to learn problem-solving strategies that can then be applied to their own particular context:

*...like stuff that helps you ask questions and helps you think about what you’re feeling rather than like, try this, because there’s only like so much a hot bath can cure.* [WS3, P2]

Participants suggested more emphasis should be placed on inviting relatives to dip in and out, in an order and frequency of their choosing, without the need to complete the intervention in a sequential order:

*Normally websites like this are just information, read it and then go. But because this is more of a programme that you can work through. So I’d have to understand that’s what it was for and that was how I’d used it in a really good clear way.* [WS3, P2]

**Emotional Support**

Participants talked about the emotional impact of supporting someone with psychosis and the importance of emotional and practical support:

*I had some professional experience [in mental health] but it’s completely different when you are emotionally involved in somebody. And it’s literally like somebody’s just parachuted you into a foreign country. You’ve no idea of what should be happening, what is available, and you need to know that sometimes to be able to get it. But the peer support is about emotional support. And I think what health professionals sometimes don’t understand is by the time you get to them you’ve been doing this for months. Twenty four hours a day, seven days a week. And the emotional toll on you.* [WS2, P2]

They talked about the importance of hearing that their experiences were not unique, the need for explicit reassurances that the development of mental health problems within the family was not their fault, and that they were doing all they could to manage the situation:

*My mum never forgets this nurse who said to her, it could happen to anybody. This is not your fault. You’re doing everything you can. And that just lifted that guilt off my parents.* [WS2, P7]
Opportunities to have social contact with similar relatives to share lived experiences and feel connected and supported were particularly valued:

But there’s nothing better than seeing that somebody else has had the same fears and guilt to start with. Worries about the future and practical travel problems, just to hear that other people have got the same issues that you have. [WS3, P1]

Participants explained that for some questions, there is a lack of informative answers on Google:

How much am I supposed to do? How strict am I supposed to be? When’s the point when I back off? And that’s not really a question that I felt I could ask Google cause I’m not going to get anything useful from that. [WS3, P2]

Instead, relatives are looking for someone to talk to even if they realize that there is nothing they can do to resolve the situation; at times knowing that they are not the only person debating the issue could serve to help them cope better.

A Recovery-Focused Approach

Although most of the discussion revolved around challenges relatives faced, the need to focus on positive outcomes was also important to relatives. One participant explained how she desperately struggled in finding positive role models for her son:

But then I realised that the positive role models don’t want to go back and look again. And there’s got to be thousands of recovered or people who are managing their condition but they don’t really want to join the club. And that would be priceless to have more positive role models. People who have managed and are managing their conditions or have completely recovered. [WS3, P1]

There was a general feeling that both relatives and people with mental health problems would benefit from hearing positive stories to give them hope that recovery is possible.

Participants expressed that supporting someone with a mental health condition is often an ongoing journey and suggested to offer a personal space in which relatives can save useful information to revisit easily in the future:

Like some kind of like scrapbook section. Not called that but that kind of thing where like people just put different stuff in. [WS3, P2]

The value of this was not only in having a useful place to store things to be revisited but also to facilitate a process of reflection on progress over time:

...it’s very affirming to go back to some of the earlier learning content to realise that you have learnt, you know. I’ve acted correctly. You have been a good carer. [WS3, P1]

Concerns About Online Support

Questioning the Confidentiality of Online Support

Participants debated on the use of Web resources in a mental health context and expressed that online support can be seen as a "big scary virtual world" for some relatives. Some participants expressed fears toward online activity, and many felt reluctant to input personal information to any website. Their fears were that once shared, information posted online could never be removed and will always be “Googleable.” There was also an ethical dilemma that, in sharing their own experiences online, they may be sharing their relatives' personal experiences without their explicit consent. Participants agreed that it is often unclear as "whose story is it" that they might be sharing online:

I don’t mind saying anything about my own medical symptoms or if I had a mental health problem but I don’t feel comfortable about using it about my relatives: No, but on the other hand if my anxiety and stress and my needs are because my relative’s issues aren’t being addressed. Then it is about me but it’s still about her. So I wouldn’t feel comfortable putting anything down there. But everybody’s different so I think there needs to be a number of ways to access this information. [WS1, P10]

Wider Impact of Being Active Online

They described several practical challenges about using the internet, including limited access and skills:

I live in the country and my internet doesn’t work half the time and my computer is probably my biggest source of stress. [WS1, P10]

However, it was not only practical issues that made them concerned. This dilemma was exacerbated by the fear of the impact their posts might have on their relative if they saw them:

I feel uncomfortable about discussing [my relative online] if my relative happened to get access to it, it could trigger a major episode. [WS1, P8]

Many reported that receiving destructive comments on social media could place significant strains on relatives:

You might just get some people who are just time wasters. You might get some destructive things. [WS2, P1]

However, they acknowledged the need for moderators:

Usually though you have moderators on sites like that. [WS2, P6]

Participants acknowledged that to eliminate stigma, mental health needs to be discussed openly but feared this could cause more damage:

But I’ve always feared letting [my relative] know how I’m feeling about things...I’m not sure how far we can open up... [WS1, P5]

In discussions around prompts, participants felt that options should be made available for people to customize the frequency and mode of delivery of prompts. They disliked receiving too many prompts and expressed that if they received prompts too
often they would feel “suffocated” or “pressured,” especially if they are having a good day and, therefore, “reject” and “unsubscribe.” They also preferred receiving person-centered prompts:

> What’s your question this week? What are you worrying about this week? You never get any e-mails that just say how are you doing? How are you [WS3, P2]

**Legitimacy of Online Support**

Simplicity, easy navigation, and professional look were all seen as features that would attract relatives by assuring them that this intervention is legitimate:

> ...cause you look at it and you go, oh wow, this looks legitimate like I can trust this. And then you start building up that trust and start using it. [WS3, P2]

Participants compared the look of a website with a building and suggested not to aim for a slick look, such as a building with shiny floors that feels corporate, instead, something professional that provides the information but looks simple. Overall, the design of the toolkit was felt to be very important in engendering a sense of trust in participants. Participants emphasized on the importance of privacy and security and that they need to be assured that the online support is a safe environment for sharing stories and experiences:

> It would have to be very secure the site, because who can access this site, I mean I don’t go on Facebook or anything like that because I just think that a lot of it is not secure. Anybody can [access], you know. [WS2, P1]

Overall, participants had mixed views about the value of online support but felt that people in the next generation may be more positive:

> We’re all of a certain age. And what I’m finding is that, the people in the group who are a lot younger are actually perfectly happy to go all over Facebook. [WS1, P1]

And may even be put off by paper-based support:

> But it’s often a generational thing and a lot of younger carers are siblings. Would never dream of getting something off paper they would automatically go online. [WS2, P6]

**Relatives Education And Coping Toolkit Web-Based Intervention Design**

The REACT Web-based intervention was developed using WordPress [61]—an open source Content Management System—and can be accessed via a weblink to sign up. However, the weblink is currently not openly available as REACT’s clinical effectiveness is still being tested under controlled conditions. The interface is responsive to various devices, including mobile phones, tablets, and desktop. The REACT Web-based intervention (Figure 1) is composed of 6 features: educational modules (REACT), list of national and local support resources (resource directory), discussion forum (REACT group), moderators (REACT supporters), personal space (my toolbox), and a blog section.

The REACT Toolkit was designed based on the REACT booklet and features 12 modules covering various aspects of mental health. Each module contains information, self-reflection activities, and short video clips of clinicians, REACT supporters, and lived experiences of relatives (who are played by actors). Further details of the modules can be found in the study by Lobban et al [54].

To support participants’ concerns around finding reliable and trusted information online, we created the resources directory feature, which aims to bring together an extensive list of Web resources that relatives may find useful at all stages of caring. The resource directory offers more detailed explanations and information on various topics relevant to supporting someone with a mental health problem. This feature has 4 main categories, each covering a range of different topics: (1) national organizations supporting relatives, that is, charity organizations; (2) government guidance, that is, the department of work and pension; (3) topic-specific information, that is, insurance and driving license; and (4) local resources to support relatives of people with mental health problems—relatives would access the UK map and by selecting the area they live in, they will be provided with a list of support available in their area.

In response to participants desire to be emotionally supported and linked to others with similar experiences, we created the REACT group—a moderated space for sharing knowledge and emotional peer support. The REACT supporters who are trained relatives with lived experience of caring for a family member moderate the REACT group are available for private questions. They also update the resource directory on a regular basis.

My Toolbox is a private space to store the information that is important to the relative. My ‘Toolbox was created in response to participants’ desire for a personal approach to be able to save interesting content and the ability to revisit in a less time-consuming and less stressful manner, particularly during crises. Throughout the intervention, relatives will see the trust and start using it. [WS3, P2]
Phase 2: Findings

We evaluated the initial system requirements against the feedback from both heuristic evaluations, and where possible, the findings are related to the Neilsen’s guideline [57]. Any identified changes were addressed by our internal software team. The majority of reported issues were relevant to Neilsen’s Consistency and Standards principle, which was focused on typos within the text, rewording some sentences, and resizing images. There were also some instances in which some features were unresponsive, for example, a video would not play or a link would not redirect, which were related to the Visibility of System Status principle. Some participants who conducted the evaluation from home reported that initially they found it difficult to understand how to use the intervention, that is, the role of My Toolbox was unclear; this corresponds to the aesthetic and minimalist design principle. Furthermore, related to the Match between System and the Real World principle, they recommended that using more images of the REACT supporters’ faces throughout the intervention would add value in terms of getting a sense of the real people behind the intervention and promoting relatability and trust. In response to the 2 former comments, we created additional short videos of the REACT supporters introducing themselves, explaining the functionalities of the REACT Web-based intervention, and providing instructions on how to navigate and use the intervention. With regard to the content of the REACT and the

Figure 1. Screenshots to show features of the Relatives Education And Coping Toolkit (REACT) Web-based intervention.

http://mental.jmir.org/2018/4/e11473/  JMIR Ment Health 2018 | vol. 5 | iss. 4 | e11473 | p.207

(page number not for citation purposes)
Match between System and the Real World principle, participants found the topics covered relevant and useful:

...this is really useful information that I was never made fully aware of when we needed it.

A number of participants highlighted a further issue with respect to the Match between System and the Real World principle, and they expressed how they disliked acronyms as they find them difficult to understand. They suggested to list both the acronyms and their full names as a “jargon buster” type approach, which was added to our resource directory. Related to the Visibility of System status principle, participants commented that they could watch the lived experience videos using their home internet network and found them useful to get a sense of “someone else understands what this is like” and to give hope to relatives when they are struggling or are in a crisis. This confirmed that the intervention is representing real-world experiences of relatives related to the Match between System and the Real World principle. Participants commented positively on the REACT group and found it easy to use:

I really like this idea of a virtual meeting place for sharing experiences and getting support, I think this might prove to be one of the most helpful areas of the site.

Discussion

Principal Findings

The aim of this study was to develop an accessible Web-based intervention to support the informational and emotional needs of relatives of people experiencing psychosis or BD. We used a user-centered design approach to better understand the needs and values of relatives. Our findings showed that relatives preferred technologies that (1) they can place their trust in, particularly when discussing a highly sensitive topic, (2) enable learning from the lived experiences of others while retaining confidentiality, and (3) they can work through in their own pace in a personalized manner. These findings have clear implications for the design of our Web-based version of REACT and for others developing similar Web-based interventions for people affected by mental health conditions. Our discussion is organized into the following design considerations: (1) designing to engender trust and (2) designing for relatives with many roles.

Designing to Engender Trust

As Briggs et al. [62] note, our findings show that it is not simply the provision of health-related information that is important, it is the establishment of trust and credibility. There was much discussion about the need for trust in information sources in the sense that they are reliable and legitimate. The guideline for designing trust into online experiences [63] suggests making it easier for users to access the enforced privacy policies to establish trust. As noted in the study by Sillence et al. [64], trust is closely associated with risk, and in the context of designing a toolkit for relatives, this goes beyond the risks surrounding self-disclosure and is more concerned about revealing information about someone else’s experiences. Relatives discussing their experiences of caring for someone with a mental health condition could be seen to give away personal information, including the identity of the person with a mental health problem. Although health is perceived as a high-risk domain for seeking support online [65], mental health faces additional challenges establishing trust with online users because of the stigma related to mental health conditions. As such, factors affecting trust in mental health need to be understood if the online support is to be valued in long-term use.

It was apparent that our participants spent a number of years reaching a point in which they understood the mental health condition enough to reach out to face-to-face support groups and to gain an understanding of the care system infrastructure. Reaching this point is a lengthy and tiresome journey, and although it feels as if they need to be part of a group to know their rights, peer support groups are small and almost invisible to relatives who are new in their caring role and may be feeling overwhelmed adapting into this role. Our findings highlighted that although relatives had difficulties finding and accessing support, privacy and security concerns may inhibit them from accessing this support online. Although they valued being connected to others with similar experiences, they raised concerns about the misuse of discussion forums and emphasized the need for moderators. Our participants wanted to know that their personal information and discussions will be kept confidential, particularly when discussing highly stigmatizing topics such as mental health. For the majority of participants, finding a way to share lived experiences while maintaining the confidentiality of oneself and the person they care for was an important value, and they would like to access tools that would support them. As such, we encourage future researchers wishing to work within this space to make it clear what happens to individuals’ data, explain what safeguarding measures are in place to protect the privacy of individuals, and clarify how the provision of a safe environment for interacting with others has been embedded within the core of the design (e.g., providing moderators and setting ground rules for interaction).

In addition, our participants wanted to know that the information provided in the toolkit was credible and that real people with clinical expertise and lived experiences of mental health problems had been engaged in its development. Aesthetics, branding, quality of information, and relevancy of the information to each individual user were all seen to influence credibility. This is consistent with findings in the broader literature around trust in health information [64, 66, 67] and highlights the necessity of engaging multiple members of health community in the design of tools aimed at targeting information provision and support needs.

Designing for Relatives With Many Roles

One of the continuing concerns participants expressed was the need for retaining a sense of ownership during care, particularly when they feel that the caring role has overtaken other life roles (e.g., being a partner, parent, or sibling). We suggest that we do not just focus on designing for the relative as a user but also explore designing for relatives with other roles and responsibilities (e.g., relatives managing a career and relatives with young children). We need to make sure that we develop online support that allows relatives to retain their identity rather than just focusing on caring. This is reflective of previous work,
which has explored the design of technologies that fit into the messy daily lives of relatives [68,69]. Similarly, online support tools should be designed in such a way to let relatives work at their own pace while being able to carry on with other aspects of their life. It was apparent in our study that relatives are not homogenous in their experiences and, thus, their priorities and their engagement with online support, therefore, having space to tailor and personalize engagement is essential.

Monk et al addressed the need to move from designing for usability to enjoyment [70], which is also echoed in feedback from our participants. Our findings indicate that relatives require technologies that take away the pressure and stress resulting from caring duties, and they preferred informational support that provides a positive, although realistic, representation of mental health problems. Our participants wanted to ensure that we provided a message that recovery is possible, that relatives will eventually identify their own coping strategies, and that the future can be bright. We tried to convey these positive messages throughout the intervention as well as the video stories of lived experiences of relatives. The assumption is that with mental health, we deal with very serious challenges, and when it comes to design of software systems, we only focus on usefulness rather than a system that can be both useful and motivating. Hence, from a design perspective, we still need to investigate positive approaches and how to promote positive emotion in this very complex and challenging domain of mental health.

Strengths and Limitations

The main strength of this study is the employment of user-centered design methodology where in-depth perspectives of relatives of people with psychosis or BD were collected. This early involvement in the design and heuristic evaluation process of the REACT Web-based intervention can increase the likelihood of developing a useful and trusted supportive toolkit. The main weakness of the study is the use of a convenience sample that was skewed toward older females aged over 65 years, with limited computer literacy. The sample was recruited through existing links and local carer groups and is, therefore, not representative of relatives supporting people with mental health problems or those likely to engage with Web-based interventions.

Despite not intending to recruit an older sample of participants, this proved beneficial. First, we consulted experienced relatives who had been providing support for their family member for a number of years and, therefore, had expert knowledge in the challenges, solutions, and support that families of people with newly diagnosed mental health problems might need. In addition, our participants had less familiarity with online support, which resulted in them sharing important concerns related to privacy, confidentiality, and trust, which may not have been shared by younger and more tech-savvy participants who are used to modern social media. Although initially we considered our largely older sample as a limitation to our study, we found it particularly helpful to hear the concerns of these relatives as it made us think about how to address these in our design. This resulted in more inclusive design decisions and opened up our toolkit to be accessible for a wider range of users.

Conclusions

Through this study, we have offered a deepened understanding of the specific needs and values of relatives of people with experiences of BD or psychosis to inform the design of a Web-based intervention to support them in their caring role. Although it is challenging to meet the needs of all end users, engaging them in the development of resources to support them is valuable and necessary. Our study has highlighted the challenges relatives face during the process of becoming caregivers and the need for providing a trustworthy, supportive tool where they can gain informational and emotional support and gain access to others with similar experiences. Our heuristic evaluation of the REACT Web-based intervention showed promise in terms of perceived usability by a small number of participants. An RCT is currently underway to evaluate its clinical effectiveness.

Acknowledgments

The authors would like to thank all the study participants for sharing their perspectives in the course of this study. The authors would also like to thank everyone within the Relatives Education And Coping Toolkit (REACT) group who were involved in developing the protocol, in particular Rita Long, Johanna Barraclough, and Nadia Akers for their support in running the workshops. This study presents independent research funded by the National Institute of Health Research (NIHR) under the Health Technology Assessment Programme (Grant Reference Number 14/49/34). The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR, or the Department of Health and Social Care. The funder played no role in the study design, conduct, or interpretation of the data. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Conflicts of Interest

None declared.

References


42. Honary et al. JMIR MENTAL HEALTH 2018 | vol. 5 | iss. 4 | e11473 | p.211


Abbreviations

**BD:** bipolar disorder

**RCT:** randomized controlled trial

**REACT:** Relatives Education And Coping Toolkit

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Monitoring Online Discussions About Suicide Among Twitter Users With Schizophrenia: Exploratory Study

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Abstract

Background: People with schizophrenia experience elevated risk of suicide. Mental health symptoms, including depression and anxiety, contribute to increased risk of suicide. Digital technology could support efforts to detect suicide risk and inform suicide prevention efforts.

Objective: This exploratory study examined the feasibility of monitoring online discussions about suicide among Twitter users who self-identify as having schizophrenia.

Methods: Posts containing the terms suicide or suicidal were collected from a sample of Twitter users who self-identify as having schizophrenia (N=203) and a random sample of control users (N=173) over a 200-day period. Frequency and timing of posts about suicide were compared between groups. The associations between posting about suicide and common mental health symptoms were examined.

Results: Twitter users who self-identify as having schizophrenia posted more tweets about suicide (mean 7.10, SD 15.98) compared to control users (mean 1.89, SD 4.79; t₁₃₇₄=-4.13, P<.001). Twitter users who self-identify as having schizophrenia showed greater odds of tweeting about suicide compared to control users (odds ratio 2.15, 95% CI 1.42-3.28). Among all users, tweets about suicide were associated with tweets about depression (r=0.62, P<.001) and anxiety (r=0.45, P<.001).

Conclusions: Twitter users who self-identify as having schizophrenia appear to commonly discuss suicide on social media, which is associated with greater discussion about other mental health symptoms. These findings should be interpreted cautiously, as it is not possible to determine whether online discussions about suicide correlate with suicide risk. However, these patterns of online discussion may be indicative of elevated risk of suicide observed in this patient group. There may be opportunities to leverage social media for supporting suicide prevention among individuals with schizophrenia.

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KEYWORDS

schizophrenia; social media; suicide; Twitter; digital technology; mental health

Introduction

Individuals living with schizophrenia experience elevated risk of suicide compared to the general population [1]. Adults with schizophrenia are nearly four times as likely to die from suicide when compared to adults in the general population (all-causes standardized mortality ratio 3.9, 95% CI 3.8-4.1) [2]. Lifetime risk of suicide among individuals with schizophrenia ranges

Social media platforms have emerged as important digital monitoring tools capable of facilitating the detection and tracking of numerous diseases and public health concerns [4]. A growing number of studies have highlighted the feasibility and promise of using popular social media for monitoring online conversations about suicide and for potentially detecting those at risk of suicide [5]. Several studies have used Twitter data to characterize suicide-related conversations [6] and to monitor suicide risk [7,8]. An exploration of Tumblr posts found that conversations about suicide were frequently shared together with content about self-harm and depression [9]. Another study investigated the psychological characteristics of social media users in China who posted conversations about suicide on the Weibo microblogging platform [10].

Research has shown that studying social media activity can yield valuable public health insights about serious mental disorders such as schizophrenia. For example, data captured from Facebook was used to characterize awareness of schizophrenia across the United States [11], while another study found that conversations about schizophrenia on Twitter were often negative, suggesting the presence of social stigma [12]. Numerous studies have also demonstrated that individuals living with schizophrenia use popular social media at comparable rates as the general population [13,14]. Further, individuals with mental illness appear to use social media to share their illness experiences or seek advice from others with similar conditions [15,16]. A series of recent studies have identified unique patterns of communication on Twitter among users who self-identify as having schizophrenia, as reflected by linguistic differences, compared to control users [17,18]; changes toward more positive sentiment following self-disclosure of mental illness on social media [19]; and greater use of conversation terms about mental health symptoms compared to control users [20].

In addition, social media such as Twitter may be especially valuable for monitoring suicide risk among individuals with schizophrenia as these platforms offer unique opportunities to engage young adults. For instance, on average, Twitter users tend to be younger compared to the overall population [21]. This is highly relevant because suicide mortality among people with schizophrenia is greatest among younger adults, where individuals 20-34 years of age are over five times as likely compared to young adults from the same age group from the general population to die due to suicide (all-causes standardized mortality ratio 5.3, 95% CI 4.9-5.7) [2]. A literature review found that risk of suicide and self-harm is also highly prominent among young individuals considered at ultra-high risk of developing psychosis [22]. As well, there is increasing recognition that individuals with schizophrenia are heavy users of social media and show unique communication patterns on these digital platforms. This combination highlights the potential to leverage social media for detecting suicide risk and informing suicide prevention efforts in this at-risk patient group. However, less is known about whether people with schizophrenia talk about suicide on social media.

An important first step toward developing strategies to use social media for supporting the detection of suicide risk among individuals with schizophrenia is to better understand how this target population talks about suicide on popular social media. Therefore, in this exploratory study, our aims were to (1) investigate the frequency of online communications about suicide among Twitter users who self-identify as having schizophrenia compared with a control group of typical Twitter users; (2) characterize the timing of tweets about suicide among Twitter users who self-identify as having schizophrenia compared with a control group of typical Twitter users; and (3) determine whether discussion about other common mental health symptoms, including depression or anxiety, is predictive of online discussions about suicide. We hypothesized that Twitter users who self-identify as having schizophrenia would be significantly more likely to post tweets containing suicide terms when compared to Twitter users from the general population, thereby reflecting the elevated risk of suicide observed among individuals with schizophrenia in real-world settings.

**Methods**

**Data Collection**

All data analyzed in this study was publicly available and was collected from the Twitter social media platform. Twitter is a popular microblogging platform where users post short statuses called “tweets” that contain a maximum of 140 characters—since 2018, this has increased to a maximum of 280 characters for each tweet. It is estimated that the more than 330 million active Twitter users post over 500 million tweets per day [23,24]. This highlights an immense source of unsolicited data with exciting potential to study various aspects of human behavior and monitor health conditions including mental illness [25]. Specifically, we selected this social media platform for this study because it has previously been used for conducting research on several different mental health conditions, including depression, bipolar disorder, and posttraumatic stress disorder [26]. Importantly, data captured from Twitter has been used in research characterizing online discussions and attitudes about schizophrenia [12,27], exploring linguistic markers of schizophrenia [17,18], and supporting efforts to detect individuals with schizophrenia [18,19]. Lastly, Twitter users tend to be younger compared to the overall population [21], which is especially important given the elevated suicide risk among young persons with schizophrenia [2]. Therefore, given that Twitter can achieve widespread reach, and that we can expand on existing related work, we determined that Twitter would be an ideal platform to potentially serve as an effective digital tool for monitoring risk of suicide among people with schizophrenia.

As popular social media platforms have emerged as an important source of user-generated content that can yield valuable insights for public health research, the ethical considerations with analyzing and disseminating this data have received greater attention [28,29]. While there remains a lack of consensus over best practices for using Twitter data in academic research [30], there is ongoing discussion surrounding concerns related to privacy, confidentiality, and informed consent [31]. To minimize
potential risks, we ensured that all data collected in our study was available in the public domain. However, additional ethical considerations are warranted, especially in the context of socially stigmatizing health conditions such as mental illness [32]. For example, disseminating user-generated content collected on Twitter could potentially place an individual at risk of harm [30] because sensitive health information, such as mental illness diagnosis or symptoms, could be made identifiable in ways that were not intended by the original user who posted the content online [33]. Therefore, to further protect the identity of the Twitter users whose data we examined in this study, we removed all usernames and identifiable details from the content that they posted online. Lastly, we do not report any specific tweets that could be used to identify the original Twitter user who posted the content online, as this is an important concern that has been discussed extensively in recent literature on the ethics of using Twitter data for research [30]. In this study, we retrieved data from Twitter’s public application programming interface over a 200-day period from January 5, 2016, to July 23, 2016. Given that we only used publicly available online data in this study, ethical review was not required.

Twitter Users and Characteristics
We identified a convenience sample of 250 Twitter users who explicitly self-identified as having a schizophrenia spectrum disorder in their profile or in a tweet. For example, the users’ profiles could indicate “person living with schizophrenia” or “I have schizophrenia diagnosis,” while a tweet could mention “this is how I manage my schizophrenia” or “I was just diagnosed with schizophrenia.” We modeled our data collection methods on prior studies that have used the Twitter platform for generating a convenience sample of users with publicly available accounts who self-identify as having a schizophrenia spectrum disorder in their profile or in a post or tweet [18,34]. To identify the sample of Twitter users with schizophrenia, we searched Twitter using the following terms: schizophrenia, schizoaffective, schizotypal, and psychosis. We then confirmed the self-reported schizophrenia diagnosis by having one researcher generate this initial list of Twitter users and then a second researcher check the details for each Twitter user on the list to ensure correct identification of users with a self-reported schizophrenia spectrum disorder.

To create a general population comparison group, we used the GET statuses/sample feature from the Twitter Developer Platform to collect a random sample of all publicly available tweets [35]. Then, two research assistants manually screened these tweets to confirm that the tweet belonged to a real person (ie, not a bot or spam account), was from a normal user (ie, not a company or corporation), and was in English. This process was intended to ensure that Twitter users included in the control group were real Twitter users. To minimize the risk of selecting any bot or spam users, both research assistants had to be in agreement of a Twitter user on each of these three criteria. We excluded any Twitter users where there was disagreement. Our goal was to create a group of users that was representative of typical Twitter users. We identified a sample of 250 control users.

We determined gender for the sample of Twitter users because numerous studies have identified a relationship between gender and suicide risk [36]; as well, mental health symptoms such as depression and anxiety have a known association with gender [37,38]. Additionally, among individuals with schizophrenia, mortality due to suicide is higher in men than in women [2]. We employed a stepwise process for coding each Twitter user’s gender as male, female, or unknown/insufficient data. Two researchers independently used these codes beginning with each Twitter user’s username, followed by profile name, profile description, profile photo, and then tweets. Both researchers then reviewed their final gender codes for each Twitter user to ensure consistency and to resolve any disagreements.

We also extracted several characteristics for the Twitter users included in this study. This involved collecting metadata from the Twitter users’ accounts, including total number of tweets, tweets per day (ie, total tweets divided by days active), tweets in last 200 days, number of friends, number of followers, favorites per day, and number of days the account has been active. We also measured each Twitter user’s impact, which is calculated as a followers-to-friends ratio where the user’s number of followers is divided by their number of friends [39]. This serves as a measure of impact and influence on Twitter because a higher ratio means that a user has many people who follow their account, but that they follow few other users’ tweets [39].

In our final sample, included in the analyses reported here, we had a total of 203 Twitter users who self-identified as having schizophrenia and 173 control users. The final number of users changed because some accounts became inaccessible (ie, private, deleted, banned, or deactivated) or were inactive (ie, no posts during the 200-day study period) at the time of data collection.

Tweets With Suicide Terms
We retrieved all tweets posted during the 200-day period from the Twitter users included in this study. Within this collection of users’ tweets, we identified only tweets that contained the keywords suicide or suicidal. Prior studies have shown that there are a variety of terms used on social media that may be indicative of suicide risk [8,40]. The term suicide is frequently contained in suicide-related conversations [8,41]. Therefore, we intentionally limited our search to these two terms to improve the certainty that the discussion content captured in this study was explicitly referring to suicide. We also considered this important because online discussions about suicide have been correlated with actual suicide risk. For example, a study from Japan showed that statements specifically mentioning the term suicide on Twitter were significantly associated with suicidal ideation and behavior [42]. In addition to searching for suicide-related terms, we also selected keywords for other mental health symptoms that are known risk factors for suicide [43]. These include the following terms: depression, depressed, anxiety, and anxious.

Timing of Tweets With Suicide Terms
To examine whether there were potential differences in the timing of tweets containing the terms suicide or suicidal between groups, we performed an analysis of tweet timing. This involved
converting the time-of-day data for tweets containing the terms suicide or suicidal to the Twitter users’ local time zones, and then classifying these tweets into the following time intervals based on a 24-hour clock: 00:00-05:59, 06:00-11:59, 12:00-17:59, and 18:00-23:59. It was possible to perform this analysis of tweet timing for only the subset of Twitter users’ tweets with available universal time code (UTC) offset data. The UTC offset is only available for a tweet when users choose to include their local time zone in their account settings.

### Statistical Analyses

We used t tests to compare continuous variables and chi-square tests to compare categorical variables between the group of Twitter users with schizophrenia and the control users. We used logistic regression models controlling for gender to compare both groups on the binary outcomes of whether or not users posted a tweet containing suicide terms (i.e., suicide or suicidal). We then used Pearson correlations to assess whether tweeting about other mental health terms (e.g., depression or anxiety) would be associated with posting a tweet with a suicide term. All analyses were performed with the Python programming language and Stata version 14.0 (StataCorp LLC).

### Results

#### Sample Characteristics

During the 200-day study period from January 2016 to July 2016, we collected a total of 1,544,122 tweets, with 819,491 tweets (53.07%) posted by the Twitter users with schizophrenia and the control users. We used logistic regression models controlling for gender to compare both groups on the binary outcomes of whether or not users posted a tweet containing suicide terms (i.e., suicide or suicidal). We then used Pearson correlations to assess whether tweeting about other mental health terms (e.g., depression or anxiety) would be associated with posting a tweet with a suicide term. All analyses were performed with the Python programming language and Stata version 14.0 (StataCorp LLC).

#### Tweets About Suicide

Differences in tweets about suicide between groups are listed in Table 1. Twitter users with schizophrenia tweeted significantly more about suicide (mean 7.10, SD 15.94) compared with control users (mean 1.89, SD 4.79; t = -4.13, P <.001). Among the 203 Twitter users with schizophrenia, 113 (55.7%) posted a total of 1441 tweets about suicide (mean 12.75, SD 19.69) compared to 65 out of 173 (37.6%) users in the control group who tweeted about suicide 327 times (mean 5.03, SD 6.75). In a logistic regression model adjusting for gender, Twitter users with schizophrenia showed significantly greater odds of tweeting about suicide compared with control users (odds ratio 2.15, 95% CI 1.42-3.28).

#### Timing of Tweets About Suicide

In our total sample of Twitter users, 71.0% (267/376) had available time zone data. There was no significant difference in availability of time zone information between Twitter users with schizophrenia (137/203, 67.5%) and control users (130/173, 75.1%). There were no differences in the proportions of tweets about suicide during each time interval between the Twitter users with schizophrenia and control users. In general, and as presented in Table 2, both groups appeared to post a comparable proportion of their tweets about suicide at each time point.

### Table 1. Tweets containing terms about suicide among Twitter users with schizophrenia and control users

<table>
<thead>
<tr>
<th>Suicide terms</th>
<th>Control Twitter users (N=173)</th>
<th>Twitter users with schizophrenia (N=203)</th>
<th>t</th>
<th>P valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tweets, n</td>
<td>Users who tweeted, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tweets per user, mean (SD)</td>
<td>(%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suicide</td>
<td>266</td>
<td>60 (34.7)</td>
<td>1095</td>
<td>5.39 (12.88)</td>
</tr>
<tr>
<td>Suicidal</td>
<td>62</td>
<td>23 (13.3)</td>
<td>367</td>
<td>1.81 (4.60)</td>
</tr>
<tr>
<td>Tweets with any suicide termsb</td>
<td>327</td>
<td>65 (37.6)</td>
<td>1441</td>
<td>7.10 (15.94)</td>
</tr>
</tbody>
</table>

P values calculated using t tests for the difference in mean (SD) tweets containing suicide or suicidal terms between Twitter users with schizophrenia and control users.

This category also includes tweets that contain both the terms suicide and suicidal.
Table 2. Timing of tweets containing the terms suicide and suicidal among Twitter users who self-identify as having schizophrenia compared to control Twitter users

<table>
<thead>
<tr>
<th>Time interval</th>
<th>Proportion of tweets among control Twitter users containing the terms suicide and suicidal (N=286), n (%)</th>
<th>Proportion of tweets among Twitter users with schizophrenia containing the terms suicide and suicidal (N=1101), n (%)</th>
<th>$\chi^2$</th>
<th>P value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>00:00-05:59</td>
<td>28 (9.8)</td>
<td>145 (13.17)</td>
<td>2.4</td>
<td>.12</td>
</tr>
<tr>
<td>06:00-11:59</td>
<td>71 (24.8)</td>
<td>260 (23.61)</td>
<td>0.2</td>
<td>.67</td>
</tr>
<tr>
<td>12:00-17:59</td>
<td>94 (32.9)</td>
<td>376 (34.15)</td>
<td>0.2</td>
<td>.68</td>
</tr>
<tr>
<td>18:00-23:59</td>
<td>93 (32.5)</td>
<td>320 (29.06)</td>
<td>1.3</td>
<td>.26</td>
</tr>
</tbody>
</table>

$^a$P values calculated using chi-square tests.

Predictors of Tweets About Suicide

Across both groups, frequency of tweets containing suicide terms was significantly associated with tweets about depression ($r=0.62, P<.001$) and with tweets about anxiety ($r=0.45, P<.001$). Correlations between suicide tweets and depression tweets, and between suicide tweets and anxiety tweets, are illustrated for each group in Figure 1 and Figure 2, respectively. Regarding Figure 1, Pearson correlations were calculated for the association between tweets containing suicide terms and tweets containing depression terms for the Twitter users with schizophrenia group ($r=0.60, P<.001$) and the control users group ($r=0.70, P<.001$). Regarding Figure 2, Pearson correlations were calculated for the association between tweets containing suicide terms and tweets containing anxiety terms for the Twitter users with schizophrenia group ($r=0.40, P<.001$) and the control users group ($r=0.62, P<.001$).

Figure 1. Association between tweets containing terms about suicide and tweets containing terms about depression among Twitter users with schizophrenia and control users.
Discussion

Principal Findings

The impact of suicide among individuals with schizophrenia is devastating. There is a well-established association between diagnosis of schizophrenia and increased risk of death from suicide, suicide attempts, and suicidal ideation [22]. Among all causes of death observed in persons with schizophrenia, suicide accounts for the highest mean years of potential life lost per death [2] and represents a major contributor to the dramatically shortened life expectancy observed in this patient group [44]. With increasing emphasis on the potential use of social media for suicide prevention [5], our findings offer an important contribution to the literature by (1) demonstrating the feasibility of identifying conversations about suicide among Twitter users who self-identify as having schizophrenia; (2) highlighting that Twitter users who self-identify as having schizophrenia are significantly more likely to talk about suicide compared to a control sample of Twitter users, which parallels trends observed in offline settings; and (3) demonstrating that the frequency of conversations about suicide on Twitter correlated significantly with discussions about depression and anxiety, another trend that is consistent with established data. Therefore, our findings represent an early indication that popular social media may be a valuable platform for monitoring discussion about suicide among persons who self-identify as having schizophrenia. Furthermore, our study offers a unique contribution to an emerging area of research aimed at using social media to support the detection of schizophrenia and for identifying individuals at risk of psychosis [17-20]. As this research using social media continues to evolve, there may be opportunities to explore online conversations on social media for simultaneously monitoring risk of psychosis and risk of suicide.

It is important to draw the connection between our findings reported here and suicide trends observed among persons with schizophrenia in the “offline” world. While it was not possible in this study to determine whether conversations about suicide among Twitter users who self-identify as having schizophrenia correlate with actual suicidal ideation or intent, our findings add to an increasing number of studies demonstrating that data captured from popular social media correlates strongly with data collected offline. For example, a recent study from Japan found that increases in conversations about suicide on Twitter were associated with increases in the number of actual suicide deaths over time [7]. Similarly, another study found that variation in Twitter conversations about suicide paralleled geographic distribution of real-world suicide rates in the United States [8]. Together, these studies suggest that discussion about suicide on Twitter may be an indicator of true suicide risk. Our study offers an additional important contribution by demonstrating strong correlations between conversations about suicide and conversations about depression or anxiety in both Twitter users who self-identify as having schizophrenia and...
control users. This is consistent with prior studies that have demonstrated that depression is a significant risk factor for suicide [45], as well as research showing that symptoms of anxiety also correlate with suicide risk [46,47]. For instance, a recent study following Reddit users over time found that those who proceed to discuss suicidal ideation were more likely to have previously posted content online reflecting various psychological and behavioral states, including increased anxiety, when compared to users who do not proceed to discuss suicidal ideation [48]. Therefore, our findings add to this recent work by further emphasizing the association between online discussion about mental health and suicidal ideation among social media users [48].

**Ethical Considerations**

Key considerations with using social media as a tool for monitoring conversations about suicide pertain to broader ethical challenges with using publicly available online data, as well as the need to carefully weigh threats to safety and privacy against benefits gained by using novel approaches to study suicide in this way. For example, we only examined publicly available data in this study, yet many individuals who openly share sensitive personal information on social media do so without fully realizing how this information will be used, who will use it, and in what ways it could potentially result in harm [33]. While the Twitter users whose data we examined in this study self-identified as having schizophrenia, it is important to recognize these individuals as belonging to a vulnerable group because disclosure of mental illnesses like schizophrenia is associated with societal stigma and risk of discrimination. Therefore, we removed usernames and all identifying information from users’ content analyzed in this study; in addition, we did not report any quoted text, as this is a recommended approach for balancing the privacy of Twitter users with the aims of research [33]. Interestingly, monitoring conversations about suicide on Twitter may uncover unanticipated crises or urgent health risks, highlighting the need to consider how best to respond to individuals potentially at risk of suicide and ensuring that these individuals receive access to necessary professional support [5]. Importantly, researchers have emphasized that the public nature of social media platforms like Twitter may yield valuable opportunities for intervention and supporting suicide prevention [5]. Future research is needed to expand on our current exploratory work for considering how social media platforms could be leveraged to support suicide prevention and early intervention among individuals with schizophrenia.

Connecting and interacting with others is a key attribute of social media platforms, which may expose individuals to unforeseen influences from others and possible risks [5]. Alternatively, social media platforms may allow individuals to seek peer-to-peer support, as has been previously observed among individuals with mental illness [15,49]; these platforms may also enable access to a valuable social support network, which is known to be associated with reduced suicide risk among persons with schizophrenia [50]. It is also necessary to carefully develop procedures and protocols that account for these ethical challenges and include strategies for risk management, as well as comprehensive approaches for protecting social media users’ safety while balancing the potential risk of suicide [51]. Ongoing efforts are needed to determine how to be mindful of potential ethical concerns while identifying novel approaches for supporting individuals with schizophrenia who may be at risk of suicide. This is especially important because there remains much uncertainty regarding ideal strategies for preventing suicide among vulnerable patient groups, such as individuals with schizophrenia [50].

**Limitations**

This was an exploratory study; therefore, caution is warranted when interpreting these findings. Several limitations should be considered. First, without access to psychiatric histories, it was not possible to confirm clinical diagnoses for the Twitter users who self-identified as having schizophrenia in this study. Additionally, these Twitter users likely differ from individuals with schizophrenia who do not disclose their illness online or who do not use social media. It is critical for future research to link content of discussions captured from social media with established clinical criteria to further support the generalizability of digital mental health detection methods [32]. Second, we were not able to collect demographic data from the Twitter users included in this analysis. National surveys indicate that Twitter users are typically younger than the general population [21], which is important when considering the implications of using social media for monitoring suicide risk in young persons; however, we were unable to determine the age of the users included in this study. This is a common challenge in public health research using social media [52]. In general, Twitter users tend to be young, have college degrees, and come from higher socioeconomic status groups [21]. A recent study showed that Twitter users with schizophrenia appeared to have high levels of education and, thus, may have fewer cognitive or functional limitations when compared to individuals with schizophrenia who do not use social media [16]. As a result, our findings likely do not generalize to individuals who do not use social media.

Third, we employed a convenience sampling approach to generate the group of Twitter users who self-identify as having schizophrenia as well as the control group. This sampling method further limits generalizability of these findings. Additionally, because the control group consisted of a randomly generated sample of Twitter users, we cannot rule out the possibility that individuals in this group could also have had a schizophrenia spectrum disorder, though the chance of this is low as schizophrenia prevalence is roughly 1% [53]. However, Twitter users in the control group could have had other types of mental illness associated with increased risk of suicide. Fourth, only a limited number of search terms for suicide were used in this study and it was not possible to confirm whether use of these terms referred to actual suicide risk or behaviors. Our selection of the terms suicide and suicidal was aimed at improving certainty that the online conversations captured in this study were in fact related to suicide; however, it is possible that use of these may have been in the context of suicide prevention or other unrelated topics. Future research will need to explore the context of social media conversations about suicide to determine whether it relates to help-seeking, sharing experiences, or offering support, and how this contributes to reduced or heightened suicide risk. Additionally, there are
several other terms that appear to reflect suicide risk on social media [8], suggesting that the current analysis may underestimate the frequency of online discussion related to suicide among this sample of Twitter users.

Conclusions

Our study takes preliminary steps toward demonstrating that Twitter users with schizophrenia appear to openly discuss suicide-related topics on Twitter and that these discussions are strongly correlated with conversations about common mental health symptoms known to be associated with actual suicide risk. This is an initial step toward informing the use of social media for monitoring suicide risk among people with serious mental illnesses such as schizophrenia. The need for effective approaches for detecting suicide risk remains a significant public health challenge [54]. The important opportunities to use social media for detecting and responding to suicide risk should not be missed. Going forward, it will be essential to weigh these benefits with potential ethical considerations related to individual privacy and ensuring adequate and timely responses to distressing content posted online. Therefore, future efforts are necessary to expand on our work presented here to develop and evaluate the use of social media for detecting suicide risk among individuals with schizophrenia, while seeking to leverage these popular online platforms for supporting suicide prevention efforts.

Acknowledgments

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Conflicts of Interest

None declared.

References


Abbreviations

UTC: universal time code
The WorkingWell Mobile Phone App for Individuals with Serious Mental Illnesses: Proof-of-Concept, Mixed-Methods Feasibility Study

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Abstract

Background: The disparities in employment for individuals with serious mental illnesses have been well documented, as have the benefits of work. Mobile technology can provide accessible in-the-moment support for these individuals. The WorkingWell mobile app was developed to meet the need for accessible follow-along supports for individuals with serious mental illnesses in the workplace.

Objective: We explore the usability, usage, usefulness, and overall feasibility of the WorkingWell mobile app with individuals with serious mental illnesses who are actively employed and receiving community-based services.

Methods: In this proof-of-concept, mixed-methods, 2-month feasibility study (N=40), employed individuals with serious mental illnesses were recruited in mental health agencies. Participants completed surveys regarding background characteristics and cellphone use at enrollment and responded to interview items regarding app usability, usage, and usefulness in technical assistance calls at 1, 2, 4, and 6 weeks of participation and in the exit interview at 8 weeks. Data on the frequency of app usage were downloaded on a daily basis. A version of the System Usability Scale (SUS) was administered in the exit interview. Overall feasibility was determined by the percent of users completing the study, responses to an interview item regarding continued use, and findings on usability, usage, and usefulness. General impressions were obtained from users regarding user support materials, technical assistance, and study procedures.

Results: Most participants were male (60%, 24/40), aged 55 or younger (70%, 28/40), white (80%, 32/40), had less than a 4-year college education (78%, 31/40), were employed part-time (98%, 39/40), had been working more than 6 months (60%, 24/40), and indicated a diagnosis of bipolar, schizoaffective, or depressive disorder (84%, 16/25). The majority of participants owned cellphones (95%, 38/40) and used them multiple times per day (83%, 33/40). Their average rating on SUS usability items was 3.93 (SD 0.77, range 1.57-5.00), reflecting positive responses. In general, participants indicated WorkingWell was “very easy,” “straightforward,” “simple,” and “user friendly.” Usability challenges were related to personal issues (eg, memory) or to difficulties with the phone or app. Data on app usage varied considerably. The most frequent navigations were to the home screen, followed by Rate My Day and My Progress, and then by Manage the Moment and Remind Me. The app was described as useful by most participants; 86% (30/35) agreed the app would help them manage better on the job. Of the 40 original participants, 35 (87%) completed the study.

Conclusions: The WorkingWell app is a feasible approach to providing accessible, as-needed employment support for individuals with serious mental illnesses. The app would benefit from modifications to address recommendations from feasibility testing.
Controlled research with larger samples, more diverse in individual characteristics and workplace settings, is essential to demonstrating the effectiveness of the app.

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KEYWORDS
mHealth; mobile apps; mental disorders; employment

Introduction

Supporting Employment

The disparities in employment for individuals disabled by mental illnesses such as schizophrenia, bipolar disorder, and major depressive disorder have been well documented [1-4], as have the benefits of work for these individuals [5-9]. Employment provides daily activity and routine, and opportunities for building social supports, with positive impact on self-esteem and independence, social integration, and community participation. Supported employment service delivery models, such as Individual Placement and Support (IPS), have demonstrated robust success in promoting competitive employment among individuals with psychiatric disabilities [10]. IPS promotes consumer choice and shared decision making regarding employment plans, collaborative involvement of consumers with the treatment team to identify and implement strategies to promote success and competence in finding competitive work, and ongoing support to help maintain a positive employment course. The effectiveness of IPS for individuals with severe psychiatric disabilities has been established in 17 randomized controlled trials [11-13]. Approximately two-thirds of clients enrolled in IPS achieve the goal of a competitive job compared to fewer than one-quarter of clients who receive other forms of vocational services [14].

Although supported employment services have demonstrated effectiveness in helping individuals achieve the goal of competitive employment [6,15], sustaining employment presents additional challenges [8,16]. Symptom severity and limitations in neurocognitive capacities, interpersonal skills, motivation to work, and self-efficacy undermine job tenure. In-person supported employment services are not routinely provided on the job, creating a gap in support for individuals with mental illness who are actively working.

The use and benefits of mobile technology in providing accessible, in-the-moment support for individuals with mental illnesses have been demonstrated [17-21]. Individuals with mental illnesses rely on Web- and technology-based health information and tracking tools, just as do individuals who are well [20-26], particularly if tools are appropriately designed and adequate training is provided [27,28]. The groundwork has been laid for technology-based tools to have a positive impact for individuals coping with challenges in the workplace [29,30].

In focus groups of supported employment service recipients conducted in the discovery phase of this study, individuals living with serious mental illnesses reported work challenges related to job characteristics, tasks, and expectations; interpersonal and social situations; illness- and treatment-related issues; lifestyle/wellness and conditions apart from work; and sustaining motivation [30]. The majority of participants owned mobile phones and were comfortable using technology.

The WorkingWell App

The WorkingWell mobile app was developed in response to the need for accessible follow-along supports for individuals with serious mental illness who are actively employed [31]. The app was developed through the collaborative efforts of researchers, providers, individuals with serious mental illnesses, an Expert Advisory Panel (including supported employment services trainers and providers), and experienced app designers. It was informed by user experience design. Iterative cycles of usability testing were conducted individually, side-by-side, and in focus groups as content, information architecture, and navigation were developed. The principles underpinning the app were drawn from evidence-based supported employment [32]. Motivational and behavior change theories and strategies were actively embedded in WorkingWell features and functions through content development as well as in the design of interactions and feedback.

Users begin their interactions with WorkingWell by setting up to three work-related goals each week, selected from a prepopulated list or by adding their own. They are provided a motivational quote and image and are reminded of their goals each day they access the app. Users are encouraged to choose new goals each week. Once they have chosen or reviewed their goals, users navigate to the home page, where they find the four main app components: Manage the Moment, Remind Me, Rate My Day, and My Progress. In Manage the Moment, coping skills and tips for dealing with challenges are provided, along with ideas for how to implement selected coping strategies. Remind Me provides tools that are built into the app for setting text message reminders, creating to-do lists, and making notes. In Rate My Day, users rate their effort in accomplishing their goals, from 1 to 5 stars, along with rating their success in other areas such as dealing with stress and finishing tasks. My Progress provides feedback based on users’ ratings (eg, “Way to go! Things are going fantastic! What can you do to keep it up?”) and a detailed record of their entries for the past 4 weeks, so users can track their progress and explore patterns in their work day activities and evaluations.

Research Questions

In this study, we explore the feasibility of use of the WorkingWell app by individuals with serious mental illnesses receiving community-based supported employment services and actively working. Research questions include:

1. Do study participants find WorkingWell easy to use (usability)?
2. Do study participants use the app, and which components are used most frequently (usage)?
3. Do they find the WorkingWell app useful with regard to managing work demands and illness issues, and which specific app features or components are most useful (usefulness)?
4. Is the WorkingWell app a reasonable, practical tool capable of being used by individuals with serious mental illnesses in dealing with employment challenges (feasibility)?

Recommendations for improvements in the WorkingWell app are solicited from study participants. Findings will inform ongoing refinements to WorkingWell and suggest future implementation approaches and research targets for individuals with serious mental illnesses as well as individuals coping with other health challenges at work.

Methods

Study Design

In this proof-of-concept, mixed-methods feasibility study, we addressed questions related to the usability, usage, usefulness, and overall feasibility of the WorkingWell mobile support tool (“app”) for working adults with serious mental illness. A complete description of the study protocol, methods, and procedures was previously published [31]. This previous publication included images of the WorkingWell app along with the WorkingWell User Guide, published as supplementary material [31]. The WorkingWell team implementing the study included the principal investigator (a doctoral-level clinical and research psychologist) and two research staff members with undergraduate degrees in social sciences and previous experience in research, trained by the principal investigator in procedures and methods relevant to the study. The researchers did not have preestablished relationships with nor provided services to study participants.

Recruitment

Participant Eligibility and Screening

A convenience sample of adults with serious mental illnesses was enrolled from six community mental health agencies in Massachusetts, Vermont, and Maryland. Criteria for study enrollment included that participants had to be (1) 18 years of age or older; (2) receiving supported employment services (and, by definition of service eligibility and disability, living with serious mental illness); (3) working an average of 10 or more hours per week; (4) employed in a position that was not, by definition, seasonal or temporary; and (5) capable of reading and writing in English at a sixth-grade reading level or higher. Participants could have been employed for any length of time at the point of study enrollment, given our interest in the usefulness of the app at various times in the employment trajectory. Participants were not required to have a minimum level of familiarity with mobile phone or computer technology to enroll in the study, as the relationship between WorkingWell use and variation in experience with mobile phones was an issue to be explored. Participants received a stipend for completing the study orientation and enrollment interview (US $25), midway during the 8-week study period at the completion of the fourth technical assistance call (US $50), and at their exit interview from the study (US $75). Agency staff members, designated as liaisons, assisted in distributing information about the study and screening individuals volunteering to participate. Research staff reviewed participants’ eligibility criteria with agency liaisons prior to enrolling participants in the study.

Sample Size

Forty participants with serious mental illness were enrolled in the study. This was determined to be an adequate sample size given the study focus on feasibility. Forty participants allowed us to investigate the range of ways in which individuals experienced using the app.

Procedures

Orientation Session and Enrollment Data Collection

Research staff traveled to agency sites to enroll participants and provide an in-person orientation to the study, mobile phone, and WorkingWell app. Orientations were conducted as individual or group sessions (up to eight participants) depending on the number of participants recruited at a particular site and participant availability. Orientation sessions varied in length due to differences in group size, lasting about 1.5 hours on average. Staff first described the study and obtained written informed consent to participate from attendees. Participants were assigned unique study identification numbers, and they completed the paper-and-pencil enrollment survey.

Participants were then provided with Android mobile phones with unlimited data plans to access WorkingWell and communicate with research staff. Phones were provided to ensure the app was implemented by all participants using a standard interface and operating system, to facilitate the staff’s ability to provide technical assistance, and to avoid creating a financial burden or barrier to study participation.

In the orientation session, research staff reviewed mobile phone and app navigation and functions using study phones. A Study Phone User Guide and WorkingWell User Guide [31] were provided to each participant. Participants were offered individualized hands-on technical assistance by researchers if required. Participants engaged in a discussion of appropriate mobile phone use in the workplace (eg, using WorkingWell during a lunch break or before or after work rather than while on the job if employment policies precluded phone use during work hours) to discourage phone or app use that would negatively impact their employment or safety.

Technical Assistance Calls

Research staff provided technical assistance to study participants on the telephone one day after the orientation session and during weeks 1, 2, 3, and 6 of study participation. The time and location of the calls were determined by participants (eg, after work hours or during a work break). At the start of each call, research staff confirmed with participants that it was a convenient time and that they were in a safe, comfortable environment (eg, not driving or distracted by environmental stimuli). Questions and prompts focused on challenges in using the mobile phone or app, general impressions of the app, how the app was used at work in the past few days or anticipated use the next time at work.
work, confidence in using the app, and any additional support or information required. In technical assistance calls 2 through 5, additional prompts were added to obtain greater detail regarding app use, including the ease of use and usefulness of specific app features and components, and the ways in which WorkingWell was incorporated into the participant’s daily schedule. Responses to technical assistance call prompts were recorded verbatim by research staff using standardized forms developed for the study. If participants missed two consecutive technical assistance calls or were out of communication with research staff for more than 3 weeks, they were considered lost to follow-up.

Participants could also access research staff members as needed by telephone call or text message. Participant-initiated communications with researchers most often related to the scheduling of technical assistance or exit interview sessions, report of a problem with the app or the study phone, request for technical assistance for specific issues, or coordination of study incentive retrieval. These calls, while infrequent, were logged in detail as memos by research staff to provide complete data on any challenges faced by participants in phone or app use. For individuals who required additional help, in-person assistance was provided at the agency site by the research staff or agency liaison.

Exit Interviews

Exit interviews were completed with participants in person, in meeting rooms at agency sites at the end of the 8-week study period. Participants completed a poststudy paper-and-pencil survey. Additional open-ended interview items focused on user experience of the app and impressions of the research experience. Responses to exit interview questions were recorded in detail by research staff in a standardized format that included a section for additional observations and field notes. All exit interviews were completed individually with participants except in two instances. One participant confirmed that the agency liaison could be present, and another participant wished for her mother to attend the session. These invited individuals did not directly participate in the interview in any way.

Measures

Participant Characteristics

Participants completed survey items regarding background and demographic characteristics at the time of study enrollment. These included questions about age, gender, race, education, employment, living situation, marital and family status, and mental health diagnosis. They completed a set of items regarding their access to, type, and frequency of cellphone use; six other items related to ease of phone use (eg, typing, sending a text message, accessing the internet, using an app, taking pictures, and using social networking sites) were rated on a 5-point scale from 1 (“can’t do at all”) to 5 (“really well”), except for ease of typing, which was rated on a scale from 1 (“not at all easy”) to 5 (“extremely easy”). These items were adapted from a prior study of mobile technologies and people with serious mental illness [17].

Usability

During the exit interview, participants completed the poststudy survey. Usability was assessed by an adapted version of the System Usability Scale (SUS) [33-35]. A subset of seven SUS items was determined to be most relevant to the study. Participants’ responses were rated on a 5-point Likert-type scale (1=“strongly disagree” to 5=“strongly agree”) to items regarding the likelihood of using the app frequently, the complexity of the app, ease of use, the need for support to use the app, whether people would learn to use the app quickly, confidence in using the app, and whether the user would have to “learn a lot” before using the app. The SUS has been applied to a wide range of technologies, has demonstrated good validity, can differentiate between usable and unusable systems, and it has demonstrated reliability even with small sample sizes [33-35].

Qualitative data on WorkingWell usability were obtained over time during technical assistance calls and the exit interview. Open-ended interview items included questions regarding whether users had difficulties logging in to the app; their confidence in using the app, given what they learned in the orientation session; whether it was easy or complicated to use the app and how they managed any challenges in app use; whether and which particular app components seemed confusing or not, along with recommendations for modifications; and what would have to happen for them to use the app regularly. In addition, in each technical assistance call, study participants were asked whether they were having any problems with the mobile phone per se and to describe them. This item was included so the research team could tease apart usability issues related to the phones rather the WorkingWell app.

Usage

Data on participant app usage were downloaded and monitored on a daily basis for quality assurance and app use tracking purposes. Data included participants’ daily number of navigations to the WorkingWell home screen and to the My Progress, Manage the Moment, Remind Me, and Rate My Day components of the app. To understand app usage in greater detail, open-ended interview items were developed and included in the technical assistance calls and the exit interview regarding when the participant tended to use the app and in what circumstances, and whether app use was integrated into a daily routine. Participants also were asked to describe a specific situation in which they used the app.

Usefulness

The usefulness of the WorkingWell app (ie, the ability to be used to achieve the user’s goal) was assessed in the poststudy survey by items regarding whether the app would help users remember why they want to work (motivation/job fit), manage better on the job (work self-efficacy), and connect with others who are supportive of their efforts to work (social support). Responses to these items were categorized as “agree,” “neutral,” or “disagree.” An additional item reflected whether the app would be useful in helping the user to stay on the job (rated on a 5-point Likert-type scale from 1=“strongly disagree” to 5=“strongly agree”). These items were developed to reflect potential mediators (eg, motivation, work self-efficacy, and
social support) as well as anticipated outcomes (eg, job tenure), and the perceived usefulness of the app in addressing these variables. Qualitative data were obtained in technical assistance calls and exit interviews regarding app components or features that were most or least useful and the best and worst things about using WorkingWell, with prompts to provide detailed descriptions.

Feasibility
Feasibility of WorkingWell (ie, the likelihood that the app could be implemented successfully and used effectively) was determined by the percent of users completing the 8-week study. An exit interview item, developed for this study, solicited feedback on how likely the participant would be to continue using the app regularly (rated on a 10-point scale from 1 = "not at all" to 10 = "extremely likely"). Users were encouraged to provide recommendations for app modifications or additions. General impressions were obtained from users regarding the WorkingWell app support materials, technical assistance, and study procedures, with an eye toward framing future refinements to app support and the research protocol. Overall feasibility of the WorkingWell app will reflect consideration of findings regarding usability, usage and usefulness, along with study completion.

Analysis
Quantitative data were entered into Qualtrics [36] databases and analyzed using SPSS version 24 [37]. Data were checked, cleaned, and managed by research staff, and item responses were recoded where necessary for consistent directionality. Descriptive statistics were computed for all items, and mean scale scores were calculated for the 6-item ease of phone use scale and the 7-item version of the SUS. Usage data were exported from the database within the app and compiled in spreadsheets for each participant. Usage plots for each participant, generated using SAS version 9.2 software [38], showed the number of navigations to various components of WorkingWell for each day within the 8-week study period.

Responses to open-ended interview items from technical assistance calls and exit interviews were exported for qualitative data analysis using the Dedoose software platform [39]. A framework approach was used to analyze qualitative data, given that the research team identified issues to investigate prior to study implementation (ie, usability, usage, usefulness, and feasibility) and developed interview items accordingly [40]. Therefore, some themes were identified in advance, while others were derived from the data as thematic coding progressed. Prior to the start of qualitative coding, the research team met to review the data, discuss the codes to be used, and informally code technical assistance calls in hard copies. Once a coding plan was established, two members of the research team coded text data, discussing and reconciling any disparate code identifications along the way. The research team prepared memos for themes reflecting study phone and app challenges, and for feedback on WorkingWell, user support materials and study procedures.

Trustworthiness of the qualitative analysis process and findings was established in multiple ways [41]. Five sets of randomly selected excerpts, coded by two members of the research team, were coded independently by the third member of the research team, achieving an average pooled kappa of .76 (range from .68 to .84), considered substantial agreement [42]. Differences were reconciled to achieve complete agreement in all cases. Due to the small sample size and exploratory nature of the study, all technical assistance calls and exit interview data were coded, rather than simply coding until data saturation was achieved. Trustworthiness was further established through peer debriefing and member checking [43] following contacts with study participants. Initial impressions, reviewed and discussed by the research team, were incorporated into subsequent interviews with later study enrollees, as well as into subsequent interviews with the same participant. Preliminary findings were reviewed in iterative cycles by independent stakeholders on the study’s Expert Advisory Group and actively working in the field.

Ethics Approval and Consent
The study design and procedures were approved by the Dartmouth-Hitchcock Medical Center Committee for the Protection of Human Subjects (#00028834), the Massachusetts Department of Mental Health Central Office Research Review Committee (#2015-21), and the Vermont Agency of Human Services Institutional Review Board. Written informed consent was obtained from all participants at the beginning of the orientation session.

Results
Participant Characteristics
All participants (N=40) were included in the analysis of responses regarding background and demographic characteristics, and cellphone use. Participant characteristics are summarized in Table 1. More than half of the participants were male (24/40, 60%). The majority were age 55 or younger (28/40, 70%), white (32/40, 80%), had less than a 4-year college education (31/40, 78%), were employed part-time (39/40, 97%), had been working more than 6 months (24/40, 60%), lived independently (25/40, 63%), were never married (26/40, 65%) nor currently living with a partner (36/40, 90%), and were not parents (28/40, 70%). Of those reporting a known mental health diagnosis, 64% (16/25) indicated a diagnosis of bipolar or depressive disorder.

The vast majority of participants reported owning cellphones (38/40, 95%) and using them multiple times per day (33/40, 83%). They described using cellphones with ease (average rating of 3.78 on a 5-point scale). Cellphone data and ease of use are summarized in Table 2.

Usability
Thirty-five of 40 enrolled participants completed 8 weeks of the study. Their average rating on the SUS scale was 3.93 (SD 0.77, range 1.57-5.00), as adapted for mobile phone apps, reflecting generally positive responses to usability items. Interestingly, the relationship between the ease of cellphone use (enrollment survey) and the SUS usability ratings was weak (r=.166).
Table 1. Demographic characteristics of study participants (N=40).

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (40)</td>
</tr>
<tr>
<td>Male</td>
<td>24 (60)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>18-35</td>
<td>11 (28)</td>
</tr>
<tr>
<td>36-55</td>
<td>17 (42)</td>
</tr>
<tr>
<td>≥56</td>
<td>12 (30)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>32 (80)</td>
</tr>
<tr>
<td>African American</td>
<td>7 (18)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>High school diploma/General Education Diploma or less</td>
<td>18 (45)</td>
</tr>
<tr>
<td>Vocational/military training/some college</td>
<td>13 (33)</td>
</tr>
<tr>
<td>4-year college degree/graduate studies</td>
<td>9 (22)</td>
</tr>
<tr>
<td><strong>Current employment</strong></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Part-time &lt;30 hours a week</td>
<td>39 (98)</td>
</tr>
<tr>
<td><strong>Time at current job</strong></td>
<td></td>
</tr>
<tr>
<td>≤6 months</td>
<td>16 (40)</td>
</tr>
<tr>
<td>&gt;6 months</td>
<td>24 (60)</td>
</tr>
<tr>
<td><strong>Current living situation</strong></td>
<td></td>
</tr>
<tr>
<td>Own house or apartment</td>
<td>25 (63)</td>
</tr>
<tr>
<td>House or apartment of parent, relative, or friend</td>
<td>9 (22)</td>
</tr>
<tr>
<td>Residential treatment program or supervised living environment</td>
<td>6 (15)</td>
</tr>
<tr>
<td><strong>Ever married</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14 (35)</td>
</tr>
<tr>
<td>No</td>
<td>26 (65)</td>
</tr>
<tr>
<td><strong>Currently living with spouse or partner</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (10)</td>
</tr>
<tr>
<td>No</td>
<td>36 (90)</td>
</tr>
<tr>
<td><strong>Has children</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12 (30)</td>
</tr>
<tr>
<td>No</td>
<td>28 (70)</td>
</tr>
<tr>
<td><strong>Mental health diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>11 (44)</td>
</tr>
<tr>
<td>Schizoaffective disorder</td>
<td>5 (20)</td>
</tr>
<tr>
<td>Depressive disorder</td>
<td>5 (20)</td>
</tr>
<tr>
<td>Anxiety disorder/posttraumatic stress disorder</td>
<td>4 (16)</td>
</tr>
</tbody>
</table>

\(^a\)n=25. Fifteen participants did not provide a specific mental health diagnosis.
Table 2. Participant-reported cellphone use at enrollment (N=40).

<table>
<thead>
<tr>
<th>Cellphone use</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellphone access, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Owns a cellphone</td>
<td>38 (95)</td>
</tr>
<tr>
<td>No access to cellphone</td>
<td>2 (5)</td>
</tr>
<tr>
<td><strong>Cellphone type, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Smartphone (phone with a data plan/internet)</td>
<td>28 (70)</td>
</tr>
<tr>
<td>Basic mobile phone (phone with no internet)</td>
<td>10 (25)</td>
</tr>
<tr>
<td>No access to cellphone</td>
<td>2 (5)</td>
</tr>
<tr>
<td><strong>Frequency of cellphone use, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Multiple times per day</td>
<td>33 (83)</td>
</tr>
<tr>
<td>One time per day or less</td>
<td>4 (10)</td>
</tr>
<tr>
<td>No access to cellphone</td>
<td>3 (7)</td>
</tr>
<tr>
<td><strong>Ease of cellphone tasks,\textsuperscript{a} mean (SD)</strong></td>
<td></td>
</tr>
<tr>
<td>Typing</td>
<td>3.48 (1.36)</td>
</tr>
<tr>
<td>Send a text message</td>
<td>3.93 (1.35)</td>
</tr>
<tr>
<td>Access the internet</td>
<td>3.88 (1.45)</td>
</tr>
<tr>
<td>Use an app</td>
<td>3.78 (1.42)</td>
</tr>
<tr>
<td>Take pictures</td>
<td>3.98 (1.21)</td>
</tr>
<tr>
<td>Use social networking sites</td>
<td>3.65 (1.44)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Ease of cellphone tasks were rated on a 5-point Likert-type scale: 1 (“can’t do at all”) to 5 (“really well”), except for ease of typing, which was rated on a scale of 1 (“not at all easy”) to 5 (“extremely easy”).

Participants, in general, indicated that the WorkingWell app was “very easy,” “straightforward,” “simple,” and “user friendly.” Some participants attributed this ease of use to the app navigation process and layout. One participant noted, “It was easy to pick up and learn, pretty straightforward. It was clear, laid out very well.” They described feeling as though there was no way to make a mistake in the app and if you did, it was easy to navigate away and attempt that task again. Participants who did not have extensive experience with mobile phones prior to participating in the study reported that they also found the app to be easy to use. For example: “I’m not a high-tech person. I don’t know anything about iPhones or how to download things, but the app is easy to use. It’s simple.”

When participants did report usability challenges, they tended to be framed as attributable to their personal challenges (eg, lack of familiarity with technology, confusion, forgetfulness) or to difficulties with the phone or app (ie, prototype layout or performance). One participant commented, “I am not very good with mechanical stuff, like setting passwords and stuff. To use the phone and app fully I have to get better at using computers and phones.” Overall, most participants were familiar with computers and/or mobile phones when they enrolled in the study. These participants seemed to have an ingrained sense of how to use basic phone functions and control settings, and to navigate to various components. The more experienced technology users often exhibited a more exploratory approach to familiarizing themselves with the phones (eg, navigating to all parts of the phone to see what was there), rather than the more regimented approach taken by many of those with less experience with this type of technology (eg, taking careful notes on navigation pathways).

Participants reported several types of app-related usability challenges regarding layout and content. One participant stated, “Navigating to the ‘My Tips’ section is kind of hard because there is so much there. And it’s hard to find the specific things I was looking for.” Another participant reported that large amounts of text were a challenge. One participant was unable to remember the meaning of some of the text, stating, “...I don’t remember what the skills mean. So, I don’t click on it [in Rate My Day] because I’m not sure if I used it.” Another participant described difficulty recognizing the implementation of specific skills in his own experience, stating, “Sometimes I don’t recognize what skill I used or didn’t use.”

One of the more common app-related challenges was prototype malfunction, for example, the appearance of unintended error messages sometimes combined with the app “freezing.” One participant described, “I was getting an error message and after that came up the screen wouldn’t do nothing. Only happened twice and then I turned it off and recharged it and it was fine.” These experiences seemed to sometimes be related to the use of the in-app “back” button. Many participants also described an app-related issue in which buttons were slow to respond or app screens were slow to load.

Usage

Study participants were advised to use WorkingWell on the days they worked during the 8-week study period. Nearly all
the participants worked part-time during the study. Twenty-eight were continuously employed, working at least 7 of the 8 weeks of their study participation. Two initiated job changes, and two were hospitalized during the 8-week study period and continued working, although fewer than the full 8 weeks. Three participants left their jobs but continued in the study while they looked for new positions. For the 31 participants reporting on the average number of hours worked per week at exit from the study, 65% (20/31) worked up to 20 hours per week on average and 35% (11/31) worked between 21 and 30 hours per week on average. These data reflect hours rather than actual days worked during the study, but they shed light on potential opportunities for app usage, given the instruction to participants to use the app on days when they were working.

Data on participant app usage varied considerably (Table 3). The most frequent navigations were to the WorkingWell home screen, which is the portal to using any of the app components. Next most used components were Rate My Day and My Progress, followed by Manage the Moment and Remind Me.

Several participants described a lack of time, energy, or focus as a personal barrier to using the app or completing app processes. As one participant described, “The big thing for me is...setting aside some time to actually work on it [the app]. I was going to do it at night, but I was too tired.” Other participants described difficulty remembering to use the app altogether. One individual described this experience as being related to symptoms of a possible medical condition, stating, “I think I have sleep apnea, so my memory is really bad and I’m always tired and I forget to do this.” Another participant described the interaction of infrequent app use with navigation difficulties saying, “I just can’t always remember, and it seems silly because there are only four [buttons]...I think if I worked more I would remember where everything is.”

Usefulness

The WorkingWell app was described as useful by the majority of study participants (Table 4). Three-quarters of the participants (27/35, 77%) indicated that the app would help them remember why they want to work, 86% (30/35) agreed that the app would help them manage better on the job, and 57% (20/35) indicated that the app would help them connect with supportive others. The average rating of overall usefulness of the app was 3.74 (SD 0.92) on the 5-point Likert-type scale.

Participants described each component of WorkingWell as useful. In general, as one participant explained, “The best part was just knowing it [the app] was there. Knowing if I was in a funk, I had tools at my disposal.” Many appreciated the motivational quotes that appeared each time the app was opened, along with the affirmations that appeared in response to ratings in Rate My Day. For example, “I really like the inspirational quote. I would log in to the app just for the quote.” Participants appreciated the goal-setting feature of the app and the benefit of reflection at the end of the day prompted by completion of the Rate My Day component. A participant reported, “When you choose the three things to focus on for the week you narrow it down, so it is easier to focus on just a few things.” Participants indicated that using the app with their employment specialist to set up goals and review their progress would have been a good support.

Another participant described, “I like ‘Rate My Day’ because I can see how I’m doing and my progress.” These ratings are compiled into weekly progress reports, valued by a number of participants. “I’ve compared all my weeks in ‘My Progress’...It’s pretty cool that you can see patterns in your ratings.” Participants who integrated ratings of their days with ratings of coping skills began to see additional patterns emerge. “I find it [Rate My Day] more useful, so I am aware of what is going on...Now I think about why and about how to talk to other people about it, like my boss.” Participants were heartened by signs of progress: “‘My Progress’ is the most useful to me. It helps me be aware that I’m making progress and improving on tasks.” Some participants who did not find the goal-setting and rating features of the app useful were disappointed that they had to limit themselves to only three goals each week and were frustrated that they needed to change or re-enter their goals weekly.

Many participants described the Manage the Moment component of the app as useful. “I like the tips it gives you in detail and can help you apply these tips on the job.” Participants found the tips regarding interpersonal relationships helpful, for example, “How I used it to improve, like, talking to my boss instead of holding it inside.” Others found the tips in Manage the Moment effective in helping with managing symptoms on the job. For example, “The biggest thing for me is my anxiety and the tasks [tips] calm me down.” Other participants found the tips on lifestyle and wellness helpful, “I’ve been overtired, and you can’t work well when you’re like that and the app is reminding me how important it is that I get enough rest.” A few participants did not find this app component useful, indicating, “Some of the skills don’t really apply to my job.”

Table 3. Participant WorkingWell app usage during the 8-week study period (N=35).

<table>
<thead>
<tr>
<th>Number of navigations to app component</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home screen</td>
<td>72.0 (43.5)</td>
<td>8-178</td>
</tr>
<tr>
<td>My Progress</td>
<td>37.8 (25.2)</td>
<td>1-98</td>
</tr>
<tr>
<td>Manage the Moment</td>
<td>16.9 (16.2)</td>
<td>1-55</td>
</tr>
<tr>
<td>Remind Me</td>
<td>14.3 (12.7)</td>
<td>1-42</td>
</tr>
<tr>
<td>Rate My Day</td>
<td>41.2 (31.0)</td>
<td>1-107</td>
</tr>
</tbody>
</table>
Table 4. WorkingWell app usefulness and feasibility ratings at study endpoint (N=35).

<table>
<thead>
<tr>
<th>Usefulness and feasibility</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The WorkingWell app would help me remember why I want to work, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>27 (77)</td>
</tr>
<tr>
<td>Neutral</td>
<td>7 (20)</td>
</tr>
<tr>
<td>Disagree</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>The WorkingWell app would help me manage better on the job, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>30 (86)</td>
</tr>
<tr>
<td>Neutral</td>
<td>5 (14)</td>
</tr>
<tr>
<td><strong>The WorkingWell app would help me to connect with people who are supportive of my efforts to work, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>20 (57)</td>
</tr>
<tr>
<td>Neutral</td>
<td>14 (40)</td>
</tr>
<tr>
<td>Disagree</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Overall, how useful would this app be in helping you stay on the job(a), mean (SD)</td>
<td>3.74 (0.92)</td>
</tr>
<tr>
<td>How likely would you be to continue using this app regularly(b), mean (SD)</td>
<td>7.99 (1.89)</td>
</tr>
</tbody>
</table>

\(a\)Usefulness of the app in helping to stay on the job rated on a 5-point Likert-type scale: 1 (“strongly disagree”) to 5 (“strongly agree”).

\(b\)Feasibility (ie, the likelihood) of continuing to use the app regularly rated on a 10-point Likert-type scale: 1 (“not at all”) to 10 (“extremely likely”).

Many participants reported that the Remind Me feature was useful. For example, “I like to use the text message reminders to send positive messages to myself. It gives you more positivity during the day.” Several indicated they used the Remind Me component to break their job tasks into small steps to make tasks more manageable. Those participants who did not find text message reminders helpful tended to already use other phone features to set reminders, such as the calendar or alarm feature. One participant suggested that one bad thing about reminders is that, “People can get dependent on them.”

**Feasibility**

Thirty-five of the 40 original participants (88%) completed the 8-week study. The ratings of the 35 study completers regarding the likelihood of using the app regularly were quite positive, with a mean of 7.99 (SD 1.89) on the 10-point scale. The five participants who did not complete 8 weeks of the study participated for a mean of 4.8 weeks (range 2.5-7 weeks) and ended participation for various reasons, including changes in work schedule that precluded participation.

Some participants mentioned that the user support materials provided to them at orientation by the research staff (eg, WorkingWell User Guide, study phone user guide) were helpful supplementary materials to the in-person orientation sessions. They served as references to consult if participants forgot how to perform a specific function in the app. Other participants described using support materials beyond those created by the research staff, such as creating individualized step-by-step instructions on how to navigate the app or checking out a phone user manual from the library to learn more about the study phone. Several participants discussed issues they had with the user support materials. One participant noted, “Papers and papers about something electronic just make me nervous.” Some participants reported seeking technical assistance from agency staff such as their job coach or employment specialist or from other support persons such as rehabilitation coordinators or counselors. They indicated that having this resource was important, as “hands-on instruction is best.” Participants also cited receiving assistance from family and friends. This help seemed to focus primarily on difficulty performing tasks on the study phones rather than with the WorkingWell app. Several participants noted that they reached out to other participants in the study to either request technical assistance or to provide it. Study participants suggested several changes to study procedures that would improve their use of the app. Some participants mentioned that having the app on their own phone, rather than a separate study phone, would make it easier to remember to use the app daily and incorporate it into their routine more conveniently.

**Discussion**

**Principal Results**

In this study we posed four questions regarding the usability, usage, usefulness, and feasibility of the WorkingWell mobile app for individuals with mental illness coping on the job. Our findings, largely positive, support the potential use and benefit of an app such as WorkingWell for this target population. Data from study participants suggest modifications that will improve the app and that are relevant to study design and procedures for next-step efficacy testing. Recommendations for modifications are provided as they reflect findings discussed subsequently.

The weak relationship between ratings of ease of cellphone use and usability of the WorkingWell app (SUS) is a positive finding. It suggests that participants’ experiences of using WorkingWell is independent of their ability to use a cellphone. Both novice and experienced cellphone users were equally able...
to use the app. WorkingWell is designed such that cellphone familiarity is not essential to use of the app.

Although WorkingWell received generally high marks and positive feedback on usability, some users found it to be too “wordy.” Some were unsure of the meaning of some of the coping skills and consequently had difficulty applying these tips in their daily lives. These findings are consistent with recommendations for critical design elements in previous research with individuals with mental illnesses: include a singular focus, simple architecture, prominent contents, explicit navigation, and inclusive hyperlinks [28]. Researchers have suggested the value of testing language used with potential end users, in this case, individuals with mental illness, who may have idiosyncratic notions regarding the meaning of commonly used words and phrases [28]. These findings suggest the potential benefit of reducing the volume of text in the next iteration of WorkingWell and conducting more extensive usability testing regarding the language used. In addition, there were several reports of app malfunction. Modifications were made to WorkingWell during the study as problems were identified.

Usage varied considerably among WorkingWell participants, ranging from minimal usage to, most likely, several times per work day. Subsequent visual inspection of graphs of individual navigations to the home screen over the course of study involvement suggested several diverse patterns ranging from those whose use peaked at the beginning of the study and then dropped off to those whose use was fairly consistent over time. During qualitative interviews some users reported that they forgot to use the app or were too tired at the end of the day. Therefore, it may be helpful for the user to set personalized text message reminders as a routine to encourage use of the app at a time that is convenient. The benefits of personalized contacts in promoting higher response rates to Web- or internet-based surveys, for example, have been demonstrated [44]. If the user is accessing WorkingWell in collaboration with a supervisor, colleague, or employment specialist to improve on-the-job functioning, they might set reminders together. It may also be helpful to program in routine reminders for app use that could be personalized by the user and modified over time as schedules and routines change.

Users provided positive feedback on the usefulness of the app. They valued the motivational quotes and supportive feedback on daily ratings. Study participants enjoyed setting goals, monitoring progress and reflecting on patterns over time in challenges, coping efforts, and ratings. Fewer found the app helpful in connecting with supportive others, suggesting the potential benefits of modifications to facilitate data sharing and the solicitation of feedback from others to increase interactivity. Some users suggested that setting goals and monitoring progress with employment specialists, for example, would be useful. Study participants also recommended building in greater capacity to tailor the app to make it more relevant to specific job sites and responsibilities.

Given the finding that 35 of 40 study participants completed the study, and including consideration of findings regarding usability, usage, and usefulness, WorkingWell was found to be a feasible approach to helping individuals with mental illness to cope on the job. The findings that the majority were continuously employed throughout the study and that those who were not had plans to seek new positions while using the app suggest that WorkingWell may be efficacious in sustaining both motivation to work and employment. The WorkingWell app was found to be useful by participants who had only been employed for a short time as well as those who had been employed for a longer period. This suggests the app can be useful not only for those coping with the stress of a new job, but for those navigating the challenges of sustaining employment over time. Although a job may become less challenging over time, as a person learns and masters the day-to-day expectations and routines, the impairments conveyed by serious mental illnesses may not change over time (eg, memory or attention deficits). Consequently, the WorkingWell app may be useful throughout an individual’s employment.

**Limitations**

The developmental mixed-methods approach of this study allowed us to look closely at the usability, usage, usefulness, and feasibility of WorkingWell. Future research on efficacy and effectiveness will require larger, more diverse samples, with a randomized controlled trial design, a longer follow-up period, and the use of targeted standardized outcomes [45]. A larger sample size would allow us to stratify the sample by individual characteristics that may be associated with outcomes to increase statistical power. Assessing the impact of the WorkingWell app in real-world practice would require participants using their own phones and data plans, as well as the testing of various levels of orientation and support to the app. Facilitating use of the app on participants’ mobile phones, rather than study-provided phones, may promote increased and routine use of the app. Alternatively, participants may find their phones or data plans burdened by WorkingWell app use. Further research will also enable us to explore the use and effectiveness of the app in diverse employment contexts. The WorkingWell app will require modifications and additional usability testing to address the recommendations provided by participants in this study.

**Comparison With Prior Work**

Prior research has provided evidence of the penetration and use of mobile phones and mobile technology by individuals with mental illness [46]. In this study, participants—admittedly willing volunteers—seemed interested in using WorkingWell and generally put it to use. The participants appeared comparable to those in other studies of supported employment [47], suggesting the potential generalizability of our findings to this population. Moreover, our findings suggest the potential usability and usefulness of WorkingWell for the larger population of individuals receiving supported employment services (eg, people with autism, first-episode psychosis, or cognitive deficits). The core elements of WorkingWell (eg, staying motivated, goal-setting and progress monitoring, managing stress, remembering job tasks and responsibilities, and getting along with others) reflect challenges for many employees in many workplaces, suggesting the potential usefulness of the app for workers and supervisors across settings.
The sound conceptual and theoretical underpinnings of WorkingWell enhance the likelihood of its effectiveness and broad applicability [48].

The process by which we developed the WorkingWell app was consistent with recent recommendations of experts in the field for the development of mHealth interventions for individuals with serious mental illness [49]. WorkingWell was developed to meet an unmet need for follow-along supports in the workplace for individuals coping with mental illness on the job. Stakeholders, including individuals with mental illness, experts in supported employment and technology-based interventions, and experienced designers were involved in every step of the development and testing of WorkingWell [30,31]. Because of their contributions, we are well-positioned to transition to future effectiveness studies once user-recommended modifications have been made.

Our findings are consistent with those of other studies of emerging mHealth and eHealth interventions targeting individuals with serious mental illnesses in terms of feasibility and acceptability [45]. Measures of feasibility and acceptability described in a recent meta-analysis of previous studies of similar technology-based approaches with diverse populations of individuals with mental illnesses include frequency of intervention use over time, response rates, attrition rates, study retention, proportion of devices that were returned undamaged, participant-reported usability, and responses obtained in qualitative interviews soliciting participant feedback [45]. Overall feasibility in our study is measured by overall study completion rate (35/40, 88%), positive scores on the item pertaining to the likelihood of continued use of the app, and feedback obtained via quantitative measures and open-ended interview items regarding usability, usage, and usefulness of WorkingWell comparable to the approaches to feasibility and acceptability used in prior studies. Our study completion rate of 88% (35/40) is in keeping with findings of participation, adherence, and completion in other similar studies that ranged from 70% to nearly 90% [45]. Differences across studies seem to be related to the targeted behaviors or symptoms, the level of support (eg, use of the app in addition to peer support or in-person sessions), and study characteristics such as target population and issues of research measures and methods [45].

Conclusions
The WorkingWell mobile app is a feasible approach to providing accessible, as-needed employment support for individuals with mental illnesses as they cope with the expectations, tasks, and social demands of work. Although WorkingWell was developed with extensive input from research, training, and practice experts, along with input from and usability testing with individuals with mental illnesses, the app would benefit from additional modifications to address recommendations from our in-depth testing. Further controlled research with larger samples, more diverse in individual characteristics (eg, work history and illness severity), and workplace settings (eg, more or less structured, routinized positions) is essential to demonstrating the effectiveness of the app in enhancing employment tenure and job satisfaction. Study protocols that include assessment of potential moderating factors, such as prior work history and illness severity, and mediating factors, such as work self-efficacy and job satisfaction, will contribute to our understanding of the ways in which supportive, technology-based tools like WorkingWell contribute to positive outcomes such as job tenure.

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Authors’ Contributions
JN is the principal investigator and is responsible for the overall design and implementation of the study. JN, SMW, and AMC codeveloped the research protocol, procedures, and necessary modifications with consultation from MAS, and prepared and submitted relevant materials for ethics approval. SMW and AMC implemented the study in community-based settings and analyzed data, with dedicated input from JN, MAS, and GJM. JN, SMW, AMC, MAS, and GJM wrote the manuscript together, and reviewed and edited all components of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest
None declared.

References


Abbreviations

IPS: Individual Placement and Support
SUS: System Usability Scale
Mental Health Mobile Phone App Usage, Concerns, and Benefits Among Psychiatric Outpatients: Comparative Survey Study

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Abstract

Background: Despite the popularity of mental health apps, it is unknown if they are actually used by those with mental illness. This study assessed whether differences in clinic setting may influence the use of mental health apps and which factors influence patient perception of apps.

Objective: The objective of this study was to gain an understanding of how individuals with mental illness use their mobile phones by exploring their access to mobile phones and their use of mental health apps.

Methods: A single time point survey study was conducted over a 2-week period in February 2018 at two nearby outpatient psychiatry clinics: one serving largely mood and anxiety disorder patients with private insurance staffed by both faculty and residents and the other serving largely psychotic disorder patients in a state Department of Mental Health (DMH) setting. A total of 25 patients at the state DMH clinic also consented for a single time point observation of apps currently installed on their personal mobile phone.

Results: A total of 113 patients at the private insurance clinic and 73 at the state DMH clinic completed the survey. Those in the private insurance clinic were more likely to download a mental health app compared to the state DMH clinic, but actual rates of reported current app usage were comparable at each clinic, approximately 10%. Verifying current apps on patients’ mobile phones at the state DMH clinic confirmed that approximately 10% had mental health apps installed. Patients at both clinics were most concerned about privacy of mental health apps, although those at the state DMH clinic viewed cost savings as the greatest benefit while those at the private clinic reported time as the greatest benefit.

Conclusions: High interest in mental health apps does not automatically translate into high use. Our results of low but similar rates of mental health app use at diverse clinics suggests DMH patients with largely psychotic disorders are as interested and engaged with apps as those in a private insurance clinic treating largely mood and anxiety disorders. Results from our study also highlight the importance of understanding how actual patients are using apps instead of relying on internet-based samples, which often yield higher results due to their likelihood of being selected.

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KEYWORDS

smartphone; digital health; mobile phone; mental health; schizophrenia; depression; psychiatry; apps
Introduction

Unmet Needs

While there is clear potential for digital tools like mobile phone apps to increase access to care and services for mental health [1], less is known about the use of apps by patients. Interest in mental health apps is linked to increased mobile phone access, with over 225 million people in the United States and over 2 billion people around the globe using these devices today [2]. There are already approximately 10,000 mental health and wellness apps available for immediate download [3], offering a myriad of services ranging from information to medication monitoring, coaching to telepsychiatry, and symptom tracking to support groups. But access and availability of mental health apps must not be conflated with safety, efficacy, or usability [4]. The majority of apps do not protect patient health data [5], have scarce evidence that they work [6,7], and are difficult to use and even harder to maintain longitudinal adherence with [8,9]. There are, of course, exceptions. Some research apps offer promise as useful clinical tools [10]. For example, one substance abuse app received FDA marketing approval in Fall 2017 [11].

In this evolving landscape of mental health apps, it is important to understand how end users, those diagnosed with and in treatment for mental illnesses, are actually using these apps and how they weigh the risks and benefits. This patient perspective is critical for informing patient-centered research and clinical efforts.

Background

Like the rest of the world, those with mental illnesses have increasing access to mobile phones. The notion of a digital divide, that those with mental illnesses may not have interest in, ability to afford, or capability to use modern digital technologies, is no longer valid [12]. A 2013–2014 study of a first episode psychosis clinic reported 71% of patients owned a mobile phone [13], and a 2014 study of 320 psychiatric outpatients from four geographically distinct clinics around the United States reported 62% ownership [14]. Many Medicaid recipients in the United States may now qualify for a free mobile phone provided by the government [15]. With mobile phone ownership across the US population between 80% and 94% for those ages 18 to 29 years, these devices have become ubiquitous. Those with lower socioeconomic status and lower levels of income and education, likely to include many with psychotic illnesses treated at state Department of Mental Health (DMH) clinics, are more likely to be mobile phone–dependent, meaning they rely on their mobile phone as their primary means of internet access and communication [16].

However, access to a mobile phone does not mean a user will download health or mental health apps. The existing literature on app use in mental illness is rapidly expanding but still limited. There are high levels of interest among the general public who may screen at risk for mental illnesses based on online self-reported questionnaires, but those who are already online and volunteer to take internet surveys are likely a unique sample predisposed to favoring technology and apps. The nature of screening tests commonly used in these online surveys, such as the 9-item Patient Health Questionnaire (PHQ-9) for depression, makes generalization of results to those with diagnosed mental illness challenging. Research studies may also offer an inflated perspective on app use. A recent systematic review suggested that while use and adherence with mental health apps range between 44% and 99% in research settings, actual rates in real-world settings may range between 1% and 29% [17]. Still, case reports suggest that some patients are using mental health apps today [18]. In fact, during 2015 in the United Kingdom, 25% of National Health Service mental health trusts recommended mobile phone apps to patients [19].

Downloading a mental health app in itself does not mean it will be used or help achieve better mental health. Evidence suggests that most mental health apps are rarely used after being downloaded and only opened a few times [8]. For example, having access to a local gym, wanting to join that gym, having a gym membership, and actually going to that gym on a regular basis are all required to reap the benefits of the gym. Having access to a mobile phone, having interest in mental health apps, and downloading mental health apps are all necessary but not sufficient to guarantee regular mental health app use.

In this paper we seek to explore mental health patient access to mobile phones and their use of mental health apps. We aimed to capture the opinions and use from two groups of patients receiving psychiatric outpatient care: insured patients from a clinic primarily treating mood and anxiety disorders and state DMH patients from a clinic primarily treating psychotic disorders. To provide initial validation of self-reported app use, we also present results of mental health app use based on a count of the number and type of apps on the mobile phones of patients at the state DMH clinic.

We hypothesize that mobile phone ownership will have increased in both the private and state DMH clinic populations since our 2014 research but remain higher in the private clinic. We expect that a majority of mobile phone owners will have downloaded apps, but in both groups rates of mental health app downloads will be low and few people will report using mental health apps today. In verifying mental health app use today, we expect that self-report rates of app use will be similar to actual app use evidence on the phone itself.

Methods

Clinics

Two clinics sites conducted the survey. The first site was an outpatient psychiatry clinic serving insured patients for primarily mood and anxiety disorders. This clinic treats adults and sees approximately 1000 patients per month. The second study site was a state DMH outpatient psychiatric clinic that serves patients for primarily psychotic disorders. This clinic also treats adults and sees approximately 1000 patients per month. Both clinics are within one-half mile from each other in the urban environment of Boston, Massachusetts. Patients in either clinic are ineligible to be seen in the other.

Surveys

Identical paper-and-pencil surveys assessing patient mobile phone ownership, use of apps, comfort with mental health app features, and perceived concerns and benefits were distributed...
to each study clinic. The survey was designed based on our prior similar research [14] as well as discussion and clinical experience with patients around their perceived benefits and concerns. Survey questions are displayed in Figure 1. The surveys were made available to all patients in the clinic, who voluntarily completed them before or during appointments and submitted completed forms to the clinic staff. Surveys, along with handouts explaining the purpose, mental health focus, and voluntary nature of the study, were offered and provided to patients by clinic staff at both sites while patients were waiting for appointments. All surveys were completed in the clinic setting. All clinic patients were eligible. The survey was made available for 2 weeks at both study sites in February 2018.

Participants reported on comfort with features of mental health apps including appointment reminders, medication reminders, symptom surveys, passive data call and text log monitoring, passive data Global Positioning System (GPS) monitoring, coaching around healthy lifestyles (diet, exercise, sleep), mindfulness or therapy exercises, and communication with their mental health clinician. Results were recorded on a Likert scale: 1=very uncomfortable, 2=a little uncomfortable, 3=neutral, 4= somewhat comfortable, and 5=very comfortable. Results were stratified by mobile phone ownership, and significant differences in comfort between mobile phone and non–mobile phone ownership were calculated with a 2-sample t test.

**Phone Assessment**

Patients at the state DMH clinic were eligible to opt in and have study staff record the names of apps on their mobile phone. For this part of the study, patients were asked to place their phone in airplane mode and allow study staff to write down the names of apps installed on their mobile phone. Because this is a novel methodology, we only examined the apps of 25 individuals as a pilot of the method.

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**Figure 1.** Survey.

<table>
<thead>
<tr>
<th>Write in your age in years: (eg, 73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please circle your gender:</td>
</tr>
<tr>
<td>MALE</td>
</tr>
<tr>
<td>Do you currently own any type of phone?</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>Is your phone a smartphone? (eg, iPhone, Android)</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>If yes to the above, what is the name of your smartphone (eg, Samsung Galaxy)</td>
</tr>
<tr>
<td>Do you use your phone for text messaging?</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>Do you download apps onto your phone?</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>Have you ever downloaded an app for your mental health?</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>Do you currently / now use any apps for your mental health?</td>
</tr>
<tr>
<td>YES</td>
</tr>
</tbody>
</table>

How comfortable or uncomfortable would you feel about a mental health app gathering or sending the following data from your smartphone in the context of your care? Place an ‘X’ in each row.

<table>
<thead>
<tr>
<th>Very Uncomfortable</th>
<th>A Little Uncomfortable</th>
<th>Neutral</th>
<th>Somewhat Comfortable</th>
<th>Very Comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appointment Reminders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Reminders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom Surveys</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Your Location (phone GPS sensor)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Your social information (call and text logs without any phone numbers or content of messages —eg, how many people you called and for how long)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaching for Healthy Living (eg, exercise, sleep, diet)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mindfulness or Therapy Exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communicating with My Clinician About My Mental Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Circle up to three top concerns you have may about mental health apps

PRIVACY ACCURACY-OF-RECOMMENDATIONS-FROM APP HARD-TO-USE

SHARING-INFORMATION-WITH-CLINICIAN COST TIME HARD-TO-SET-UP

Circle up to three top benefits you may see in mental health apps

PRIVACY ACCURACY-OF-RECOMMENDATIONS-FROM APP EASY-TO-USE

SHARING-INFORMATION-WITH-CLINICIAN COST TIME EASY-TO-SET-UP
Patients from the state DMH clinic were selected due to the lack of knowledge of app use in state DMH patients compared to private clinic patients [14]. In the future, we will expand this methodology to a greater number of individuals from both clinics.

**Analysis**

Patients received no compensation or incentives to complete surveys but were paid US $20 to partake in the structured interview, which included recording the names of apps installed on their mobile phone. Patients had to own a smartphone to be eligible for this second part of the study. Recorded apps were organized by category according to their classification in the commercial marketplace at the time of the study. Results were entered into password-protected Excel spreadsheet software (Microsoft Corp), and all analyses and graphs were completed in the R programming language (R Foundation for Statistical Computing). Given the nature of the collected data, we applied descriptive statistics including $t$ tests, chi-square tests, and other related methods. The institutional review boards at each of the study sites approved the study, and a waiver of informed consent was obtained for each site.

**Results**

**Demographics**

Of the estimated 500 patient visits to each clinic during the 2-week study duration, 113 patients completed the survey at the private clinic and 72 did so at the state DMH clinic, which is similar to prior completion rates in our 2013 survey. For the purpose of analysis, ages were bucketed into categories including 25 years and younger, 26 to 35 years, 36 to 45 years, 46 to 55 years, and 56 years and older. The mean age of patients in the state DMH clinic was 35.4 years and in the private clinic was 41.9 years. Other demographics and results of mobile phone and app ownership and use are presented in Table 1.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Private clinic (n=113)</th>
<th>State DMH clinic (n=72)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, male, n (%)</td>
<td>62 (53.9)</td>
<td>32 (45.8)</td>
<td>&lt;.30$^b$</td>
</tr>
<tr>
<td>Age (years), n (%)</td>
<td></td>
<td></td>
<td>&lt;.001$^c$</td>
</tr>
<tr>
<td>&lt;25</td>
<td>5 (4.4)</td>
<td>13 (18.0)</td>
<td></td>
</tr>
<tr>
<td>25-35</td>
<td>34 (30.0)</td>
<td>30 (55.6)</td>
<td></td>
</tr>
<tr>
<td>36-45</td>
<td>28 (24.8)</td>
<td>11 (15.3)</td>
<td></td>
</tr>
<tr>
<td>46-55</td>
<td>27 (23.9)</td>
<td>13 (18.0)</td>
<td></td>
</tr>
<tr>
<td>&gt;56</td>
<td>19 (16.8)</td>
<td>5 (6.9)</td>
<td></td>
</tr>
<tr>
<td>Any phone ownership, n (%)</td>
<td>111 (98.2)</td>
<td>61 (84.7)</td>
<td>&lt;.001$^e$</td>
</tr>
<tr>
<td>Smartphone ownership, n (%)</td>
<td>102 (90.2)</td>
<td>48 (66.6)</td>
<td>&lt;.001$^d$</td>
</tr>
<tr>
<td>Downloaded apps, n (%)</td>
<td>99 (87.6)</td>
<td>36 (50.0)</td>
<td>&lt;.001$^d$</td>
</tr>
<tr>
<td>Downloaded mental health apps, n</td>
<td>35 (30.9)</td>
<td>17 (23.6)</td>
<td>.28$^d$</td>
</tr>
<tr>
<td>Used mental health apps, n (%)</td>
<td>11 (9.7)</td>
<td>7 (9.7)</td>
<td>&gt;.99$^d$</td>
</tr>
</tbody>
</table>

$^a$DMH: Department of Mental Health.

$^b$t test after $F$ test to assess equal variance, $P=.78$.

$^c$X$_{14}^2$=15.9.

$^d$t test.

Table 2. Mobile phone ownership, app downloads, mental health app downloads, and mental health app use reported by state Department of Mental Health clinic patients.

<table>
<thead>
<tr>
<th>Age group</th>
<th>Smartphone ownership, n (%)</th>
<th>Downloaded apps, n (%)</th>
<th>Downloaded mental health apps, n (%)</th>
<th>Currently using a mental health app, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25 years (n=13)</td>
<td>12 (92)</td>
<td>11 (85)</td>
<td>4 (31)</td>
<td>2 (15)</td>
</tr>
<tr>
<td>26-35 years (n=30)</td>
<td>26 (87)</td>
<td>19 (63)</td>
<td>8 (27)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>36-45 years (n=11)</td>
<td>6 (45)</td>
<td>3 (27)</td>
<td>3 (27)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>46-55 years (n=13)</td>
<td>3 (23)</td>
<td>2 (15)</td>
<td>2 (15)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>&gt;56 years (n=5)</td>
<td>1 (20)</td>
<td>1 (20)</td>
<td>1 (20)</td>
<td>1 (20)</td>
</tr>
</tbody>
</table>
State Department of Mental Health Clinic

Percentage of mobile phone ownership in the state DMH clinic was highest among younger demographics, which mirrors national trends. However, mobile phone ownership did not guarantee interest in mental health apps. The overall prevalence of downloading a mental health app was 2.66 times lower compared to mobile phone ownership. Rates of downloading mental health apps were nearly equivalent over the first 3 age groups, suggesting interest is not limited to the youngest demographics. Roughly 1 in 6 patients at the state DMH clinic who reported owning a mobile phone also reported currently using a mental health app. Results are summarized in Table 2 and shown in Figure 2.

All features were found to be significant. Those who owned a smartphone reported more comfort with all features. The most discomfort was reported for passive data monitoring via GPS and call/text logs.

Private Clinic

Percentage of mobile phone ownership in the private clinic was also highest among younger demographics, and mobile phone ownership did not guarantee interest in mental health apps. The overall prevalence of downloading a mental health app was 1.85 times lower compared to mobile phone ownership versus 2.66 times lower in the state DMH clinic. Downloading a mental health app did not guarantee active use today, which was 5 times lower compared to prevalence of download. Unlike in the state DMH clinic, there were higher rates of downloading an app among younger demographics. Mobile phone ownership was also higher overall compared to the state DMH clinic. Results are summarized in Table 3 and shown in Figure 3.

Those in the private clinic also reported higher levels of comfort with app features. Like at the state DMH clinic, a 2-sample t test found all features to be significant. As above, those who owned a smartphone reported more comfort with all features. The most discomfort was reported for passive data monitoring via GPS and call/text logs, which was also found in the state DMH clinic sample.

Figure 2. Mobile phone ownership, app downloads, mental health app downloads, and mental health app use reported by state Department of Mental Health clinic patients.

Table 3. Mobile phone ownership, app downloads, mental health app downloads, and mental health app use reported by private clinic patients.

<table>
<thead>
<tr>
<th>Age group</th>
<th>Smartphone ownership, n (%)</th>
<th>Downloaded apps, n (%)</th>
<th>Downloaded mental health apps, n (%)</th>
<th>Currently using a mental health app, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25 years (n=13)</td>
<td>5 (100)</td>
<td>5 (100)</td>
<td>4 (80)</td>
<td>3 (60)</td>
</tr>
<tr>
<td>26-35 years (n=30)</td>
<td>34 (100)</td>
<td>33 (97)</td>
<td>15 (44)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>36-45 years (n=11)</td>
<td>27 (96)</td>
<td>27 (96)</td>
<td>8 (29)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>46-55 years (n=13)</td>
<td>25 (27)</td>
<td>24 (89)</td>
<td>6 (22)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>&gt;56 years (n=5)</td>
<td>11 (19)</td>
<td>10 (52)</td>
<td>2 (11)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>
Comparison Between Clinics

Apple and Android phones were not evenly distributed across clinic types. Apple phones were 3.5 times more prevalent in the private clinic compared with the state DMH clinic (49 vs 14), and Android phones were 1.55 times more prevalent in the state DMH clinic (34 vs 53). Lack of mobile phone ownership was 2.18 times more prevalent in the state DMH clinic (11 vs 34).

The number of app downloads also varied by clinic type. Those in the private clinic were nearly 3 times as likely to download an app compared with those in the state DMH clinic. But there was not a statistically significant difference by clinic type for currently using a mental health app, with both populations reporting approximately 9.7% use.

Reported comfort with mental health app features also varied by clinic. Those in the state DMH clinic reported feeling less comfortable with all features than the private clinic, except for passive monitoring. However, there was no statistically significant difference in comfort with passive monitoring with GPS and active monitoring with symptom surveys between clinics. All other differences were statistically significant from 2-sample t tests, as seen in Table 4.

Figure 3. Mobile phone ownership, app downloads, mental health app downloads, and mental health app use reported by private clinic patients.

Table 4. Comfort levels for mobile phone app features, measured with 5-point Likert scale and stratified by clinic type.

<table>
<thead>
<tr>
<th>Feature</th>
<th>State DMH clinic</th>
<th>Private clinic</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appointment reminders</td>
<td>3.82&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4.15&lt;sup&gt;c&lt;/sup&gt;</td>
<td>.01</td>
</tr>
<tr>
<td>Medication reminders</td>
<td>3.31&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.71&lt;sup&gt;b&lt;/sup&gt;</td>
<td>.003</td>
</tr>
<tr>
<td>Symptom surveys</td>
<td>3.11&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.50&lt;sup&gt;b&lt;/sup&gt;</td>
<td>.06</td>
</tr>
<tr>
<td>Passive call/text monitoring</td>
<td>2.39&lt;sup&gt;d&lt;/sup&gt;</td>
<td>2.32&lt;sup&gt;d&lt;/sup&gt;</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Passive GPS&lt;sup&gt;e&lt;/sup&gt; monitoring</td>
<td>2.78&lt;sup&gt;d&lt;/sup&gt;</td>
<td>2.31&lt;sup&gt;d&lt;/sup&gt;</td>
<td>.63</td>
</tr>
<tr>
<td>Coaching</td>
<td>3.1&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.49&lt;sup&gt;b&lt;/sup&gt;</td>
<td>.008</td>
</tr>
<tr>
<td>Mindfulness and therapy</td>
<td>3.17&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.75&lt;sup&gt;b&lt;/sup&gt;</td>
<td>.001</td>
</tr>
<tr>
<td>Communication with clinician</td>
<td>2.92&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3.54&lt;sup&gt;b&lt;/sup&gt;</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<sup>a</sup>DMH: Department of Mental Health.
<sup>b</sup>Neutral.
<sup>c</sup>Somewhat comfortable.
<sup>d</sup>Very uncomfortable.
<sup>e</sup>GPS: Global Positioning System.
Patient concerns about mental health apps also varied by clinic, as shown in Figure 4 on the left. Across both clinics, privacy and accuracy were top concerns—although those in the private clinic reported significantly higher levels of concern for both. The setup and installation of mental health apps were viewed as the second highest concern among those in the state DMH clinic but the lowest concern among those in the private clinic. There was no significant difference in terms of usability, sharing data with clinicians, cost, or time. In terms of benefits, both groups reported similar responses. The only significant differences were between privacy and cost savings, as shown in Figure 4 on the right. Those at the state DMH clinic reported cost savings as the number one benefit of mental health apps and both groups reported privacy as having the lowest benefit from the choices presented.

Validation of App Use
A total of 25 patients at the state DMH clinic allowed us to record the number and type of apps currently installed on their mobile phone. Of the patients who reported owning a mobile phone at the state DMH clinic, 17% (8/48) reported using mental health apps. Of the patients whose mobile phone apps were examined, only 12% (3/25) had actually downloaded mental health apps, providing preliminary validation for the self-reported data. However, in discussing mental health apps installed on the mobile phone, we learned that patients rarely used them. One patient explained he had installed a mental health coaching app but rarely used it, as he did not want to pay for the coaching features of the app. Another reported she had installed 2 mindfulness apps on her mobile phone at the urging of her social worker but rarely used them. A third had a symptom and medication monitoring app that he rarely used.
Thus, although these 3 patients did have mental health apps installed on their phones and used them occasionally, none appeared to be satisfied with or actively using them. Of interest, we found that 20% (5/25) of patients had installed horoscope apps (classified under lifestyle in Figure 5) and reported strong interest and engagement with these. While these patients may not have been actively using mental health apps, they did have many other types of apps on their phone, as reflected in Figure 5, which presents mean proportions of app categories. Health and fitness apps were the sixth most common mean proportion, and these largely represented step counter apps that patients reported using to track physical activity.

Discussion

Principal Findings

In this study, we surveyed 72 outpatients at a state DMH clinic treating largely psychotic disorders and 113 outpatients at a private clinic treating largely mood and anxiety disorders regarding access to and use of mental health apps. We found high rates of mobile phone ownership across both groups but lower rates of downloading and currently using mental health apps. In the state DMH clinic, the rate of downloading a mental health app was stable across the youngest 3 demographics, suggesting interest across a broader range of ages compared to the private clinic, where rates of downloads decreased in older age groups. After confirming mental health app use in the state DMH clinic, we found that self-reported app use was consistent but actual use, determined through discussion with patients, was less.

The potential of digital mental health tools like apps is fueled by their easy accessibility via mobile phones. In 2014, we reported that mobile phone ownership at the state DMH clinic was 49% [20] and at the private clinic 72% [4], and now their numbers have increased to 66% and 90%, respectively. But as seen in Figures 2 and 3, high rates of mobile phone ownership among those with psychiatric illnesses does not guarantee high rates of mental health app use. Even so, the 10% of patients who reported using a mental health app suggest bridging the new digital divide of app use has begun. The fact that reported app use did not differ between the private and state DMH clinics suggest patients’ early uptake of apps is not restricted to certain disease states or clinic populations. The fact that access to mobile phones was still lower at the state DMH clinic may reflect the lower socioeconomic status of this population, although our study was not designed to answer this question. But it does raise the issues that social determents of health likely impact digital health and there is a need to ensure equity in this evolving space.

A unique aspect of this study is the verification of reported mental health app usage by looking at the actual apps on the phones of a subset of patients. In the state DMH clinic, 9.7% of patients reported currently using mental health apps. Upon inspection of 25 patients’ phones, we found 12% had mental health apps installed, but when questioned the patients said they rarely used them. This raises the issue of how to accurately assess app use, as even objective measures of installed apps are not necessarily accurate. Although not the focus of our study, it is notable that health and fitness category apps were the sixth most prevalent type of app installed on patients’ mobile phones. The fact that games, social, media, music, and navigation represent the highest proportion of installed apps likely reflects that those with serious mental illnesses use their mobile phones in similar manners to the general public, as suggested in prior research [21]. It may be useful for future research to consider these top app categories and how features from these apps can be incorporated in mental health apps to improve uptake and use.
Our results suggest that patients have the most comfort with features such as appointment reminders and the least with passive data tracking features such as GPS and call/text log monitoring. Across both state and private clinics, those who owned a smartphone reported greater comfort for all features compared to those who did not. Those in the private clinic also reported greater comfort for all features compared to those in the state DMH clinic except for passive monitoring. However, the lack of any statistically significant difference for GPS tracking across both clinics and similarly low comfort scores for call/text monitoring represents a challenge to the often-posited advantage of mobile phone–based digital phenotyping [22]. While it is feasible today to gather sensor data from mobile phones and use this wealth of real-time data for a myriad of purposes, the privacy and ethical impacts of digital phenotyping are not lost on patients [23,24]. Outside of clinical studies, which involve volunteers who are compensated, will actual patients be willing to install digital phenotyping apps on their phones? On a more positive note, our results suggest that other features such as appointment reminders and app-based mindfulness or therapy exercises are likely to be better received. The popularity of psychic, not psychiatric, apps from our sample of 25 state DMH clinic patients also suggests that this class of app was popular in our sample.

Understanding the perceived benefits and concerns of mental health app users is necessary to ensure these tools are responsive to end user needs. Comparing both clinics, overall responses for benefits and concerns were similar. Although both groups felt privacy and accuracy were top concerns of mental health apps, those in the private clinic reported higher levels of concern for both. The state DMH clinic population reported higher levels of concern regarding difficulty setting up apps on their mobile phone. This suggests an opportunity to potentially increase uptake of apps in populations similar to our state DMH clinic sample by offering assistance in helping patients set up and install mobile phone apps. A technology navigator, a concept introduced by Ben-Zeev and colleagues [25], could fill this role and also offer information on privacy and accuracy of apps to help patients make more informed decisions around these chief points of concern. Comparing benefits across clinics, the fact that low cost was the top reported benefit among the state DMH clinic raises several issues for the digital health field. First, efforts to commercialize apps and charge fees could derail use among the most ill patients. This theory is buttressed by published case reports [18] and qualitative results from 1 of the 3 study participants who had a mental health app installed on her phone but reported lack of use because of cost. Second, although cost was seen as the top benefit and privacy a top concern, often the reason that an app may be free or low cost is because it is marketing or selling the users’ personal health information to third parties [26]. Thus, privacy and costs are tightly entwined in today’s health app ecosystem resulting in a paradox of both hindering and helping mental health app adoption.

Our results on mobile phone and app use are similar to recent reports. A 2016 survey of mobile phone ownership among those with mental illness offering peer support in New Hampshire identified that 58% owned a mobile phone, 61% had downloaded or used apps, and 72% use social media. This same study reported that 23% of these peers had used a mental health app [27], which is similar to our result of 23.6% in the state DMH clinic and 30.9% in the private clinic. The 2-year difference between studies may also explain higher rates of app adoption in our results. Our finding of high rates of mobile phone ownership in younger patients at the state DMH clinic (92% in those younger than 25 years and 87% in those aged 26 to 35 years) is similar to results from a study conducted in 2015 in a first-episode psychosis clinic where mobile phone ownership was 71% [13]. Again the 3-year difference between studies may help explain why our rates are higher. Our results that appointment reminder was the app feature with the highest reported comfort level is similar to a 2016 study of veterans receiving mental health treatment, also conducted in Boston, where appointment reminders were found to be the feature of highest interest [28]. Finally, another study surveying 82 mood and anxiety disorders patients in 2016–2017 regarding installing a mental health app found that just over 30% said they would be willing, which closely matches the 36% from the private clinic in our study who stated they have downloaded a mental health app [29].

Limitations

Our study has several weaknesses that must be considered. While both clinics were within 1 mile of each other, both were also in a dense urban environment, suggesting our results may not be generalizable to rural settings. Like any survey study, there is concern for selection bias, although we note our rate of participation is similar to prior studies of this type [4,19,24]. Also, the self-reported nature of this study makes results difficult to verify, although our efforts to examine the actual apps installed on 25 mobile phones suggests our results are consistent with what apps are actually on patients’ phones.

Conclusion

The potential of digital health to transform mental health requires more than access to mobile phones. Our results suggest that while mental health patients increasingly have access to mobile phones, far fewer are actually downloading and even fewer still using mental health apps. Bridging this new digital divide between access and use requires both understanding of the features patients want in apps as well as appreciating their concerns and desires. Tools like the American Psychiatric Association’s app evaluation framework can help guide informed decision making around selecting the right app for a patient’s needs—one that is safe, evidence based, engaging, and integrated into care [4]. To ensure these new digital tools remain useful to all patients and that the digital divide does not widen, we suggest continued efforts to look beyond internet-based samples of mental health app users and ensure that the perspectives of actual patients in care today are heard and acted upon.
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Conflicts of Interest

This manuscript was initially submitted and accepted to the Journal of Internet Medical Research, but was moved to JMIR Mental Health per the authors' request. No other conflicts of interest are declared by the authors.

References


Abbreviations

DMH: Department of Mental Health
GPS: Global Positioning System
PHQ-9: Patient Health Questionnaire–9 item
Application and Effectiveness of Telehealth to Support Severe Mental Illness Management: Systematic Review

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Abstract

Background: People with severe mental illness (SMI) must receive early interventions to prevent mental health deterioration or relapse. Telecommunications and other technologies are increasingly being used to assist in health care delivery using “telehealth,” which includes telephones and mobile phones, computers, remote sensors, the internet, and other devices, to provide immediate real-time information to service users to improve the management of chronic health conditions. Some initial findings have suggested that technology could improve the quality of life of people with SMI.

Objective: In this systematic review, we aimed to identify the various uses and efficacy of telehealth technology for SMI.

Methods: We systematically searched electronic databases from inception to March 2016 (MEDLINE, EMBASE, PsycINFO, Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine Database, Health Technology Assessment, CINAHL Plus, and NHS Economic Evaluations Database) to identify randomized controlled trials evaluating telehealth for adults with SMI published in English. Additional literature was identified through searching reference lists of key articles. The articles meeting the inclusion criteria were systematically reviewed and assessed for quality and risk of bias.

Results: Our search identified 31 articles describing 29 trials as eligible for the review. The included studies evaluated the use of computers to deliver cognitive rehabilitation (15 trials), patient education (3 trials), and Web-based self-management interventions (2 trials) and to support consultations (1 trial). Virtual reality was used to simulate work and social situations (2 trials) and to deliver cognitive training (1 trial). Telephones were used to prompt service users to take medications (3 trials) and to report symptoms to their health care team (1 trial). Remote sensors were used to monitor medication use (1 trial). Telephone support was found effective in improving medication adherence and reducing the severity of symptoms and inpatient days. Computer-assisted cognitive rehabilitation was effective in improving cognitive function. The impact of telehealth on other outcomes was inconsistent. The results of this review should be taken in the context of varied quality in study design, with only 5 studies demonstrating a low risk of bias.

Conclusions: A growing variety of telehealth technologies are being used to support the management of SMI. Specific technology types have been found to be effective for some outcomes (eg, telephone and remote medication monitoring for adherence to treatment), while other types of telehealth technologies (eg, delivery of patient education using computers) had no benefit over traditional nurse-based methods and were less acceptable to patients. Further research is warranted to establish the full potential benefits of telehealth for improving the quality of life in people with SMI, acceptability from the service user perspective, and cost-effectiveness. The findings of this review are limited by the poor quality of many of the studies reviewed.

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Introduction

Telecommunications and other technologies are increasingly being used to assist in health care delivery and are collectively known as “telehealth.” Telehealth is broadly defined as the use of applications in health care including telephones, mobile phones, computers, the internet, and audio and video processing to provide service users with immediate real-time information aimed at enhancing the management of their condition or its symptoms [1-3]. Telehealth has been found to be effective in managing a range of long-term conditions, including respiratory and cardiac diseases and diabetes [4-7]. Benefits include reductions in health service use [4-7], including hospitalization and emergency department visits, and improved clinical outcomes [4,7], for example, glycemic control in people with diabetes [4]. Some initial evidence also suggests that technology is found to be acceptable by users to support health management, particularly in terms of convenience [8]. While studies measuring the acceptability of using technology to support health care are still emerging, a review by Or and Karsh [9] identified specific factors that predict the acceptability of telehealth for long-term conditions, including younger age, higher levels of education, prior experience, perceived usefulness and ease of use, and satisfaction [9].

Severe mental illness (SMI) is commonly defined by the presence of persistent and extensive functional disability [10] and includes psychotic disorder, schizophrenia, schizoaffective disorder, major depressive disorder, and bipolar disorder. Previous systematic reviews have evaluated either the use of one specific type of telehealth, for example, telephone prompts, to promote appointment attendance [11,12] or the use of telehealth more broadly in a specific mental illness. Some initial findings have suggested that technology-based prompts could improve quality of life and SMI symptoms in people with SMI. However, the quality of the evidence has been found to be low [12]. Furthermore, the review of telephone prompts was published in 2009, and given the rise in the use of technology, an updated review is due. In 2 reviews, a range of applications for general mental health, including dementia, child psychiatry, suicide prevention, substance misuse, and psychotic disorders, were evaluated [13,14] and evidence for benefits to mood, trauma-related symptoms, and suicide attempts and better medication adherence was found. However, a review of the range of available telehealth technologies and their use to support people with SMI does not exist. Given the current multitude of available telehealth technologies and the rapid increase in their use, a further review is required to identify the range of uses for telehealth in the context of SMI and whether they can lead to increased service user engagement and improved psychological and clinical outcomes across SMI.

The aims of this review are to (1) identify and describe how telehealth interventions for people with SMI have been implemented to date and (2) synthesize the evidence in relation to the effectiveness or efficacy of available interventions.

Methods

Study Eligibility

Studies were selected for inclusion in the review if they met the following criteria:

1. Adults aged ≥18 years diagnosed with SMI defined as psychotic disorder, schizophrenia, schizoaffective disorder, major depressive disorder, and bipolar disorder as defined by Johnson [10]. If studies included service users with and without SMI, only data that could be extracted for users with SMI were included. Studies for which it was unclear whether participants in a population of “young people” were aged ≥18 years were not included.
2. Randomized controlled trials (RCTs) available in English language.
3. Interventions that used telehealth technology targeted to improve the management of SMI.
4. Articles measuring the following outcome measures were considered for this review:
   • General or disease-specific psychological or psychosocial outcomes, including quality of life or mood, using generic or disease-specific validated tools.
   • Clinical outcomes including reduction in psychotic symptoms, introduction of new antipsychotics, increased intensity of medication, hospital readmission, mortality rates, and progression of SMI.
   • Attendance as an outpatient or in primary care.
   • Adherence to treatment, including medication or recommended psychological support.

Studies were excluded if SMI was caused by dementia or brain injury, they were not available in English, they investigated telecare or social care technology such as remote sensors for falls, the intervention focused on carers or health care professionals rather than service users, participants were not randomized, technology was not the primary focus of the intervention, and participants had major depressive disorder or other mood disorders without psychosis.

Search Strategy

Electronic searches using the following databases were conducted from inception to March 2016: MEDLINE, EMBASE, PsycINFO, Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine Database, Health Technology Assessment, CINAHL Plus with Full Text via EBSCOhost, and NHS Economic Evaluations Database by searching “all fields” using the following search terms: TELEHEALTH, TELE*, TECHNOLOGY, E*HEALTH, M*HEALTH, ONLINE, WEB*, INTERNET, COMPUTER, MOBILE, APP, VIRTUAL CONSULATION, PHONE, POCKET PC, IPHONE, SHORT MESSAGE SERVICE, SMS, TEXT MESSAG*, WIRELESS, SMARTPHONE, REAL-TIME, ELECTRONIC DIAR* AND INTERVENTION, PROGRAM*, THERAPY, SUPPORT, EDUCATION, TRAINING and SEVERE MENTAL ILLNESS, MENTAL...
DISORDER, PSYCHOTIC DISORDER, MOOD, AFFECTIVE DISORDER, PERSONALITY DISORDER, BIPOLAR DISORDER, SCHIZOPHRENIA, DEPRESSION, SCHIZOAFFECTIVE DISORDER and RANDOMIZED, TRIAL, CLINICAL TRIAL, COMPARATIVE STUDY, SYSTEMATIC REVIEW, META-ANALYSIS, REVIEW, CROSSOVER PROCEDURE, DOUBLE BLIND*, and SINGLE BLIND*.

The first author checked titles, and all 3 authors reviewed abstracts to exclude any irrelevant articles. Full texts of the remaining articles were obtained; all 3 authors screened these. Any disagreements were discussed within the research team to reach consensus. References were searched for additional papers.

Data Extraction and Management

The first author extracted data using a standardized form developed by the Cochrane Collaboration [15], which included information on the following: study characteristics (including aim and design), participants (including population description, inclusion and exclusion criteria, and baseline imbalances), features of the intervention and comparison groups (including description, timing, and providers), outcome measures, statistical methods used in analysis, results, and conclusions.

Risk of Bias

The Cochrane Collaboration tool to assess the risk of bias in RCTs [16] was used. The Cochrane risk of bias tool includes a list of potential sources of bias in clinical trials in 7 main areas: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias [16]. The rating scale for each area of bias ranges from “low risk of bias” to “high risk of bias” and an option of “unclear risk of bias” for studies that do not provide enough details to be able to make a clear judgment [16]. Two of the review authors (SLW, KM) independently judged each article for risk of bias, discussing disagreements until a consensus was reached.

Results

Studies identified

Electronic searches identified 13,907 unique articles, and reference searches of key articles identified a further 17 potentially eligible articles. The inclusion criteria were met by 31 articles, which have been presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses [17] diagram (Figure 1). A meta-analysis was not performed due to the heterogeneity of the interventions, including their methods of delivery and the outcome measures of the included studies. The characteristics of the final 31 articles can be seen in Multimedia Appendix 1.

The 31 articles reported 29 trials. A total of 17 trials focused on people with schizophrenia, 9 on people with schizophrenia or schizoaffective disorder or psychotic disorder, and 3 on people with bipolar disorder. A range of telehealth devices were used with varying aims. Computers were used to improve cognitive functioning and disease-specific knowledge; websites aimed to improve psychosocial functioning; hand-held devices were used to improve communication with medical staff; telephones were used to improve medication adherence and disease-specific symptoms; virtual reality (VR) aimed to improve social and work-related functioning; and electronic medication dispensers aimed to improve adherence. The specific outcome measures included medication adherence (4 studies), social functioning (including work behavior; 5 studies), health care utilization (4 studies), neurocognitive functioning (16 studies), knowledge about medication or SMI (2 studies), self-esteem (3 studies), self-efficacy (1 study), quality of life (4 studies), mood (4 studies), insight into condition (1 study), perceptions of deprivation of liberty (1 study), satisfaction with life or treatment (5 studies), and illness perceptions (1 study). The 29 included trials recruited a total of 4338 participants. Sample sizes ranged from 29 to 507. Details about each intervention can be seen in Multimedia Appendix 2.

Risk of Bias

Results for the risk of bias assessment can be found in Multimedia Appendix 3. Of note, only 5 studies were rated as high quality. One study demonstrated a particularly high and, at times, unclear risk of bias for the majority of sources of bias [18]. Several studies did not provide enough details to be able to make a clear judgment that they had not introduced bias into their findings.

Intervention Effectiveness

Results for each of the 31 studies can be found in Multimedia Appendix 4. A description of the findings is presented in the following sections.

Cognitive Outcomes

Of the 31 articles reviewed, 20 reported the impact of telehealth for SMI on cognitive outcomes. Neurocognitive functioning was measured in 18 studies and encompassed memory, attention, executive functioning, and visual perception. Of these, 15 studies measured the impact of computer-assisted cognitive rehabilitation (CACR) on neurocognitive functioning [19-33], of which 11 found statistically significant improvements [21-25,27,29-32,34]; furthermore, 2 of the 18 studies evaluated the use of VR for cognitive rehabilitation [34] and vocational rehabilitation [35] for adults with schizophrenia. VR was found to have a significant effect on cognitive functioning in both studies [34,35]. One study [36] evaluated the use of offline personalized computer-based health education compared with nurse-delivered health education and a combination of both interventions, but it found no significant differences from baseline to follow-up in any of the trial arms on measures of neurocognitive functioning or knowledge about schizophrenia [36,37].

To summarize the findings for cognitive outcomes, 11 of 15 studies found CACR to be beneficial for cognitive outcomes, and VR-based cognitive and vocational training was found to be effective for cognitive function, while computer-based patient education was found to have no benefit for cognitive outcomes over nurse-delivered education.
Psychosocial Outcomes

Of the 31 articles reviewed, 21 reported the impact of telehealth on psychosocial outcomes. These included positive and negative symptoms [22,23,25,28,29,31,37-39], social adaptation including social adjustment and cognition [22,25,28,29,32,40-42], quality of life [21,22,37,39-41,43], mood [32,37,40,44,45], satisfaction with care [43], self-esteem [19,25,40], self-efficacy [35], illness perceptions [40], insight [36], and perceptions of deprivation of liberty [46].

Positive and Negative Symptoms

The effectiveness of CACR on schizophrenia symptoms was evaluated in 6 studies [19,22,23,25,28,31], of which 4 did not find any effect; however, 2 found a beneficial effect on negative symptoms [19,28]. Positive and global symptoms were also measured in 1 study, finding a beneficial effect on positive symptoms but not global symptoms [28].

Telephone-based nurse support reduced positive schizophrenia symptoms compared with a control group, but no differences were observed for negative or global schizophrenia symptoms [37]. Telemonitoring [38] had a beneficial effect on positive and negative schizophrenia symptoms over standard care, although a nontechnology “pill counting” group also showed improved symptoms. Computer-mediated structured consultations [39] did not have any impact on symptoms.

Social Adaptation

The included trials measured several different aspects of social adaptation. These included social cognition, social adjustment, and social professional and family functioning. Of the 31 studies, 8 evaluated the impact of telehealth on social adaptation, encompassing social adjustment and social cognition, of which 3 reported a benefit. Of 5 trials of CACR, 2 reported a beneficial effect on the social and living conditions subscales of the Health of the Nation Outcome Scales [28,47], social adjustment (defined as role performance), and social cognition (defined as
awareness of relationships), which were measured using a combination of existing outcome measures [29]. However, others found no effect of CACR on social autonomy [22], social professional and family functioning [32], or social cognition as measured using the MATRICS Consensus Cognitive Battery [25,48].

A Web-based self-management intervention [41] improved social functioning, but a Web-based cognitive behavioral therapy (CBT)-based intervention (alone or with peer support) [40] did not affect the perceptions of stigmatization. Using VR to deliver social skills training [42] did not differ from social skills training with role play on social problem solving, social adjustment, or stigma.

**Quality of Life**

The impact of telehealth for SMI on quality of life was reported in 7 articles. Of these, 3 studies found a significant benefit of telehealth for SMI. CACR had a significant effect on the overall quality of life and a self-directedness subscale in 1 study [21] but not in another [22]. The use of computer-mediated structured consultations (“DIALOG”) improved the quality of life at a 12-month follow-up [39]. Service users with a shorter duration of illness and a better “perceived helping alliance” with key workers prior to receiving DIALOG improved more in subjective quality of life than with standard care [43]. Hansson et al [43] also found that people with more severe negative schizophrenia symptoms prior to the intervention experienced a greater improvement in the quality of life after receiving DIALOG. Web-based self-management [41] had a significant effect on both physical and psychological quality of life, but nurse-based telephone support [37] was not effective.

Satisfaction with life was measured in 2 studies. There were no significant differences between “MoodSwings,” “MoodSwings” plus Web-based peer support, and a standard care control group on satisfaction with life [40]. Similarly, there was no difference between an information technology education group and a standard care group on satisfaction with life [46].

**Mood**

A nurse-delivered monthly telephone monitoring intervention [44,45] reduced depressive symptoms for bipolar disorder after 12 months, but this effect was not maintained at the 2-year follow-up. Furthermore, a significant reduction in mania was found at the 2-year follow-up, but not at the initial 12-month assessment. No benefit was found for CACR [32], a Web-based CBT–based intervention [40], or a telephone-based nurse support intervention [37] over a no treatment control. The control condition in Proudfoot et al’s [40] study, which involved information about bipolar disorder being emailed to participants weekly, is noteworthy.

**Satisfaction With Health Care**

The effectiveness of telehealth on satisfaction with health care was measured in 1 trial. Computer-mediated consultations improved treatment satisfaction [43].

**Self-Esteem**

The impact of telehealth for SMI on self-esteem was measured in 3 studies. Self-esteem was not improved by CACR [19,25], or by a Web-based CBT–based intervention [40].

**Self-Efficacy**

The 1 study that measured self-efficacy found no differences between VR vocational training, therapist-administered vocational training, and a nontraining control group in terms of self-efficacy for performing work-related tasks [35]. None of the computer-based education trials found a significant impact on insight into schizophrenia [36] or perceived deprivation of liberty among adults with schizophrenia [46].

To summarize the findings for psychosocial outcomes, CACR was found to have no effect on schizophrenia symptoms in the majority of studies that measured this outcome and had no effect on mood over standard care. Of the 3 studies that measured the impact of CACR on psychosocial adjustment, 2 found an improvement. Telephone support was found to reduce the severity of positive symptoms and depressive symptoms in schizophrenia, and remote telemonitoring was found to improve global schizophrenia symptoms over pill counting alone. Computer-mediated structured consultations and Web-based self-management for bipolar disorder were both found to lead to improvements in quality of life. While Web-based patient education improved social functioning, it had no effect on mood. VR had no benefits in improving nonverbal social skills over traditional face-to-face training.

**Behavioral Outcomes**

Of the 31 studies, 10 measured the effectiveness of telehealth interventions on behavioral outcomes. Outcomes included adherence to treatment [18,37,38,49]; health care utilization, including number of inpatient days and amount of antipsychotic medication taken [38,41,44,50]; work habits [23,35]; and conversational skills, including nonverbal skills [42].

**Adherence to Treatment**

Of the 4 studies that measured adherence to treatment, significant improvements were found with nurse-based telephone support [37,49] and telemonitoring [38], but not for computer-based medication education [18].

**Health Care Utilization**

Of the 4 studies that evaluated the use of telehealth in health care utilization, all found a significant positive effect. Remote medication monitoring [38] led to fewer medical and emergency visits than pill counting alone and standard care. Telemonitoring of symptoms [50] led to significantly fewer inpatient days compared with a control group that received standard care. Simon et al [44] found better adherence to atypical antipsychotic use and increased attendance for medication management visits in service users who received nurse-based telephone support. Todd et al [41] reported that medication and service use reduced, on average, in the self-management website group and increased, on average, for the standard group, although statistical analysis of the difference was not reported.
Work Habits
Of the 2 studies that measured work habits, which involved direct observation of work behavior and an interview with the work supervisor, both found the telehealth intervention to be effective. CACR [23] had a significant effect on work habits, and VR [35] was as effective as therapist-delivered vocational training for work-related tasks, with a significant improvement seen in both groups.

Conversational Skills
Park et al [42] found that enabling service users to practice their social skills using VR after receiving social skills training had a significant effect on their conversational skills and assertiveness compared with a face-to-face role-playing group (without VR), although the role-playing group showed greater improvement in nonverbal skills.

To summarize the findings for behavioral outcomes, telephone support and remote telemonitoring consistently led to improvements in medication adherence and reduced inpatient days, while computer-based education had no effect. Telemonitoring and Web-based CBT–based self-management both led to reduced emergency health care visits. CACR and VR were both effective for improving work behavior and VR improved assertiveness in social situations over traditional face-to-face training.

Acceptability
Of note, only 1 of the included studies formally measured whether participants found the intervention they received to be acceptable. Frangou et al [38] measured acceptability, ease of use within routine care, and perceived effectiveness qualitatively from the perspective of service users and their health care professionals. There was unanimous agreement among service users that the telemonitoring intervention helped them manage their condition and was easy to use and incorporate into daily life, and caregivers shared these views [38]. While Park et al [42] did not report measuring “acceptability,” they did record “interest in participation” using a 2-item questionnaire, which evaluated participants’ interest in the session they received and their expectations for the next session. The VR group scored higher on interest in participation than the traditional social skills training group [42], suggesting a preference for technology. Jones et al [36] similarly did not refer to “acceptability” but assessed participants’ opinions about the computer-based education intervention combined with nurse-based education versus computer-based or nurse-based education alone. Significantly more service users in the nurse-based education group perceived the information they received as definitely relevant to them compared with the computer-delivered education group and the combination group, despite the nurse-delivered intervention providing the same content as the computer system [36].

One indicator of acceptability may be significant dropout rates from the intervention group. Most of the included studies did not present a substantial dropout rate, although not all studies adequately reported the reasons for dropout. Of the studies reporting a substantial dropout rate, Proudfoot et al [40] reported a higher dropout from the website condition (30%) than from the website plus peer support condition (19%). Jones et al [36] reported substantial dropouts from the computer-delivered (41%) and nurse-delivered education (46%) conditions compared with the combined condition (29%). Reasons for dropout from the computer education group included refusal to continue taking part, the intervention being unsafe, and physical problems limiting the ability to continue with the intervention [36]. Rass et al [26] also reported a higher dropout from a CACR group (19%) than from either control condition (0%), including 3 participants who stopped attending the intervention and 2 who did not complete final follow-up assessments. In a longitudinal study assessing telephone monitoring plus a structured group psychoeducational program, while the authors reported a high level of contact in the telephone element of the intervention (85% of participants completed 12 or more telephone contacts), group participation dropped substantially to 51% after 12 months [45], suggesting that a group-based education intervention may be less acceptable than telephone monitoring in adults with bipolar disorder.

Discussion
Principal Results
The aims of this review were (1) to identify which, and how, telehealth interventions have been trialed for people with SMI and (2) to synthesize the evidence in relation to the effectiveness or efficacy of these interventions. This review identified 31 articles describing 29 trials, including a total of 4338 participants with schizophrenia, schizoaffective disorder, psychotic disorder, and bipolar disorder. The studies in the included articles evaluated the use of computers for cognitive rehabilitation, patient education, consultations with key workers, and interactive Web-based CBT–based self-management interventions; the use of VR to simulate work and social situations and to deliver cognitive training; the use of telephones to prompt medication use and to report SMI symptoms to health care teams; and the use of remote sensors to monitor medication use.

This review found evidence for using some types of technology to support the management of SMI while finding that not all technology is effective, depending on the outcome of interest. Interventions containing telephone support from the medical team, including phone calls and short message service text messaging prompts about medication, were consistently found to be effective in improving medication adherence while also reducing the severity of mania symptoms and reducing inpatient days. CACR was found to be effective in improving cognitive outcomes in schizophrenia in most, but not all, studies. A Web-based CBT-based self-management intervention for bipolar disorder was found to be effective at improving quality of life and social functioning. The use of VR was found to be effective in improving work-related behavior, conversational skills, assertiveness, and cognitive functioning, although face-to-face social skills training was found to be more effective in improving nonverbal social skills than VR-delivered training. Computers appeared not to have a superior benefit for delivering patient education over traditional nurse-delivered education, and in fact, participants preferred the nurse-delivered method.
This finding is perhaps reflective of the nature of interactions with health care staff, which can provide a personal and individualized approach to supporting people with SMI, for example, by offering opportunities like discussing diagnoses and modeling nonverbal social cues. Hand-held devices to support health care consultations were found to be effective in improving quality of life and satisfaction with care, but not in improving positive or negative schizophrenia symptoms. Telementoring was found to be effective in improving medication adherence and also led to fewer medical and emergency visits, including inpatient days, while simultaneously improving schizophrenia symptoms.

Notably, 5 studies demonstrated a low risk of bias for 6 out of the 7 sources of bias listed in the Cochrane risk of bias tool [28,39,41,43,44], and 6 studies demonstrated a low risk of bias for 5 out of the 7 sources [23,37,40,45,49,50]. One study demonstrated a particularly high and, at times, unclear risk of bias for the majority of sources of bias [18]. Several studies did not provide enough details to be able to make a clear judgment that they had not introduced bias into their findings, particularly in reference to whether participants were assigned to groups using an adequate randomization method and whether allocation had been truly concealed. The findings of this review should, therefore, be viewed in light of the potential bias introduced into the findings of some of the studies included.

The variety of comparison groups employed in the studies included in this review is also noteworthy. In the majority of articles (n=17), the authors reported that the comparison group received standard care or treatment as usual. This may have differed across trials. For example, in the context of inpatient care, this included medication and attendance at routine therapy groups [33], but in the context of community care, this might have included medication, physician visits, and support from available community centers [49]. However, for 9 of the studies, the control group received a comparative intervention, consisting of health care professional-delivered education about their condition [18,29], text-delivered education [40], therapist-delivered skills training or psychosocial interventions [28,35,42], or computer-delivered activity, such as computer games or education about their condition [21,25,36].

Comparison With Prior Work

This review supports the findings of previous reviews evaluating cognitive training in schizophrenia [51,52], although evidence suggests that cognitive training is effective regardless of whether it is delivered via computer technologies or noncomputerized psychological interventions [51]. Substantial variations in the intensity and duration of the interventions that used software to support neurocognitive training may have impacted the results of these studies. If training was particularly intensive, for example, half a day or delivered over several months, it is possible that this might have overburdened participants with SMI, leading to a lack of significant findings, or reduced participants’ attention abilities. A recent meta-analysis suggests that as little as 5-15 hours of cognitive remediation could be sufficient for improving cognitive outcomes in people with schizophrenia [52], suggesting that more intensive cognitive training may not be necessary and that future interventions should be designed with this in mind.

CACR was most commonly assessed offline using personal computers and CD-ROM software, with little change in the software used over time. With the rise in more sophisticated technologies, including VR, which in this review was found to improve social and neurocognitive outcomes in people with SMI, perhaps we can expect to see VR interventions delivered more widely to support SMI outcomes in the coming years. VR has the potential to provide usable and safe, ecologically valid assistance in the management of SMI, as already found in general health care [53]. In particular, our findings support a recent systematic review of VR for people with SMI, which was found to be more interesting training than control conditions [54].

We identified surprisingly few studies that had evaluated Web-based interventions to support individuals with SMI. Educational websites were not found to be effective for improving knowledge about medication, adherence, self-esteem, insights into SMI, or deprivation of liberty over traditional nurse-delivered education. However, when websites provided more interactive elements than traditional education, such as peer support or CBT-based self-management techniques, improvements in quality of life, mood, and social adaptation were seen. Further research on the psychosocial benefits of Web-based interventions for people with SMI is suggested, particularly given the small number of studies to date and the growing evidence for such interventions in common mental health disorders, including anxiety and depression [55,56]. Web-based interventions will, however, need to take the specific needs of people with SMI into account to improve accessibility. For example, service users often report that common website design guidelines produce websites that are confusing for them to use, particularly in the presence of cognitive deficits [57].

The finding that telephones were effective for promoting adherence to medication use and attendance at health care appointments was consistent with a recent systematic review [58] of mobile phone-based technologies for supporting general health care and another review for the use of remote technology in SMI [58]. Further evidence suggests that the use of telephones has a beneficial impact on adherence over interventions that do not use technology, for example, psychoeducation for patients who are nonadherent due to forgetfulness [59]. While telephone-based interventions may not consistently improve clinical factors associated with SMI, the findings of the studies included in this review give early promise to the use of telephones in supporting adults with SMI to manage their medication. With advances in the function of telephones, including smartphone apps, this provides further opportunities for supporting people with SMI in the future. One might have expected more interventions, however, as Bakker et al [60] recently emphasized, mental health apps have not to date utilized the designs made available by physical health and social networking apps nor have the hundreds of apps available been tested using formal experimental methods.

The present review also found that the use of telephones improved patients’ attitudes toward using their treatment as

well as their quality of life. Leach and Christensen [61] suggest that telephones are acceptable and cost-effective uses of technology to support health care due to their accessibility and convenience. A large-scale survey of users of mental health services in the United States in 2013 found that 72% users reported owning a mobile device, and both users and nonusers expressed an interest in future services being offered through mobile devices [62], suggesting that accessing a mobile device may not pose a barrier to people with SMI.

The positive findings regarding the use of telemonitoring to improve global schizophrenia symptoms, medication adherence, and medical and emergency visits are consistent with the reviews that have found positive effects of telemonitoring for managing chronic health conditions, including heart failure [63] and respiratory conditions [64]. Furthermore, a recent review of the use of remote technology for SMI found this to be a feasible and acceptable method of health care delivery [65]. These are positive initial results for a form of telehealth that was found to be acceptable from both the service user and health care perspective, and future research evaluating the use of telemonitoring for SMI could have implications for the delivery of future services for people with SMI.

The finding that computer-mediated consultations led to improvements in quality of life and reduced unmet need in service users with SMI is promising for a novel use of technology, where there is currently a limited evidence base. One recent qualitative study reports that health care professionals perceive tablet computers to fill a need between smartphones and desktop computers and have some value in supporting consultations with patients [66]. Tablet computers offered support in structuring consultations, ensuring that patients’ priorities were discussed [39]; thus, patients might feel their needs have been better dealt with.

Few studies evaluated the use of remote medication telemonitoring, computer-mediated consultations, or Web-based self-management resources, suggesting these are novel technologies for managing SMI, although all were found to be effective for improving psychosocial and behavioral outcomes. We were surprised to find the limited use of these more advanced technologies in an SMI context given the rise in their use to support broader health care in recent years, for example, Web-based self-management programs for diabetes [67]. We suggest that future research should seek to establish the full potential benefits of these novel uses of telehealth for improving the management of SMI.

Of note is the varied quality of the studies included in the review, with only 5 studies rated as high quality. This suggests that high levels of bias were potentially introduced into the results of these studies. Of particular note is the small sample size of the majority of articles in this review, with 19 of the total 31 studies having samples of <100 participants. Furthermore, the type of comparison or control group employed might have had an influence on the effect size of the intervention evaluated, and the variety of comparison groups included in this review is noteworthy. The generalizability of the findings from many of these studies is, therefore, limited.

Limitations

To our knowledge, this is the first systematic review of RCTs across a range of telehealth technology interventions delivered to people with SMI. The studies included in this review measured a plethora of outcomes using heterogeneous measures and a range of interventions, making meta-analysis of the results impossible. In addition, we excluded articles that had not been published in English. It is possible, therefore, that we excluded relevant foreign language articles from this review. One author performed the data extraction process; while this was not verified by a second author, all authors were involved in the screening process, and 2 authors independently completed the risk of bias assessment. Thus, several stages of the review process were validated by more than 1 author.

The lack of studies that formally evaluated the acceptability of telehealth interventions is noteworthy. Of those that did measure the opinions of their participants, telehealth was found to be acceptable, particularly in comparison with more traditional face-to-face methods of the delivery. However, this may depend on whether a face-to-face element to the intervention is also offered, as it has been suggested that this may be preferable over unguided interventions [68]. If telehealth is to be developed to support the care of people with SMI, it is important that acceptability of the interventions is considered as part of the evaluation and formally measured. From a health-commissioning perspective, it is also possible that telehealth delivery costs are higher than those of usual care [1]. Cost-effectiveness was not formally evaluated by the studies included in this review; thus, it is unclear whether this is also the case with interventions in SMI. Future studies should evaluate the costs of using technology to support the management of SMI.

Conclusions

This systematic review has identified a range of ways in which telehealth has been used to support the management of SMI and its symptoms. The studies found some strengths of cognitive remediation for schizophrenia, whether delivered through a personal computer and CD-ROM or VR. The use of telephone support from the medical team was consistently found to be effective for improving medication adherence and reducing the severity of symptoms and inpatient days. Few studies evaluated the use of remote medication telemonitoring, VR, Web-based self-management, and hand-held devices, suggesting that these are novel technologies for managing SMI, although all were found to be effective in improving some psychosocial and behavioral outcomes. Patient preferences should be assessed and accommodated, as some may prefer traditional methods of delivery with health care staff over computer-based methods. Given the poor quality of all but 5 of the included trials and that few studies have evaluated the acceptability and cost-effectiveness of using technology to support people with SMI, further studies are needed to establish the potential benefits to these areas.
Acknowledgments
This was an unfunded project. All authors developed the research question and assisted with performing the systematic search and review. SLW prepared the first draft of the manuscript, and all authors contributed to and agreed on the final draft.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Characteristics of participants included in the eligible trials.

[PDF File (Adobe PDF File), 137KB - mental_v5i4e62_app1.pdf ]

Multimedia Appendix 2
Descriptions of the interventions included in the review.

[PDF File (Adobe PDF File), 124KB - mental_v5i4e62_app2.pdf ]

Multimedia Appendix 3
Risk of bias assessment.

[PDF File (Adobe PDF File), 111KB - mental_v5i4e62_app3.pdf ]

Multimedia Appendix 4
Results of included studies.

[PDF File (Adobe PDF File), 193KB - mental_v5i4e62_app4.pdf ]

References


Abbreviations

CACR: computer-assisted cognitive remediation
CBT: cognitive behavioral therapy
RCT: randomized controlled trial
SMI: severe mental illness
VR: virtual reality
An eHealth Platform for the Support of a Brazilian Regional Network of Mental Health Care (eHealth-Interop): Development of an Interoperability Platform for Mental Care Integration

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Abstract

Background: The electronic exchange of health-related data can support different professionals and services to act in a more coordinated and transparent manner and make the management of health service networks more efficient. Although mental health care is one of the areas that can benefit from a secure health information exchange (HIE), as it usually involves long-term and multiprofessional care, there are few published studies on this topic, particularly in low- and middle-income countries.

Objective: The aim of this study was to design, implement, and evaluate an electronic health (eHealth) platform that allows the technical and informational support of a Brazilian regional network of mental health care. This solution was to enable HIE, improve data quality, and identify and monitor patients over time and in different services.

Methods: The proposed platform is based on client-server architecture to be deployed on the Web following a Web services communication model. The interoperability information model was based on international and Brazilian health standards. To test platform usage, we have utilized the case of the mental health care network of the XIII Regional Health Department of the São Paulo state, Brazil. Data were extracted from 5 different sources, involving 26 municipalities, and included national demographic data, data from primary health care, data from requests for psychiatric hospitalizations performed by community services, and data obtained from 2 psychiatric hospitals about hospitalizations. Data quality metrics such as accuracy and completeness were evaluated to test the proposed solution.

Results: The eHealth-Interop integration platform was designed, developed, and tested. It contains a built-in terminology server and a record linkage module to support patients’ identification and deduplication. The proposed interoperability environment was able to integrate information in the mental health care network case with the support of 5 international and national terminologies. In total, 27,353 records containing demographic and clinical data were integrated into eHealth-Interop. Of these records, 34.91% (9548/27,353) were identified as patients who were present in more than 1 data source with different levels of accuracy and completeness. The data quality analysis was performed on 26 demographic attributes for each integrable patient record, totaling 248,248 comparisons. In general, it was possible to achieve an improvement of 18.40% (45,678/248,248) in completeness and 1.10% (2731/248,248) in syntactic accuracy over the test dataset after integration and deduplication.

Conclusions: The proposed platform established an eHealth solution to fill the gap in the availability and quality of information within a network of health services to improve the continuity of care and the health services management. It has been successfully applied in the context of mental health care and is flexible to be tested in other areas of care.

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KEYWORDS

eHealth; mental health; health information exchange; health information interoperability; medical record linkage; continuity of patient care

Introduction

Background
The care of mental disorders frequently requires a coordination of efforts among different health care professionals, services, and care levels (primary, secondary, and tertiary) [1]. There is also a frequent need to integrate the care of mental disorders with the care of nonpsychiatric health problems (such as cardiovascular disorders, diabetes, maternal health, HIV/AIDS, and cancer) for the same people. This type of comorbidity is common, and there is evidence that an adequate management of behavioral problems can positively impact other health conditions [2,3].

However, all around the world, an adequate continuity of care—defined as the coordination and integration of different health care events to meet patient care needs in a coherent, connected, and consistent manner [4]—is commonly affected by the lack of consistent information exchange between different services in care levels [5].

An extensive research area in computer science that seeks to assist in the problem of fragmentation of health care information systems is interoperability and data integration. The Institute of Electrical and Electronics Engineers Standards Computer Dictionary defines interoperability as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged” [6]. In the health care domain, Healthcare Information and Management Systems Society (HIMSS) defines interoperability as the ability of different information systems and applications to communicate, exchange data, and transparently use such data and associated information [7].

Health information systems that offer support to physicians and other health professionals are often not integrated [8], and the exchange of health information relating to the same patient between different care levels and different health institutions is usually nonexistent or incomplete. This can affect the continuity of care and communication among different care providers.

Coffey et al [9] point out that the fragmentation of services undermines mental health care by creating a barrier between different providers and the patient, making it difficult to provide effective treatment. According to Spiranovic et al [10], poor data quality, inconsistencies and discrepancies in information, and lack of interoperability among health information systems are some of the main difficulties for the secondary use of electronic health record data, including the public health management.

Brazil is a middle-income country with the world’s fifth largest population. Since 1988, a complex national health system (highly decentralized) has been implemented, with responsibilities in the funding and management divided between the 3 federated levels (cities, states, and country). The national health system is also composed of a mix of public and private, and profit and nonprofit services [11]. As in other countries, the prevalence of mental disorders is high, and the comorbidity between mental disorders and nonpsychiatric health problems is common [12]. Furthermore, because the regional integration between services is still limited and extremely challenging, there is an urgent need to develop appropriated and feasible integration strategies and solutions for mental health services [13].

Objective
Considering the need for a computational environment to facilitate the exchange of health information to improve the continuity of care between care levels, the eHealth-Interop computing platform was designed and deployed. The main objective of the eHealth-Interop platform is to provide a service for the exchange of standardized information on mental health, promoting the improvement of the quality of information and its availability in a transparent way for all the regional services responsible for mental health care.

Methods

Context of the Study: The Mental Health Care Network of the XIII Regional Health Department of the Sao Paulo State, Brazil

In Brazil, public mental health care has to be carried out through regional public mental health care networks (MHCNs), whose objectives are to guarantee the continuity and integrality of care through the different services and care levels [14].

The XIII Regional Health Department (RHD) covers over 26 municipalities [15], with approximately 1,400,000 inhabitants [16], where Ribeirão Preto is the main city. The development and current features of its MHCN are described in detail elsewhere [17-19]. Briefly, it comprises (1) primary health care, community-based mental health, and emergency services managed by the 26 municipalities; (2) acute inpatient psychiatric beds, outpatient specialized clinics, and a day hospital located at 2 state psychiatric hospitals and 1 state university general hospital; and (3) long-term residential mental health care facilities managed by municipalities and the state.

The extreme financial and administrative decentralization of public health services in Brazil (with the different health services, within a same health region, managed either by the municipal or by the state or even by the federal sphere) results in enormous heterogeneity of computerized information systems used by different services and professionals. For example, within the XIII Region of Health of the State of São Paulo, each of its 26 municipalities has 1 specific information system. Furthermore, each state-sphere health service has its own information system. The same happens with the private health services hired by the municipal or state public authority. Each one has its own computerized information system that is not shared with other services.

In the last 5 years, the Brazilian Ministry of Health has made available for primary care–level services a computerized information system called e-SUS AB [20] as part of a strategy to improve the interchange and integration of health care information. For the psychiatric care, referral and counter-referral in the region are articulated at the regional level through an information system called SISAM (Sistema de Informação em Saúde Mental; in English, mental health
information system) [17], which has a module for appointments scheduling in community mental health care units, too.

Although the different services present in the network have mechanisms to integrate care between them, as recommended by Brazilian health legislation (such as the SISAM itself and periodic meetings between services representatives) [17,18], from the informational and computational point of view, support systems of the different services are not integrated. This situation presents an immense difficulty for the health information exchange (HIE) between different services and professionals necessary for the efficient and safe management of the needs and demands of each health system user.

Therefore, information loss, data duplicity, lack of consistency, and rework are common. In this scenario, the work reported here was focused on the integration of 5 information sources from different information systems that support MHCN in the various care levels. The information sources are as follows: SISAM; e-SUS AB; data from 2 state psychiatric hospitals; and access to Web services of the Brazilian Ministry of Health for integration, with patients’ demographic data through the national health card.

Interoperability Information Model

In the eHealth-Interop platform, the interoperability data model corresponds to the information set that is exchanged and made available to health professionals at different care levels. To define this set of information, we analyzed the main processes involved in patient care. The identification of the main processes occurred in meetings with the professionals involved in the MHCN using a sociotechnical approach. With this approach, potential users and technical developers act together during the planning, development, and implementation of computational solutions [21,22]. The professionals were (1) clinicians from specialized hospitals, community mental health services, and primary health care; (2) municipal and regional health services managers; and (3) specialized technicians in health informatics. From these meetings, possible care events were identified and prioritized to share information. Moreover, 4 different events were highlighted: (1) patient entry into the network care, (2) assessment in primary care, (3) the admission in psychiatric hospital service, and (4) the discharge of these services. For each process, a set of data elements was defined based on analysis of existing documents. Finally, proposed data elements were reviewed by mental health specialists for information inclusion or exclusion (Figure 1).

The documents analyzed include records used in MHCN logistic instruments, national standards, and international documents. The records used are SISAM demographic form and a regional mental health specialized hospital discharge summary. Furthermore, the minimal health dataset structured by the Brazilian Ministry of Health was analyzed [23], together with the discharge summary proposed by the Associação Brasileira de Normas Técnicas (Brazilian Association of Technical Standards technical group on health informatics) [24].

Besides this set of national documents, documents from the United Kingdom, Canada, and Australia were also analyzed. From Australia, the following documents were analyzed: national minimum dataset—admitted patient mental health care [25], national minimum dataset—residential mental health care [26], and national minimum dataset—community mental health care [27]. From the United Kingdom, the mental health and learning disabilities dataset [28] was analyzed, and the document analyzed from Canada was the common dataset—mental health [29]. We also reviewed the information highlighted in a paper describing minimum data to continuity of care [30].

As a result of the described process, a set of information was defined for each of the 4 events: demographic form, with patient demographic and identification information; primary care assessment, with clinical information from primary care; admission form, with information of the hospitalization request and the admission moment; and the discharge summary, with data of the whole hospitalization process. These information sets were reviewed, reformulated, and approved by a group of around 20 professionals, representative of the several health services and municipalities involved in MHCN.

Figure 1. Process for generating the interoperability information model.
Interoperability

The defined interoperability data models serve as a conceptual basis for the HIE. The eHealth-Interop platform acts as a central repository of the data exchanged. All communication is performed through Web services available at the eHealth-Interop. Each data source, which is the information system in the different health services, sends and queries data from its patients through Web service clients that communicate with eHealth-Interop.

The process of sending patient data can be compared with the extraction-transformation-load steps in a classical data integration process. First, the data of interest are extracted from the local databases in the format that is specific to each information system. Then, the data are transformed to the interoperability data model previously defined. These transformed data are then uploaded to eHealth-Interop using specific end points provided by the platform Web services application programming interface (API). Thereafter, the data undergo a syntactic and duplicity analysis, aiming to improve the quality of the information. If the patient’s record is already recorded in eHealth-Interop, the new information will be aggregated, making a more complete record.

Data Quality Analysis

The analysis of the effectiveness of quality improvement, obtained from data integration provided by the proposed interoperability solution, was performed through the measurement of data quality. Data quality metrics used were as follows:

- Completeness represents the degree to which a given collection of data has the data it should represent. Data completeness is defined as the level of missing data for a data element.
- Syntactic accuracy represents the degree to which the given data are correct and reliable. Syntactic accuracy measures the degree to which the given data correspond to a possible value in the dataset, for example, age must be between 0 and 120 years.
- Duplicity represents the degree to which the given data are unnecessarily duplicated within a dataset of interest, for example, 2 or more records belonging to a same record in the same data source.

The data quality metrics of completeness and syntactic accuracy were calculated considering the data sources in 3 different moments during the data interoperability process. In the first moment, the data are available based on as they are originally represented in the different data sources. In a second moment, the data are available considering the normalization process into the data source adapters. During this process, each value of each attribute is transformed (if necessary) to conform to the defined interoperability data model. In a third moment, different records belonging to the same patient, which are originally in different sources, are integrated into a single record, and then the quality metrics are applied over them.

The duplication analysis was performed to verify the use of the record linkage (RL) algorithms and was applied over a set of records in the second stage that did not have deterministic identifiers.

Health Data Standards

During the design and implementation stage of eHealth-Interop and its components, 2 health information standards served as the basis: the Integrating the Healthcare Enterprise (IHE) and the Health Level-7 Fast Healthcare Interoperability Resources (HL7-FHIR).

IHE is a joint initiative initially formed by the HIMSS and Radiological Society of North America in 1988 [31]. The IHE aims to coordinate the use of health information standards, terminologies, and protocols to enable plug-and-play interoperability between systems from different vendors. The IHE Patient Identifier Cross-Referencing (PIX) profile is an integration profile that defines a methodology for cross-referencing patient identifiers from different sources [32]. FHIR is an HL7 standard that seeks to enable the construction of effective interoperability between applications using Web development standards [33].

The general principles of development enforced by HL7-FHIR, such as RESTful architecture; use of Web development standards such as JavaScript Object Notation (JSON) and open authorization (OAuth); and definition of concise and flexible data models have been adopted for the management of clinical and demographic data in eHealth-Interop. The HL7-FHIR terminology module specification was implemented for the eHealth-Interop terminology server. The IHE PIX profile served as the basis for the overall planning of the patient identification process, although not completely adopted. In this context, eHealth-Interop acts as the patient actor identifier cross-reference manager, and we rely on the patient identity feed, patient identity management, and PIX query transactions to define some of the services responsible for managing demographic data.

Results

eHealth-Interop Architecture

The architecture of a computational system seeks to define the general structures such as its main elements, the relationships between these elements, and the properties of the elements and these relationships [34]. According to Soni et al [35], the conceptual architecture of a system defines a high-level structure and is independent of the implementation and technical decisions.

Taking into account that regional care delivery is made up of different actors located at different points in a given region, the Web environment was defined as the basis for the integration platform following a client-server architecture. The proposed conceptual architecture of eHealth-Interop is shown in Figure 2. The architecture follows a model with 3 main layers: data layer, semantic layer, and communication layer. The data layer is where the data to be integrated are represented and stored; semantic layer, in which the mediating schemas, terminologies, ontologies, local codifications, and mappings between them are
described; and finally, the communication layer, where security aspects and communication with the data sources are managed.

**Figure 2.** Conceptual architecture of eHealth-Interop. API: application programming interface; DB: database; DS: datasource.

Each layer has specific components. Functionalities of each component are described below.

In the data layer, data are stored following a dual model, ensuring the differentiation between demographic and clinical information. This distinction seeks to establish a solid foundation for patient identification algorithms and at the same time make the database flexible to be extended to different application contexts in the medical field [36]. Another important component of the data layer is the RL module. This module is responsible for ensuring that there is no duplication of patient registration through the information provided in the demographic database.

The semantic layer is mainly composed of a terminology server responsible for the storage of codifications, terminologies, and ontologies as well as their relationships. It also comprises the clinical and sociodemographic concepts that compose the information models and the schema management module that connects the information model with the terminologies and communicates with databases.

The communication layer is responsible for generating the service API from the information models represented in the semantic layer and for promoting a secure communication by the security module that verifies the authentication and authorization of the person responsible for the process of data sending and retrieval. The exchange of information from the data source to the interoperability platform is done through adapters that are software agents that translate the source schema into the global model provided by the service interface.

**Terminology Server**

Medical vocabulary is highly heterogeneous, and several information artifacts are constantly emerging aiming to standardize not only medical concepts but also relationships between them. These artifacts are usually named codifications, terminologies, controlled vocabularies, and ontologies, among others [37]. The terminology server is a software component that provides several services for metadata management related to medical concepts. In HIE context, the terminology server is important to ensure not only the standardization of terms but also the information quality being integrated. The
eHealth-Interop terminology server was designed based on the terminology specification of the HL7-FHIR and has part of its design based on the Object Management Group common terminology services 2 [38] specification.

**Figure 3.** Terminology server components.

The main classes implemented are CodeSystem, ConceptDefinition, ConceptMap, and mapping (Figure 3). CodeSystem represents a particular ontology or terminology; it represents the total set of codes and their meanings. Concepts represent a particular concept or term in an ontology or terminology. ConceptMap represents a mapping between two CodeSystems or part of it. A mapping represents a relationship between two concepts from different CodeSystems.

In the medical context, or specific mental health, CodeSystem represents more complex terminologies such as Systematized Nomenclature of Medicine (SNOMED) [39], classifications such as 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10), and even local value sets such as to represent sexual orientation. ConceptDefinition are specific concepts, for example, the diagnosis of ICD-10, F03-Dementia. Mapping can represent the mapping between two ontologies such as CID10 and SNOMED, or the mapping between a local encoding (sexual orientation) and SNOMED, for example. ConceptMap are the individual concept-to-concept mapping, for example, dementia (F03) of the ICD10 that can be mapped as equivalent to the concept of dementia disorder (C0497327).

To support the information model defined for continued care in the MHCNs, 5 terminologies have been used:

- ICD-10
- International Classification of Functioning, Disability, and Health
- International Classification of Primary Care
- Table of Procedures, Medications and Orthotics, Prostheses, and Materials of the Unified Health System in Brazil
- Brazilian Classification of Occupations

In addition, local value sets were created to represent different concepts such as sex, marital status, and sexual orientation, among others. These codifications, for the most part, are in agreement with those used in the national information system for primary care or based on information models from a national standard for discharge summary.
**Record Linkage Module**

RL can be defined generally as the process of identifying records from different sources that correspond to the same real-world entity [40]. The RL process is also known as entity resolution, deduplication, entity matching, merge or purge problem, data reconciliation, or in a clinical context as patient matching, among others. The RL process is essential to ensure the integrity of information and data quality during HIE and data integration.

The health information system usually implements the RL based on a deterministic method in which certain precise rules are defined to guarantee the uniqueness of a patient’s record. In mental health context and in other areas such as medical emergencies, it is often not possible to obtain a unique identification or reliable information from patients. Therefore, using a deterministic method for patient RL is not always possible. In addition, duplication may occur from erroneous manual registration by users operating health information systems. These errors and lack of information can be propagated in a scenario of HIE in which several systems are involved.

To solve this kind of inconsistency, eHealth-Interop comprises an RL module that uses a 2-stage verification to ensure the uniqueness of the patient record. This process is summarized in Figure 4. The first step is to extract patient identifiers, for example, patient’s national identifier or health record number and apply the deterministic linkage using those identifiers. If a patient is not found, probabilistic linkage algorithms are applied using demographic information. When probabilistic linkage algorithms find a possible duplicity of identity, this duplicated record is assigned to a human audit process in which an expert analyzes the information and decides if the duplication really occurred or not.

**Security Server**

Information security and privacy are important aspects of any information system. In the medical field, it usually becomes a major barrier for the exchange of health information between different institutions [41]. The concern with information security and privacy was considered in different stages during the eHealth-Interop development, that is, in the conceptual design of the integration platform architecture, for data exchange mechanism adoption, and also for the definition of the user data access hierarchy.

The division of the data layer architecture in 2 different repositories, which store patient demographic information and clinical information separately, allows these repositories to be made available on different physical locations with different access methods, increasing security at system level.

All data access is done through Web services that use the HTTPS protocol, establishing a secure communication channel between the client and the server, where the data are encrypted [42]. Every client application to interoperate with eHealth-Interop platform must be previously registered, as well as the users who will access the data through this application. HTTPS ensures that information exchanged in eHealth-Interop is encrypted during the process of transfer between clients. Data stored in databases, by default, is not encrypted because of performance improvements. Nonetheless, all patient unique identification information is stored separately with more restricted access to ensure the safety of this information.

A hierarchy of user access was also implemented following the model already defined by MHCN professionals. In this model, the professionals of the municipal health services have access to the patient’s data only from their own municipality, allowing these data to be accessed by another service in case of a transfer. The regional hospital services have access to the data about those patients who are referred to them. The access is provided based on the OAuth2 protocol [43]. The data privacy model adopted follows the model already established in MHCN and based on the model established by the Ministry of Health in Brazil for primary care. In this case, all professionals involved in patient care have access to shared data. For example, for a patient who underwent treatment in a mental health clinic and then was admitted to a specialized hospital, practitioners from both facilities have access to the patient’s information. The eHealth-Interop enables the definition of stricter or permissive data access strategies depending in the application context. All actions are stored in a logging system, allowing the establishment of an audit trail.

**Communication Application Programming Interface**

All communication between the different information sources and the eHealth-Interop platform is done through Web services. The Web services provide a series of functionalities for registration and query of patient demographic data in the platform as well as all the clinical information associated with them. Clinical information is represented on information model defined a priori in clinical documents that are exchanged during different moments of the patient care process. A Web tool was also developed to assist the construction of adapters displaying all the services available in eHealth-Interop as well as how to access them (Figure 5).

In addition, a Web administration application was also built (Figure 6). Through this Web administration application, it is possible to manage all users and applications that have access to eHealth-Interop as well as the terminology server and to audit possible duplicate records found by the RL module.
Figure 4. Information flow during patient registry in eHealth-Interop.

1. Patient demographic form
2. Extract patient identifiers
3. Apply deterministic linkage
4. Patient found?
   - Yes: Save demographic form and link with existing patient record
   - No: Save demographic form and new patient record
5. Apply probabilistic linkage
6. Patient found?
   - Yes: Mark new patient as potential duplicate
   - No: No action taken
Figure 5. eHealth-Interop Web services API description tool. API: application programming interface.

Figure 6. eHealth-Interop administration system.
Integrated Care Web Application

To allow the analysis of the integrated information, a Web application tool was created that acts as client of the eHealth-Interop server. This tool is coupled with SISAM, allowing access to all professionals who work in mental health in the region, based on reuse of predefined and agreed access levels. In this way, access for patient demographic information and clinical information about appointments in the different care levels (primary, secondary, and tertiary) are provided.

This Web application also provides access to a timeline of patient care events (Figure 7).

Technical Details

The implementation of this conceptual architecture was made using the LoopBack framework [44] and was deployed using Node.js programming language. In the data layer, the separation in 2 databases, relational and nonrelational database, was mainly because of 3 reasons. First, all demographic and security information is stored in the relational database using MySQL [45]. This set of information is fixed and is less likely to be altered over time. Second, clinical information grouped in documents that represent health events is more flexible and can be modified according to the clinical context. The data model for representing these documents is based on JSON schema. For this, the nonrelational database MongoDB [46] was chosen, seeking greater flexibility and adaptability of the data model. Finally, this division also allows greater security and anonymity of information, as the database may be available in different locations.

The software API Dedupe [47] was used for the RL module implementation. The Web services application was built using the OpenAPI specification standard [48]. The eHealth-Interop admin Web application was built using the Angular version 2, which is a typescript framework to build Web applications.

The eHealth-Interop performance with the dataset available for testing was satisfactory, with no delay during its use (less than 1 second time of response). It is also important to consider that the set of events that generate access to eHealth-Interop simultaneously is low. Stress testing is needed for scenarios where a much larger volume of data is used concurrently.

Use Case Example in the Mental Health Care Network

A total of 27,353 patient health records were obtained from the 5 data sources used in this work for a period from 2011 to 2016. Out of these, 9547 (34.90%, 9547/27,353) records have been integrated in eHealth-Interop platform. In these records, the same patient is present in at least two different sources of information with the same identification data. The total number of unique patient records after integration was 4252, which means there were approximately 2.25 records per patient in the original dataset. The number of data sources having the same patient’s record are presented in Table 1.

Completeness and syntactic accuracy analyses were performed over patients’ demographic data. In total, 26 different attributes

Figure 7. Web application tool to access integrated health care information.
have been analyzed. For each attribute of each record, a value of 1 or 0 of completeness was assigned, based on the presence or absence of any data. Thereafter, the syntactic accuracy analyses were performed for those attributes with completeness value equals to 1. The syntactic accuracy analysis was done at attribute level for each patient record. Rules of syntactic analysis were defined for each attribute. Some of these rules are demonstrated in Table 2. Completeness and syntactic accuracy analyzes were performed field-by-field of the 9548 integrable records, totaling to 248,248 (9548 × 26) analyzed fields.

Then, each attribute value was tested according to the defined rule of the respective attribute. For example, if the patient has the birth date as February 2, 1970, then the rule is applied to verify if this value is a valid birth date. If the value passes in the test, then it has a value of syntactic accuracy equal to 1, otherwise the value will be zero. Table 3 shows such analysis for all demographic dataset before and after data integration in eHealth-Interop.

Results presented in Table 3 refer to the total set of integrated demographic information. Tests were improved by splitting demographic information into subgroups to better understand how eHealth-Interop acted over data quality. Each subgroup consists of a set of related information. Four subgroups were defined as follows: general, identification, contact, and address. The general subgroup consists of general demographic information such as name, mother’s name, father’s name, gender, and date of birth. The identification subgroup is composed of key attributes for patient unique identification, including identifiers used at national and local health level. The contact subgroup includes residential telephone, cell phone number, and email. The address subgroup includes the residence address information of the patient such as city name, street name, and house number. Tables 4 and 5 show the completeness and accuracy analysis, respectively, for each subgroup before and after the data integration through eHealth-Interop.

In case of inconsistent data (2 different birthdates) when performing the entity integration, the value that is syntactically correct is adopted. If both values pass the test, the one from the record with highest value of completeness is adopted. Nevertheless, all the original data from both integrated records are stored before the integration. It is possible to change the canonical record later.

For duplicity analysis, a cured dataset was organized with records that did not have unique identifiers. Then, a semiautomatic strategy was conducted: initially the RL module was used to perform a preselection of possible duplications and then, in the next step, each duplication result was manually verified for the determination of a true positive set of duplicates.

Table 1. Distribution of the number of integrable patient records per data source.

<table>
<thead>
<tr>
<th>Number of data sources having the same</th>
<th>Number of unique patient’s records (n=4252), n (%)</th>
<th>Total of integrated records (n=9548), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>patient’s record</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3247 (76.36)</td>
<td>6494 (68.02)</td>
</tr>
<tr>
<td>3</td>
<td>968 (22.77)</td>
<td>2904 (30.41)</td>
</tr>
<tr>
<td>4</td>
<td>35 (0.82)</td>
<td>140 (1.47)</td>
</tr>
<tr>
<td>5</td>
<td>2 (0.05)</td>
<td>10 (0.10)</td>
</tr>
</tbody>
</table>

Table 2. Example of syntactic rules used in the syntactic accuracy analysis.

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Syntactic rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthdate</td>
<td>A valid date, considering that maximum age is 120 years</td>
</tr>
<tr>
<td>Municipality of residence and birth</td>
<td>A name of a registered Brazilian municipality</td>
</tr>
<tr>
<td>National health card and national identification number</td>
<td>Predefined numeric rule to validate the specific field</td>
</tr>
<tr>
<td>Cell phone and residential telephone number</td>
<td>A numeric value of possible length of a valid Brazilian phone number</td>
</tr>
</tbody>
</table>

Table 3. Completeness and accuracy analysis in the whole dataset of integrated records (n=248,248).

<table>
<thead>
<tr>
<th>Measures</th>
<th>Completeness</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nonintegrated, n ( %)</td>
<td>Integrated, n ( %)</td>
</tr>
<tr>
<td>Minimum</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Maximum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>140,186 (56.47)</td>
<td>185,863 (74.87)</td>
</tr>
<tr>
<td>SD</td>
<td>83,957 (33.82)</td>
<td>87,234 (35.14)</td>
</tr>
</tbody>
</table>

_a A dash indicates that no difference was observed.
Principal Findings

Coordination and continuity of care at different care levels have been a challenge in many health systems. Major informational barriers for continuity of care are the lack of support information mechanisms to ensure information exchange among health providers. Health information systems are important tools to overcome these barriers, but fragmentation and heterogeneity, particularly prominent in the Brazilian national health system, do not allow to achieve the greatest advantages from their use.

To solve this kind of limitation, a computational interoperable health care platform was designed and deployed to establish an HIE environment. In eHealth-Interop, sociodemographic and clinical information are split into 2 different repositories, aiming to provide data security and extensibility.

In the definition of the interoperability information model, in a joint decision with health professionals, it was decided to consider as much as possible of the defined national standards, while taking into account the other documents already used locally by the services and some international documents as well. Some concepts were out of context with respect to mental health, such as surgical procedures performed and allergies. Despite this, the strategy of keeping this information as optional locally by the services and some international documents as well.

The RL algorithm has been configured to take into account the patient’s name and mother’s name because they have 100% of Completeness after data integration. The adopted threshold was 0.75 (referring to the probability of finding a duplicate), seeking for a high sensitivity for duplications detection. From a total of 6427 records tested, 1066 duplications were automatically preidentified, and from those, 226 were manually confirmed. The duplicity analysis served as proof of concept of the RL module with the pre-established settings.

In eHealth-Interop, sociodemographic and clinical information are split into 2 different repositories, aiming to provide data security and extensibility.

Table 4. Completeness analysis of demographic information divided in subgroups (n=248,248).

<table>
<thead>
<tr>
<th>Completeness</th>
<th>General integration</th>
<th>Identification integration</th>
<th>Contact integration</th>
<th>Address integration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before, n (%)</td>
<td>After, n (%)</td>
<td>Diff</td>
<td>Before, n (%)</td>
</tr>
<tr>
<td>Minimum</td>
<td>0 (0.00)</td>
<td>3103 (1.25)</td>
<td>+1.25</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Maximum</td>
<td>248,248 (100.00)</td>
<td>248,248 (100.00)</td>
<td>+0.00</td>
<td>234,768 (94.57)</td>
</tr>
<tr>
<td>Mean</td>
<td>155,329 (62.57)</td>
<td>188,718 (76.02)</td>
<td>+13.45</td>
<td>141,774 (57.11)</td>
</tr>
<tr>
<td>SD</td>
<td>87,383 (35.20)</td>
<td>87,905 (35.41)</td>
<td>+0.21</td>
<td>99,895 (40.24)</td>
</tr>
</tbody>
</table>

The RL algorithm has been configured to take into account the patient’s name and mother’s name because they have 100% of Completeness after data integration. The adopted threshold was 0.75 (referring to the probability of finding a duplicate), seeking for a high sensitivity for duplications detection. From a total of 6427 records tested, 1066 duplications were automatically preidentified, and from those, 226 were manually confirmed. The duplicity analysis served as proof of concept of the RL module with the pre-established settings.

Table 5. Accuracy analysis of demographic information (n=248,248).

<table>
<thead>
<tr>
<th>Accuracy</th>
<th>General integration</th>
<th>Identification integration</th>
<th>Contact integration</th>
<th>Address integration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before, n (%)</td>
<td>After, n (%)</td>
<td>Diff</td>
<td>Before, n (%)</td>
</tr>
<tr>
<td>Minimum</td>
<td>137,579 (55.42)</td>
<td>170,472 (68.67)</td>
<td>+13.25</td>
<td>237,449 (95.65)</td>
</tr>
<tr>
<td>Maximum</td>
<td>248,248 (100.00)</td>
<td>248,248 (100.00)</td>
<td>+0.00</td>
<td>248,248 (100.00)</td>
</tr>
<tr>
<td>Mean</td>
<td>232,931 (93.83)</td>
<td>236,357 (95.21)</td>
<td>+1.38</td>
<td>243,184 (97.96)</td>
</tr>
<tr>
<td>SD</td>
<td>34,382 (13.85)</td>
<td>24,527 (9.88)</td>
<td>−3.97</td>
<td>5437 (2.19)</td>
</tr>
</tbody>
</table>

Discussion

The RL algorithm has been configured to take into account the patient’s name and mother’s name because they have 100% of Completeness after data integration. The adopted threshold was 0.75 (referring to the probability of finding a duplicate), seeking for a high sensitivity for duplications detection. From a total of 6427 records tested, 1066 duplications were automatically preidentified, and from those, 226 were manually confirmed. The duplicity analysis served as proof of concept of the RL module with the pre-established settings.

Principal Findings

Coordination and continuity of care at different care levels have been a challenge in many health systems. Major informational barriers for continuity of care are the lack of support information mechanisms to ensure information exchange among health providers. Health information systems are important tools to overcome these barriers, but fragmentation and heterogeneity, particularly prominent in the Brazilian national health system, do not allow to achieve the greatest advantages from their use.

To solve this kind of limitation, a computational interoperable health care platform was designed and deployed to establish an HIE environment. In eHealth-Interop, sociodemographic and clinical information are split into 2 different repositories, aiming to provide data security and extensibility.

In the definition of the interoperability information model, in a joint decision with health professionals, it was decided to consider as much as possible of the defined national standards, while taking into account the other documents already used locally by the services and some international documents as well. Some concepts were out of context with respect to mental health, such as surgical procedures performed and allergies. Despite this, the strategy of keeping this information as optional in the data model was adopted. The standardization and use of international documents allows a comparison with other services and contexts.

Although there are several initiatives for HIE, few of these works are applied in the context of mental health. In this context, some characteristics are quite relevant from the point of view of information sharing, such as a greater number of patient passages by different health services, often generating more readmissions and patient’s demographic information not always reliable, generating patients without unique identifiers. The eHealth-Interop acts as integration middleware, flexible to allow the sharing of information, even in situations of low reliability but having mechanisms to improve quality and ensure entity integration such as the RL module and the terminologies service.

Another important result of this work was the measurement of data quality metrics to gauge the impact of the eHealth-Interop platform in informational continuity of care, as impact of HIE are not yet adequately studied [49,50].

Limitations

In the mental health use case described, the eHealth-Interop supported HIE between primary health care and mental hospital care, but it was not possible to conduct tests with specialized ambulatory care data. However, the platform is able to automatically generate the Web services API and the database schema to store this information if necessary.

Although the HL7-FHIR standard and the IHE PIX profile have been used as the basis for the definition of eHealth-Interop architecture and the interoperability model, they were not fully adopted. It was not possible to fully adopt the standards, mainly because it would be highly costly to enforce the adaptation by the stakeholders involved. It was then opted for as an intermediate strategy, where the basic principles were adopted but with a more flexible and simplified approach, allowing greater adaptation to the client systems that are part of the MHCNs. A future step will be the conformation of the API involving clinical and demographic data management for the HL7-FHIR standard and not just the terminology service.

Another limitation of this project is that in the mental health use case, there is no mapping between the concepts of the adopted terminologies. The eHealth-Interop supports interterminology mapping; however, there was no need to translate concept from 1 terminology to another for the initial application.

Related Work

Several reviews analyzing the usage, barriers, facilitators, impact, and cost of HIE have been conducted [41,49-51]. Low data quality is one of the challenges described and a possible cause is poor patient matching process [41]. This issue becomes critical depending on the context, as in the case of homeless patients [52].

In the technical domain, there are several papers proposing the implementation of platforms for the exchange of health information [53-55]. Yuksel et al [53] developed the SALUS platform (Scalable, standard-based Interoperability Framework for Sustainable Proactive Post Market Safety Studies), an ontology-based interoperability framework designed to conduct observational studies from data extracted from different data sources. Moraes et al [54] proposed a methodology for the exchange of information through multi-agent systems based on OpenEHR used for cardiac surgery planning. Rac-Albu et al [55] proposed a method, based on HL7 v2, for exchanging medical documents seeking the interoperability of health data in Romania.

There are few HIE studies in the context of mental health. Cifuentes et al [56] analyzed strategies for care integration between mental health and primary care level. One barrier to achieve this integration is the lack of interoperability between information systems. Shank et al [57] evaluated, through a statewide survey, the behavioral health providers’ beliefs about HIE. The authors concluded that most providers support the use of HIE, although they also worry about the safety and cost of deploying these solutions.

Although there are several studies and proposals for establishing an HIE environment, this remains an open problem, and its use is still limited [58]. In this paper, we described the whole process of development and use of an HIE tool in a challenging medical context, that is, in the case of mental health. In conjunction with key stakeholders, relevant processes were mapped, and interoperability data models were constructed. We described a multilayer conceptual architecture that supports data exchange. This proposal covers two important aspects: the problem of dealing with different health terminologies and the use of a detailed patient identifier process that encompasses patients without unique identifiers. We tested the solution in a real-world environment.

Conclusions and Future Directions

The eHealth-Interop is a computing platform designed for health information system interoperability. This proposal was successfully implemented and tested in the context of mental health care. This platform has been built to be (1) flexible, so it can be applied in other scenarios and clinical domains and (2) robust, so records of patients with little information can be integrated and completed.

As future work, we intend to support the creation of alerts and automatic warnings based on specific process, for example, when a patient is hospitalized, a warning is generated for a certain health service warning about the event. We also intend to enable semantic querying using a SPARQL end point and implement algorithms to help the process of semantic markup, as well as add similarity functions to the terminology server, allowing a broad approach in concept searching.

Acknowledgments

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Authors’ Contributions

NSBM, PMAM, and DA were responsible for the platform technical design, methods, and computational techniques involved in the work. JIAM provided medical, mental health, and Brazilian public health knowledge for the development of the project as well as helped in the contact with the different professionals of the regional health network who collaborated with the project. NSBM implemented the designed solution and conducted the quality tests and assessments. All authors participated in writing and reviewing the manuscript for publication.
None declared.

References


Abbreviations
API: application programming interface
FHIR: Fast Healthcare Information Resource
HIE: health information exchange
HIMSS: Healthcare Information and Management Systems Society
HL7: Health Level-7
ICD-10: International Statistical Classification of Diseases and Related Health Problems
IHE: Integrating the Healthcare Enterprise
MHCN: mental health care network
PIX: Patient Identifier Cross-Referencing
RHD: Regional Health Department
RL: record linkage
SISAM: Sistema de Informacao em Saude Mental
SNOMED: Systematized Nomenclature of Medicine
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Psychiatrists' Attitudes Toward Disruptive New Technologies: Mixed-Methods Study

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Abstract

Background: Recent discoveries in the fields of machine learning (ML), Ecological Momentary Assessment (EMA), computerized adaptive testing (CAT), digital phenotype, imaging, and biomarkers have brought about a new paradigm shift in medicine.

Objective: The aim of this study was to explore psychiatrists' perspectives on this paradigm through the prism of new clinical decision support systems (CDSSs). Our primary objective was to assess the acceptability of these new technologies. Our secondary objective was to characterize the factors affecting their acceptability.

Methods: A sample of psychiatrists was recruited through a mailing list. Respondents completed a Web-based survey. A quantitative study with an original form of assessment involving the screenplay method was implemented involving 3 scenarios, each featuring 1 of the 3 support systems, namely, EMA and CAT, biosensors comprising a connected wristband-based digital phenotype, and an ML-based blood test or magnetic resonance imaging (MRI). We investigated 4 acceptability domains based on International Organization for Standardization and Nielsen models (usefulness, usability, reliability, and risk).

Results: We recorded 515 observations. Regarding our primary objective, overall acceptability was moderate. MRI coupled with ML was considered to be the most useful system, and the connected wristband was considered the least. All the systems were described as risky (410/515, 79.6%). Regarding our secondary objective, acceptability was strongly influenced by socioepidemiological variables (professional culture), such as gender, age, and theoretical approach.

Conclusions: This is the first study to assess psychiatrists' views on new CDSSs. Data revealed moderate acceptability, but our analysis shows that this is more the result of the lack of knowledge about these new technologies rather than a strong rejection. Furthermore, we found strong correspondences between acceptability profiles and professional culture profiles. Many medical, forensics, and ethical issues were raised, including therapeutic relationship, data security, data storage, and privacy risk. It is essential for psychiatrists to receive training and become involved in the development of new technologies.

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KEYWORDS
acceptability; clinical decision support systems; computerized adaptive testing; digital phenotype; ecological momentary assessment; machine learning; mobile phone; professional culture
**Introduction**

Recent discoveries in the fields of genetics, imaging, and biomarkers, together with the development of medical informatics, are leading us to rethink psychiatry. The practices, representations, ethics, and beliefs of practitioners could be disrupted. In science, the ability to predict [1] the occurrence of a morbid event opens up important perspectives—not only preventive or curative but also ethical. At the interface between electronic health, new technologies, and clinical observation, a large number of new tools are currently being developed for the early detection of psychotic or mood disorders and for the prediction of their course. A growing number of studies are reporting on the use of computerized assistance, especially artificial intelligence, in the form of new clinical decision support systems (CDSSs), and current changes to these systems tend to associate 2 concepts: digital phenotyping and machine learning (ML).

Torus and Gualtieri underlined the potential usefulness of connected objects in the field of mental health [2], as many devices now include multiple sensors (accelerometer, heart rate sensor, sleep tracker, skin conductance sensor, light sensor, etc). The prospect of being able to gather real-time physiological data from fitness trackers as well as from symptom checkers in smartwatches is an attractive one, and there is increasing interest in using real-time patient data as biomarkers for illness. Their team recently developed the concept of the digital phenotype of pathology. This refers to capture by computerized measurement tools of specific characteristics of psychiatric disorders [3,4]. Some behaviors or symptoms may be objectifiable and quantifiable by computer tools, thereby constituting an e-semiotic (semiotics mediated by computerized tools). Thus, the graphorrhoea observed in manic episodes can be reflected in an increase in the number of short service message text messages sent, and depressive psychomotor retardation can be assessed by an accelerometer [5].

Sensor miniaturization and the ubiquitous use of smartphones mean that it is now possible to collect a large amount of data that psychiatrists had never previously been able to access. Models based on these new signs are emerging in the field of schizophrenia [6] and mood disorders [5]. These passive data are collected in background tasks for which no intervention is necessary. To reduce observer bias, the individual is not always aware when the data are being collected. Detection may involve a mobile phone and its onboard sensors (global positioning system, accelerometer, verbal flow detector, etc) or connected wearable objects that allow biometric monitoring to take place in the real-time. Data can also be collected actively by Ecological Momentary Assessment (EMA) on a smartphone, but the collection of live data requires action on the part of the patient. EMA involves the evaluation of symptoms from day to day in the patient’s habitual environment, and as they evaluate themselves (right then, not later; right there, not elsewhere) there can be no recall biases [7,8]. This method allows a much more individualized approach to introducing precision diagnosis in psychiatry [9], as symptoms are connected through a system of causal relations, with symptoms impacting on each other (i.e., insomnia impacting on depressive symptoms, depressive symptoms impacting on anxiety symptoms, hallucinations impacting on delusions, etc). In addition, many symptoms may be context-dependent (i.e., increasing alcohol craving when approaching a bar). EMA can capture dimensional variation in mental states in response to other mental states or environmental variation, resulting in a diagnosis that is both precise and contextual.

All these data, far too copious to be analyzed manually, can be processed by computer software, allowing patients to be classified according to their illness. As we have seen, new technologies (smartphone, computers, and biomarkers) and the parallel expansion of medical informatics and artificial intelligence have brought about a paradigm shift toward a more personalized and predictive form of medicine [10]. But if some disorders can be recognized by computer models and if diseases or relapses can be detected earlier or more precisely by machines or smartphones, what role will health care providers play in the future?

The advent of these technologies calls into question psychiatrists’ professional culture. This sociological concept, derived from the sociology of professions, refers to the fact that professionals refer not only to theoretical knowledge or experience but also to a set of customs, a specific language, and a set of common values [11,12]. According to sociology, a professional activity profoundly influences the identity of the individuals who exercise it. These individuals are defined by their membership of the profession, conceived of as a fully-fledged social group and a culture bearer, sharing values and beliefs as well as a common way of expressing them [13,14]. In that aspect, some authors are already suggesting that psychiatrists are an endangered species [15]. Indeed, psychiatrists diverge from other medical specialties in terms of the predominance of clinical reasoning, the lack of specific or valid imaging techniques or biological tests, and the importance given to intuition, clinical sensitivity, and the therapeutic relationship. From this point of view, the psychotherapeutic dimension of the psychiatric interview could be challenged by these new technologies.

To our knowledge, there has been little research in this area, and although several studies have recently focused on the acceptability of these technologies for patients or patient compliance, potential prescribers have never been questioned on the subject. The acceptability of these technologies must, therefore, be assessed at different levels, namely, usability (intention to use), utility (technology’s contribution), reliability (including accuracy, effectiveness, and efficiency), and risk, which constitute important dimensions of medical reasoning.

The main objective of this study was to analyze psychiatrists’ perspectives on these new technologies by assessing the acceptability of 3 CDSSs: (1) smartphone-based EMA, (2) connected wristband-based digital phenotype, and (3) ML-based prediction magnetic resonance imaging (MRI) or blood test. We used a model specifically developed for this purpose with a multidisciplinary approach (psychiatric and sociological). The secondary objective was to characterize the factors affecting this acceptability and, consequently, indirectly affecting the psychiatrists’ professional culture.

http://mental.jmir.org/2018/4/e10240/
Methods

Study Design
We conducted a qualitative and quantitative study via a computerized survey (Google-Form), in collaboration with the Sociology and Anthropology Laboratory of the University of Burgundy Franche-Comté (LaSA, UBFC).

Target Population and Sample Composition
This study focused on a population of psychiatrists working in France. They ranged from residents to senior psychiatrists, working in psychiatric facilities, general or university hospitals, or private practices. Requirement of Ethical Committee’s approval was waived.

Survey Development
We used an original form of assessment, with 2 researchers at Sociology and Anthropology Laboratory of the University of Burgundy Franche-Comté, based on the screenplay method, an assessment method used to expose respondents to challenging and problematic clinical cases, in order to ask them to express what should be done or what they themselves have done to act with competency in such situations. By confronting the psychiatrists with systems or devices that are still essentially restricted to the field of research, we were able to review some aspects of reality that are not captured by other types of evocation. The 3 scenarios used here allow practitioners to think about devices that are currently in the research domain and are not used (or little used) in daily routine.

The screenplay method featured 3 clinical case presentations involving new technologies (Table 1 and Multimedia Appendix 1).

All the questions were designed during 3 focus groups including psychiatrists and sociologists and were tested with cross-validation on a sample of psychiatrists working at Saint-Antoine Hospital in Paris, France. They ranged from residents to senior psychiatrists, working in psychiatric facilities, general or university hospitals, or private practices. Requirement of Ethical Committee’s approval was waived.

Survey Development
We used an original form of assessment, with 2 researchers at Sociology and Anthropology Laboratory of the University of Burgundy Franche-Comté, based on the screenplay method, an assessment method used to expose respondents to challenging and problematic clinical cases, in order to ask them to express what should be done or what they themselves have done to act with competency in such situations. By confronting the psychiatrists with systems or devices that are still essentially restricted to the field of research, we were able to review some aspects of reality that are not captured by other types of evocation. The 3 scenarios used here allow practitioners to think about devices that are currently in the research domain and are not used (or little used) in daily routine.

The screenplay method featured 3 clinical case presentations involving new technologies (Table 1 and Multimedia Appendix 1).

All the questions were designed during 3 focus groups including psychiatrists and sociologists and were tested with cross-validation on a sample of psychiatrists working at Saint-Antoine Hospital in Paris, France. The first part of the survey (15 questions) collected epidemiological data: sex, job, place of practice, theoretical and practical training (neurobiological, psychoanalytic, integrative, cognitive behavioral therapy, etc), workplace, year of graduation, and practice area (adult psychiatry, child psychiatry, forensic psychiatry, etc). The second part assessed the acceptability of the support systems and the psychiatrists’ professional culture, with 15 questions per scenario (total of 60 questions). To avoid responder focus being too much on confounding factors (ie, the shortage of health personnel aspect), we asked direct questions about the devices in our questionnaire (Textbox 1). A blank field allowed us to collect qualitative data in the form of feedback at the end of the survey.

Assessment of Acceptability
The various technologies described above can be studied from a sociological perspective by examining the factors that prevent or, conversely, encourage their use. Several dimensions that can influence acceptability were included in an acceptability model specifically developed for the study and inspired by research on human-machine interaction and management information systems, combining the Nielsen, International Organization for Standardization, and Shackel models [21,22] (see Multimedia Appendix 2). The variables most frequently associated with acceptability are usability (ie, intention to use), supposed usefulness, and reliability [23-25]. In our model, we assessed 4 variables: usefulness, usability, reliability, and risk (Textbox 1). For each variable, participants responded to the questions on a Likert-like scale ranging from 1 to 6, depending on the item. To gauge the acceptability of each system, we calculated a composite score with 3 values (positive, intermediate, and negative).

Psychiatrists’ Professional Culture
The purpose of each item was to bring out the characteristics of the sociological concept known as psychiatrists’ professional culture: what made them psychiatrists, with which technologies they would refuse to compromise, and how they saw themselves in relation to other specialists. We took 2 major areas of professional culture into account. First, we investigated the psychiatrists’ scientificity level, reflected by the use of biometric data, MRI, blood tests, and physical examinations (assuming that the more scientifically-minded the psychiatrists are, the more willing they are to use complementary examinations). Second, we probed the psychiatrists’ specific relationship with technology by analyzing the hopes and fears generated by these new tools (ie, did they think that these technologies would help them or replace them?; see Textbox 2).

Table 1. Screenplay method.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Detection and diagnosis of a mood disorder using computerized adaptive testing [16] and smartphone-based Ecological Momentary Assessment in a young patient suspected of having a depressive disorder [17]</td>
<td>To evaluate the acceptability of a machine instead of a psychiatrist for making a diagnosis</td>
</tr>
<tr>
<td>2. Early detection of depressive relapse using an electronic connected wristband (biosensors) [18] to assess the digital phenotype of a patient with a recurrent depressive disorder in remission</td>
<td>To investigate the psychiatrists’ views on the intrusion of a connected object between them and their patients. Investigate their views on the device’s ability in early detection</td>
</tr>
</tbody>
</table>
Textbox 1. Acceptability assessment.

Scenario 1 (Ecological Momentary Assessment and computerized adaptive testing)
1. In absolute terms, do you think that the devices presented in this scenario (smartphone-based Ecological Momentary Assessment) are useful? Same question for computerized adaptive testing
2. Would you use this type of device for depressive disorder diagnosis?
3. Do you think that the devices presented in this scenario are reliable?
4. Do you think that the devices presented in this scenario are at risk?
5. If yes, why?
6. Do you think that the devices presented in this scenario allow you to do:
   - tasks that waste your time?
   - tasks that you don’t like to do?
   - tasks that you don’t know how to do?

Scenario 2 (Digital phenotype)
1. In absolute terms, do you think that the devices presented in this scenario (connected wristband allowing biometric data collection) are useful?
2. Would you prescribe this type of device for early detection of a depressive relapse?
3. Do you think that the devices presented in this scenario are reliable?
4. Do you think that the devices presented in this scenario are at risk?
5. If yes, why?
6. Do you think that the devices presented in this scenario allow you to do:
   - tasks that waste your time?
   - tasks that you don’t like to do?
   - tasks that you don’t know how to do?

Scenario 3 (Machine learning)
1. In absolute terms, do you think that the devices presented in this scenario (magnetic resonance imaging and machine learning) are useful? Same question for blood test
2. Would you prescribe this type of device for psychotic transition prediction?
3. Do you think that the devices presented in this scenario are reliable?
4. Do you think that the devices presented in this scenario are at risk?
5. If yes, why?
6. Do you think that the devices presented in this scenario allow you to do:
   - tasks that waste your time?
   - tasks that you don’t like to do?
   - tasks that you don’t know how to do?
Textbox 2. Professional culture assessment.

1. For all the 3 scenarios:
   - Do you think that these devices make you lose part of your role?
   - Do you think that these devices could be useful for general practitioners?
   - Do you think these devices influence the therapeutic relationship?
   - Do you think these devices are better than the psychiatrist in that specific matter?
   - Do you think that there is a risk that these devices replace the psychiatrist in that specific matter?

2. Specific for scenario 2:
   - Do you think that this device constitutes an intrusion on the patient’s life?
   - Do you use that kind of data (psychomotor retardation, heart rate, biometrics, etc) in the follow-up of your depressive patients?

3. Specific for scenario 3:
   - Do you think that this kind of probabilistic reasoning based on an algorithm can have a place in your practice?
   - Do you think that the use of this kind of device needs specific technical abilities?

Data Collection
The survey was created with Google Forms and sent by email to the relevant professionals via several mailing lists (residents’ association, private practice associations, clinical facilities, personal social networks, etc). Respondents could answer via an internet browser. After a short introductory text, the scenarios appeared one after the other, each followed by the corresponding questions. The survey was anonymous and took about 10-15 minutes to complete.

Data Analysis
We performed an initial descriptive analysis of the population using multiple regression analysis. Comparisons of proportions were carried out using a z test with Bonferroni correction. Pearson correlation coefficients were used to analyze correlations between variables. The variables were compared with nonparametric chi-square tests or with Fisher’s test when the conditions for chi-square application were not met, using Microsoft Excel, SPSS v24, and R statistical software. The significance level was set at 5%, such that differences with a P value <.05 were deemed to be significant. In order to achieve 95% statistical power with an alpha risk of .05, the bibliographic analysis indicated that 374 participants were required (bearing in mind that there were 12,591 psychiatrists in France in 2016) [26]. Qualitative variables were partially analyzed by LaSA using Modalisa (in press).

Results
Survey Implementation
The Web-based survey was available between June 30 and August 8, 2016. A total of 528 responses were received. We excluded 5 empty surveys, 5 duplicates, and 3 incomplete surveys (no responses to at least 1 whole scenario) such that 515 surveys were included in the analysis.

Demographics
The study population was predominantly female (299/515, 58.1%), mainly composed of young psychiatrists who had already graduated or were set to do so between 2010 and 2020 (342/515, 66.4%), and the majority of practitioners worked in adult psychiatry (270/515, 52.4%). Residents made up a large proportion of the sample (241/515, 46.8%), followed by hospital practitioners (148/515, 28.7%) and private practitioners (49/515, 9.5%). The 2 most common theoretical approaches were “several approaches focusing on neurobiology or cognitive behavioral therapy” and “integrative practice” (see Multimedia Appendix 3).

Primary Outcome: Acceptability of Support Systems
Quantitative Analysis
The overall acceptability was moderate (Table 2). Positive scores only outweighed negative scores for ML. They did not differ significantly for computerized adaptive testing (CAT) or EMA, and the fewest positive scores were for the connected wristband (Figure 1 and Table 2). MRI coupled with ML was considered to be the most useful system, although when asked about reliability, participants gave CAT most positive scores. All the systems were deemed to be potentially risky (211/515, 41.1%) or risky (198/515, 38.5%). MRI and blood tests had the most favorable risk profile (ie, fewest negative scores). For those who responded that there was a risk (potential or real), the main risks were medical (regardless of the technology), then ethical (especially regarding MRI and blood tests), and finally legal (mainly with regard to the connected wristband).

Qualitative Analysis
Qualitative analysis explored the obstacles to the acceptability of these new technologies. There were 3 major issues emerging from the analysis, with a variable distribution according to different scenarios: medical, ethical, and forensic (Textbox 3).
Subgroup Analysis
A cross-analysis of the epidemiological data and acceptability profiles was performed (Table 3).

Secondary Outcome: Characterization of Psychiatrists’ Professional Culture
We asked 3 questions that allowed us to study the place of psychiatrists compared with other medical specialists in terms of scientificity by probing the importance they gave to physical signs (ie, biometric data), technology, and algorithmic thinking. These questions made it possible to distinguish between psychiatrists who:

1. make extensive use of biometric data in their practice,
2. give a prominent place to predictability based on algorithms,
3. view technology not as replacing them but as playing a complementary role.

They also allowed us to highlight the degree of opposition to these dimensions, including affirming the primacy of the human relationship and the refusal or rejection of technology. We were able to place psychiatrists on a continuum running from a medical to psychological subtype and conducted an analysis in which these profiles were crossed with the epidemiological data. This analysis revealed a perfect match between acceptability scores and psychiatrists’ professional culture: the medical profile had the highest acceptability score.

Table 2. Acceptability score.

<table>
<thead>
<tr>
<th>Acceptability domains and technology</th>
<th>Positive score (5-6), %</th>
<th>Intermediate score (3-4), %</th>
<th>Negative score (1-2), %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Utility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA&lt;sup&gt;a&lt;/sup&gt; or CAT&lt;sup&gt;b&lt;/sup&gt;</td>
<td>25.9</td>
<td>53.4</td>
<td>20.7</td>
</tr>
<tr>
<td>Connected wristband</td>
<td>15.3</td>
<td>58.4</td>
<td>26.3</td>
</tr>
<tr>
<td>Machine learning</td>
<td>34.7</td>
<td>51.5</td>
<td>13.75</td>
</tr>
<tr>
<td><strong>Usability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA or CAT</td>
<td>17.65</td>
<td>63.7</td>
<td>18.8</td>
</tr>
<tr>
<td>Connected wristband</td>
<td>17.7</td>
<td>55.9</td>
<td>26.4</td>
</tr>
<tr>
<td>Machine learning</td>
<td>30.45</td>
<td>54.5</td>
<td>15.05</td>
</tr>
<tr>
<td><strong>Reliability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA or CAT</td>
<td>30.05</td>
<td>28.6</td>
<td>9.95</td>
</tr>
<tr>
<td>Connected wristband</td>
<td>10.7</td>
<td>52.3</td>
<td>14.8</td>
</tr>
<tr>
<td>Machine learning</td>
<td>13.75</td>
<td>57.15</td>
<td>9.45</td>
</tr>
<tr>
<td><strong>Risk</strong>&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA or CAT</td>
<td>12.3</td>
<td>45.7</td>
<td>42</td>
</tr>
<tr>
<td>Connected wristband</td>
<td>18.3</td>
<td>46.8</td>
<td>34.9</td>
</tr>
<tr>
<td>Machine learning</td>
<td>29.6</td>
<td>41.1</td>
<td>29.3</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA or CAT</td>
<td>21.47</td>
<td>47.85</td>
<td>22.86</td>
</tr>
<tr>
<td>Connected wristband</td>
<td>15.5</td>
<td>53.35</td>
<td>25.6</td>
</tr>
<tr>
<td>Machine learning</td>
<td>27.12</td>
<td>51.07</td>
<td>16.88</td>
</tr>
</tbody>
</table>

<sup>a</sup>EMA: Ecological Momentary Assessment.
<sup>b</sup>CAT: computerized adaptive testing.
<sup>c</sup>For the risk domain, positive and negative scores were inverted.
Figure 1. Acceptability and score classification of the 3 scenarios. CAT: computerized adaptive testing; EMA: Ecological Momentary Assessment; ML: machine learning; MRI: magnetic resonance imaging.

Textbox 3. Major issues raised by psychiatrists.

1. Medical:
   - Alteration of the therapeutic relationship
   - Generating anxious counter-reactions (wearable device, prediction)
   - False-positive, false-negative

2. Ethical:
   - Impact of preemptive antipsychotic treatment
   - Impact of predicting a potentially incurable disease
   - Stigmatization risk
   - Used to compensate for increasing shortages of health professionals in some areas
   - Associated in people’s minds with the electronic ankle tagging of prisoners
   - Feeling of being controlled

3. Forensic:
   - Delegate a monitoring task to a machine
   - Data privacy
   - Medical liability
The subgroup analysis showed that acceptability was strongly mediated by a psychiatrist’s profile and, more specifically, by sex, theoretical approach, mode of practice, role, and experience. One may wonder why the youngest (residents) have a more negative acceptability profile than the others, while intuitively we could think that they would be more favorable to new technologies given their different usage profile. The qualitative sociological analysis of the data shows that it could be a counter-reaction in relation to the feeling of being dispossessed of a recently hard-won knowledge (i.e., “If a machine is able to do better than me, then why did I spend 4 years in training?”). This effect diminishes with age.

The questions probing the psychiatrists’ professional culture indicated that a certain type of professional culture corresponded to a certain acceptability profile. Our analysis suggests that there were several subgroups, which differed in almost every aspect, with psychiatrists whose professional culture could be defined as medical at one extreme and those who had a more psychodynamic culture at the other extreme. The question of prediction [29] seems more sensitive for certain categories, especially child psychiatrists and forensics practitioners who are the most reluctant in this area, which illustrates the important current debate on neuroprediction [30,31].

The number of usable responses we collected (N=515) allowed us to have a representative sample of a good size and a geographical distribution that did not influence the data (no significant differences between the regions). Compared with other survey-based studies, this was a large sample as most studies on psychiatrists collect between 50 and 150 responses. The qualitative analysis allowed us to identify a typology of French psychiatrists that featured 2 contrasting schools of thought. The use of quantitative data, including ratings on 3- or 6-point scales, scientifically show the validity of this type of data collection. It should also be noted that all the scripts had bibliographic references at the end, allowing responders to learn about these studies.
allowed us to undertake a relatively fine-tuned analysis. Furthermore, the questions were developed from a model specifically adapted to medical technology acceptance and inspired by several valid theoretical models [21,22].

Qualitative analysis allows us to explore the different fields of acceptability, raising several constraints. The main obstacle was the psychiatrists’ fear that they would do more harm than good either by generating anxious counter-reactions (especially with regard to the EMA smartphone app and connected wristband) or by creating a risk of overtreatment by diagnosing problems that did not exist. This evokes the notion of self-fulfilling prophecies developed by Robert K Merton [33], which consists, from a false starting hypothesis, of provoking a behavior that makes this initially false hypothesis become true. An anxious reaction may be one of the consequences, which may increase the risk of recurrence, but we could argue that this could also apply to any form of care (including medication). Much of the feedback focused on the third scenario (which had the highest acceptability profile), with questions about which course of action to pursue if the MRI or the blood tests predicted a transition to psychosis and pointing out the risk of jumping to diagnostic conclusions. Several respondents indicated that they would refuse to introduce a preemptive antipsychotic treatment based on a prediction made in this way. Several commented that there was no point in predicting an incurable disease. In fact, this is an interesting result itself, as it shows that the vast majority of psychiatrists interviewed have no idea what to do if there is a risk of psychotic transition. Recent works highlight the importance of a number of measures to limit this risk (fatty acids, low-doses of atypical antipsychotic, active surveillance, open dialogue, etc.), and clearly, many psychiatrists are not aware of this [34].

Feedback on the second scenario raised the same questions, with the idea that it is not ethically acceptable for a psychiatrist to delegate a monitoring task to a machine. This technology elicited particular ethical and political considerations based on the notion that these connected wristbands are associated in people’s minds with the electronic ankle tagging of prisoners and that they are part of a political agenda used to compensate for shortages of health professionals in some areas. From our point of view, although there is indeed an incentive for the development of telemedicine given the current medical demography in France, when we evaluate the impact of a depressive or psychotic recurrence on the life of a patient, it is clear that technologies that allow better monitoring of their condition should not cause a rejection but rather an interest, especially since these technologies have been developed by doctors (and in a number of cases with patients) and not by politicians. Regarding the first scenario, some respondents argued that this technology could result in the loss of opportunity, especially if it prevented practitioners from diagnosing other problems because the focus was on the system’s diagnosis, and some mentioned the risk of practitioners losing their clinical sensitivity through lack of practice. This type of reasoning applied to other fields of medicine when additional tests or new investigation tools were developed. We do not think that the development of the stethoscope made cardiologists lose their clinical sense, we think that it improved them. These technologies must become complementary psychiatric examinations and complement the currently subjective approach employed by psychiatrists in diagnosis or prediction.

Assumptions and Recommendations

Significant disparities between devices highlight varying degrees of acceptability, both technology-dependent (previously known technology such as MRI seems better accepted, while connected objects are less well-known) and the underlying theoretical presupposition. Thus, the prediction of a psychotic transition remains subject to many fears, whereas the computerized questionnaires are not. Paradoxically, it is the MRI coupled with ML that psychiatrists find most useful. There are 2 issues very clearly raised here: the psychiatrists questioned in this survey are very minimally informed, notably on the scientificity of these devices, although many studies have already been published and the practitioners do not necessarily know what to do with the new data that these machines can obtain, that is, they have very little knowledge about what to do if there is a risk of psychotic transition, they are not familiar with the concepts of precision medicine, and so on. In this context, it seems very important to increase training measures on new technologies, particularly by integrating this into the resident teaching program. For the past 3 years in France, most psychiatric congresses have offered an innovation session or a new technology session; this seems to be an interesting way to promote these new tools but needs to be expanded.

Furthermore, our results assume that new technologies are challenging the psychological subtype of psychiatrist while consolidating the medical subtype. Neurobiological psychiatrists are not challenged by these technologies, which they regard rather as tools that extend or complement their practice. Regardless of the system, psychiatrists with a psychoanalytic orientation are clearly reluctant, and we suggest that it is both the use of scales and the technological dimension that account for their negative stance. This assumption is reinforced by the large number of comments that evoked the technology’s impact on the therapeutic relationship. Special measures should be taken to reassure that specific subtype of psychiatrist by demonstrating that these systems are part of a global care that does not negate the psychological aspect of the disease and that it allows an improvement in patient care.

Many ethical issues were raised by this study, and data security, data storage, privacy, and hacking risk have yet to be resolved. Disease detection or risk prediction, whether in the case of depressive relapse or transition to psychosis, is necessarily stressful for patients and brings the risk of excessive focus and an anxious counter-reaction. To offset these risks, it is essential for psychiatrists to be involved in the development of new technologies, to prevent their loss of control over them. Developers have a major interest in communicating better about the design of these tools and the algorithms they want to be used in the future. In order to complete our research, a comparative study using the same methodology is being developed to better understand the acceptability of these technologies by patients, nurses, and general practitioners.
**Limitations of the Study**

The main limitation could be tautological in that the differences we found between various acceptability profiles may simply have reflected a difference in theoretical approach (neurobiological psychiatrists vs the rest). This suggests that the technologies we studied were based on a theoretical presupposition that was purely neurobiological. While it is true that the third scenario had a clear neurobiological emphasis, the same cannot be said for the other two. In the first scenario, the use of smartphone-based EMA raised the question of scales, but scales presuppose nothing of the etiopathogenesis of the disorder being assessed. Furthermore, CAT does not use scales, as it simulates the psychiatrist’s way of thinking by choosing a specific question from a database made up of more than 500 items. The same applies to the connected wristband as biometric data capture only means that some depression symptoms can be objectified (e.g., psychomotor retardation)—a fact that no psychiatrist can refute. It was, therefore, not the opposition between neurobiological and psychodynamic issues that were assessed in our study but the relationship with technology exhibited by different subtypes of psychiatrists.

**Conclusion**

The type of professional culture (theoretical background and practice) appeared to exert a strong influence on the acceptability of the technologies we studied. Overall acceptability was moderate, and respondents expressed many reservations and raised many ethical and ideological questions. Indeed, a probability derived from the analyzed data cannot systematically be transformed into diagnostic or therapeutic certainty. Some of their concerns are relevant and their skepticism can be understood although many of the issues raised are in fact devoid of reality and reflect a great lack of knowledge of the current state of research on these new technologies. It is surely necessary for psychiatrists to adopt a clear stance with regard to these radical changes that are upsetting traditional practice, and for them to be able to do this, they must be informed, interested, and allowed to contribute to the development of these new technologies [35,36], going as far as joining the “disruptors of health sciences” [37]. The acceptability model we developed, using a complex sociological methodology featuring clinical case scenarios intended to elicit emotional responses, needs to be replicated.

**Acknowledgments**

The authors gratefully thank all participating psychiatrists for their help.

**Authors’ Contributions**

AB and SM designed the study and performed the analytic calculations. AB and FF wrote the manuscript. LO and CG performed the qualitative analysis, and both contributed to the theoretical sociological background. CSP helped supervise the project and contributed to the editing. SM conceived the original idea and was in charge of overall direction and planning. All authors discussed the results and contributed to the final manuscript.

**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**

Screenplay method for the 3 scenarios.

[PDF File (Adobe PDF File), 31KB - mental_v5i4e10240_app1.pdf ]

**Multimedia Appendix 2**

Acceptability model.

[PDF File (Adobe PDF File), 118KB - mental_v5i4e10240_app2.pdf ]

**Multimedia Appendix 3**

Sociodemographic characteristics of respondents and psychiatrists’ professional culture.

[PDF File (Adobe PDF File), 49KB - mental_v5i4e10240_app3.pdf ]

**References**


Abbreviations

CAT: computerized adaptive testing
CDSS: clinical decision support system
EMA: Ecological Momentary Assessment
ML: machine learning
MRI: magnetic resonance imaging

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Text Mining Mental Health Reports for Issues Impacting Today’s College Students: Qualitative Study

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Abstract

Background: A growing number of college students are experiencing personal circumstances or encountering situations that feel overwhelming and negatively affect their academic studies and other aspects of life on campus. To meet this growing demand for counseling services, US colleges and universities are offering a growing variety of mental health services that provide support and services to students in distress.

Objective: In this study, we explore mental health issues impacting college students using a corpus of news articles, foundation reports, and media stories. Mental health concerns within this population have been on the rise. Uncovering the most salient themes articulated in current news and literature reports can better enable higher education institutions to provide health services to its students.

Methods: We used SAS Text Miner to analyze 165 references that were published from 2010 to 2015 and focused on mental health among college students. Key clusters were identified to reveal the themes that were most significant to the topic.

Results: The final cluster analysis yielded six themes in students’ mental health experiences in higher education (ie, age, race, crime, student services, aftermath, victim). Two themes, increasing demand for student services provided by campus counseling centers (113/165, 68.5%) and the increased mental health risks faced by racial and ethnic minorities (30/165, 18.2%), dominated the discourse.

Conclusions: Higher education institutions are actively engaged in extending mental health services and offering targeted outreach to students of color. Cluster analysis identified that institutions are devoting more and innovative resources in response to the growing number students who experience mental health concerns. However, there is a need to focus on proactive approaches to mitigate the causes of mental health and the aftermath of a negative experience, particularly violence and sexual assault. Such strategies can potentially influence how students navigate their health information seeking and how information and communication technologies, including mobile apps, can partially address the needs of college students.

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KEYWORDS
text mining; mental health; college students; information and communication technologies
Introduction

While attending college, students may experience personal circumstances or encounter situations that feel overwhelming and negatively affect their academic studies and other aspects of life on campus. To meet this growing demand for counseling services, US colleges and universities are offering a growing variety of mental health services that provide advice, counseling, and services to students in distress. For example, in 2015, the Center for Collegiate Mental Health delivered their annual report of data contributed by member institutions. There were 100,736 unique college students seeking mental health treatment, 2770 clinicians, and 770,000 appointments across 139 college and university counseling centers [1]. The following year, the center reported that there were 150,483 unique college students seeking mental health treatment (a 50% increase from the previous year) from 3419 clinicians. This resulted in over 1 million appointments across the 139 college campuses [2]. Half the students seeking counseling were already in some form of treatment, and one-third were prescribed medication before their arrival to campus. In 2017, the center reported that there were 161,014 unique students seeking treatment, 3592 clinicians, and 1,255,052 appointments across 147 institutions. When compared with the data presented in the 2015 report, this represented a 60% increase in unique students seeking help and a 62.9% increase in appointments requested, whereas only a 29.6% increase in available clinicians.

The National Alliance on Mental Illness (NAMI) 2012 report entitled College Students Speak: A Survey Report on Mental Health is based on a national survey of 765 college students diagnosed with a mental health condition [3]. The sample was predominantly female (627/765, 82%), with fewer male (122/765, 16%) and transsexual (15/765, 2%) respondents. In all, 82% (627/765) of the respondents were white. African Americans (46/765) and multiracial students (46/765) equally represented 6% of the sample, whereas Asian Americans (38/765) and Hispanics/Latinos (38/765) accounted for equal representation at 5% each. Another 3% (23/765) of the sample was American Indian, and 1% (8/765) were Pacific Islanders. Students noted various concerns regarding mental health on college campuses—namely, dropping out of school, lack of disclosure (and the associated stigma), necessity of awareness activities, deficiencies in online information-seeking skills, appropriate avenues for securing academic accommodations, and clinical and crisis support. Despite these needs for mental health resources and counseling services, health information-and help-seeking practices vary widely among young adults with regard to race/ethnicity, content type, content developer, and culture along with social and traditional media platforms [4-8]. According to Substance Abuse and Mental Health Services Administration (SAMHSA), persons between the ages of 16 and 25 years with a mental health condition are less likely than other age groups to seek and receive health information and assistance [9].

A *New York Times* article reported how higher education institutions are addressing depression and mental illness among college students and implementing outreach efforts to increase both awareness and availability of health services [10]. Regardless of age, mental health has significant economic and social implications that impact daily living. Salient to college students, mental health issues are associated with lower grade point averages, higher probability of dropout rates, and increased stigma [3,8,10,11].

In October 2016, The Chronicle of Higher Education released its compilation, *Mental Health Issues in Students* [12]. This report is a collection of nine articles discussing the growing trend of increased mental health stressors experienced by college students and details initiatives that several colleges are using to address these issues. The report stated an alarming statistic: “Nearly one-third of university counseling centers must put students seeking help on waiting lists” (p 3). Moreover, limited financial resources among some students as well as constrained, and even shrinking, institutional budgets continue to point to the need to uncover the major themes associated with the mental health discourse.

While a growing number of US citizens are using online sources for health information seeking [13], college students use the internet more often than the wider population. There is widespread use of cellular phones and other mobile devices, computers, Web-based technologies, and social media for accessing and disseminating information. However, there is a substantial need for mobile health services for youths and young adults [14], but some evidence-based and empirically validated research is taking place. For example, researchers developed a moderated online social therapy intervention (MOST+) to deliver anonymous evidenced-based mental health care in real time. The tool provides Web chat counseling with a clinician, interactive user-directed online therapy, expert and peer moderation, and private and secure peer-to-peer social networking [14]. Others examined mental health support for African American college students (who are less likely to seek mental health support from a university institutional service) and reported that microblogging (eg, Tumblr) can be a powerful tool for expressive and instrumental social support. In addition, user-centered and participatory design of these information and communication technology (ICT) platforms can offer health care professionals, educators, and providers insights into how to better engage target populations, improve medical decision making, and increase efficacy in the technology design process [15,16].

Given the increased attention to mental health among college students, the purpose of our study is to uncover hidden patterns and themes in news articles, foundation reports, and media stories on our topic to identify areas that have garnered attention as well as areas that have been underexplored. To better understand these dynamics, we collected and analyzed via text mining methods news articles, foundation reports, and media stories related to mental health and college students. Our study applies a text mining approach discussed by Ananiadou and colleagues [17] for accelerating the process of systematic analysis for the domain of collegiate mental health. We contend that using an inductive approach to uncovering these factors can provide insights to academic institutions and mental health service providers as they seek to improve awareness and create culturally relevant services and activities as well as cultivate climates that are supportive and inclusive of and responsive to...
diverse student populations. These institutional efforts are particularly critical given recent college campus debates around social and political activism, the microaggressions that ensue, sinking budgets, and increased legal and ethical conflicts confronting higher education.

**Methods**

**Data Source**

Text mining can be defined as the computational discovery of new, previously unknown information by automatically extracting information from different written sources [18]. Text mining combines computational and statistical methods to extract previously unknown information from heterogeneous and unstructured written documents. Text mining draws from a number of fields, including data mining, machine learning, natural language processing, computational linguistics, statistics, and information retrieval [19].

The text mining process starts by curating a large collection of documents, which can come from disjointed and disparate literature. The documents can include unstructured and semistructured data, such as email and full-text documents. The curation process can be done manually by researchers, but this laborious task requires considerable expertise [20]. When automated, text mining can greatly reduce curation time and produce a larger corpus of news articles, foundation reports, and media stories. Although the overall accuracy of the corpus may be lower [20], analyzing data from heterogeneous sources is a common problem in data mining applications. However, work from other fields, such as biology, biomedicine, and oncology, has found utility in analyzing heterogeneous data sources in tandem [21].

After the curation process, whether a hands-on literature search or computationally produced, the text mining tool will retrieve a particular document and preprocess it by checking format and character sets. Finally, in the text analysis phase, techniques such as clustering, categorization, concept linkage, topic tracking, and information visualization are used to discover information embedded in the documents [19]. Text analysis facilitates the extraction of information from the increasing body of text online in scholarly, open access publications.

Researchers [22] discussed the role of text mining in health care contexts, offering that, “Text mining is of interest because a large volume of ‘unstructured’ data (eg, narratives, event descriptions) is submitted as part of adverse event reporting” (p 429).

Applying text mining methods to mental health narratives, we identified articles including both college students and mental health published from 2010 to 2015 in *The Chronicle of Higher Education*, *Insider Higher Education*, *Diverse, Ethnic Newswatch*, and the *Journal of Blacks in Higher Education*. In total, we collected 165 documents using combinations of the keywords, “college students,” “mental health,” and “mental services.” This collection was comprised of two parts: (1) identifying potential sources and keywords and (2) searching sources using the keywords and saving articles that met a set of criteria and formed our corpus of heterogeneous data sources [21]. Duplicate articles were removed from the corpus to avoid overcounting any member of the corpus or biasing the data.

We aggregated 165 articles that we analyzed in SAS Enterprise Miner with Text Miner 12.1. SAS Text Miner produces four outputs: (1) a text parsing analysis that pulls words from the documents and determines its part of speech and importance, (2) a text filtering analysis that determines which words to discard or keep for further analysis, (3) a text topic analysis that groups articles into similar topics defined by words, and (4) a text cluster analysis that places articles into clusters based on common words that are shared between articles. These steps in our quantitative analyses are automated using SAS Text Mining.

In a secondary portion of our analyses, we adopted a qualitative approach using quotes from the corpus to engage in a sensemaking process (acquisition, reflection, and action) to better understand context and meaning [23].

**Results**

**Quantitative Results**

**Parsing and Filtering**

The first two steps in the text mining process are parsing (Table 1) and filtering (Figures 1 and 2). These two steps enabled us to identify the initial role (eg, noun, verb, adjective) and attribute (eg, alpha, mixed, abbreviation, entity) of each term in the corpus, and remove insignificant terms (eg, the, a, an, be, do) from the parse. In the parsing analysis, the attributes refer to the importance of the word. Abbreviations and entities are unimportant, mixed may be important, and alpha is important.

**Text Topic**

The text topic analysis identified a total of 25 topics; however, three were concerned with sharing the articles themselves or with other extraneous data. Therefore, there were only 22 salient topics identified by the text topic analysis. In Table 2, we present all 25 topics (the three removed topics are ID numbers 23, 24, and 25). Table 2 also contains the number of terms present in the dataset and the number of documents represented in each topic.

Table 2 illustrates themes regarding college-lived experiences related to current events of civil unrest on campuses. For instance, there are substantial terms and documents containing words such as “Virginia, racism, Berkeley, tweet, college services.” These are undoubtedly stressful campus activities related to recent social and cultural events (eg, University of Virginia, Berkeley, violence, protests, counterprotests, racism, racial), use of social media technologies (eg, Facebook, Twitter), college matriculation (eg, graduate student, institution), and mental health concerns (eg, well-being, depression, sexual assault, and accommodation).
Table 1. Text parsing results: roles and attributes by frequency.

<table>
<thead>
<tr>
<th>Term</th>
<th>Role</th>
<th>Attribute</th>
<th>Frequency</th>
<th>Documents (N)</th>
<th>Keep</th>
<th>Status</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Be</td>
<td>Verb</td>
<td>Alpha</td>
<td>11,484</td>
<td>136</td>
<td>No</td>
<td>Drop</td>
<td>0.000</td>
</tr>
<tr>
<td>A</td>
<td>Noun</td>
<td>Alpha</td>
<td>5672</td>
<td>136</td>
<td>No</td>
<td>Drop</td>
<td>0.000</td>
</tr>
<tr>
<td>Student</td>
<td>Noun</td>
<td>Alpha</td>
<td>5065</td>
<td>136</td>
<td>Yes</td>
<td>Keep</td>
<td>0.183</td>
</tr>
<tr>
<td>Other</td>
<td>Adjective</td>
<td>Alpha</td>
<td>1139</td>
<td>131</td>
<td>No</td>
<td>Drop</td>
<td>0.000</td>
</tr>
<tr>
<td>University</td>
<td>Proposition</td>
<td>Alpha</td>
<td>1483</td>
<td>131</td>
<td>Yes</td>
<td>Keep</td>
<td>0.180</td>
</tr>
<tr>
<td>Campus</td>
<td>Noun</td>
<td>Alpha</td>
<td>1454</td>
<td>119</td>
<td>Yes</td>
<td>Keep</td>
<td>0.179</td>
</tr>
</tbody>
</table>

Figure 1. Text filtering results: attributes by frequency.
Figure 2. Parts of speech from text filtering: roles by frequency.
### Table 2. Text topic analysis results.

<table>
<thead>
<tr>
<th>Topic ID</th>
<th>Topic</th>
<th>Terms (n)</th>
<th>Documents (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>commission, reform, virginia, commitment, involuntary</td>
<td>691</td>
<td>4165</td>
</tr>
<tr>
<td>2</td>
<td>stalk, violence, crime, domestic, domestic violence</td>
<td>353</td>
<td>12,165</td>
</tr>
<tr>
<td>3</td>
<td>block, open, abstract, newspaper article, scholunivauthors</td>
<td>519</td>
<td>8165</td>
</tr>
<tr>
<td>4</td>
<td>foundation, poll, kids, Harris, en</td>
<td>537</td>
<td>6165</td>
</tr>
<tr>
<td>5</td>
<td>Penn, ic, Berkeley, stu, Tucker</td>
<td>1013</td>
<td>9165</td>
</tr>
<tr>
<td>6</td>
<td>receipt, health, black, care, health</td>
<td>545</td>
<td>16,165</td>
</tr>
<tr>
<td>7</td>
<td>grad link, graduate, graduate student, Facebook</td>
<td>755</td>
<td>19,165</td>
</tr>
<tr>
<td>8</td>
<td>food, insecurity, food homeless, hungry</td>
<td>491</td>
<td>9165</td>
</tr>
<tr>
<td>9</td>
<td>Montclair, minority, program outreach, home</td>
<td>411</td>
<td>7165</td>
</tr>
<tr>
<td>10</td>
<td>duty, UCLA, foreseeable, court, protect</td>
<td>521</td>
<td>9165</td>
</tr>
<tr>
<td>11</td>
<td>counsel, counsel center, center, link, institution</td>
<td>566</td>
<td>24,165</td>
</tr>
<tr>
<td>12</td>
<td>cortisol, depressive, disorder, warning, alcohol</td>
<td>796</td>
<td>11,165</td>
</tr>
<tr>
<td>13</td>
<td>fund, Steve, Evan, line, rose</td>
<td>560</td>
<td>10,165</td>
</tr>
<tr>
<td>14</td>
<td>fax, phone, yes, north, institutions</td>
<td>771</td>
<td>4165</td>
</tr>
<tr>
<td>15</td>
<td>racism, black student, black, racial, color</td>
<td>678</td>
<td>18,165</td>
</tr>
<tr>
<td>16</td>
<td>institution, service, student, program</td>
<td>765</td>
<td>16,165</td>
</tr>
<tr>
<td>17</td>
<td>gun, conceal, law, weapon, ban</td>
<td>543</td>
<td>12,165</td>
</tr>
<tr>
<td>18</td>
<td>mental health, mental health condition, accommodation</td>
<td>586</td>
<td>18,165</td>
</tr>
<tr>
<td>19</td>
<td>harassment, academy, sexual harassment, sexual, assault</td>
<td>586</td>
<td>11,165</td>
</tr>
<tr>
<td>20</td>
<td>percent, student, sexual, report, college</td>
<td>874</td>
<td>11,165</td>
</tr>
<tr>
<td>21</td>
<td>brain, DSM, illness, mental, NIMH</td>
<td>726</td>
<td>14,165</td>
</tr>
<tr>
<td>22</td>
<td>institution, mental, college, health, athlete</td>
<td>708</td>
<td>17,165</td>
</tr>
<tr>
<td>23</td>
<td>well-being, scale, sample, item</td>
<td>698</td>
<td>10,165</td>
</tr>
<tr>
<td>24</td>
<td>link, Facebook, Twitter, share, APA</td>
<td>772</td>
<td>14,165</td>
</tr>
<tr>
<td>25</td>
<td>user, tweet, PTSD, et al, de</td>
<td>827</td>
<td>9165</td>
</tr>
</tbody>
</table>

### Text Cluster

The text cluster analysis identified six distinct clusters of articles in the dataset. In Table 3, we present each of the clusters, a brief description of the cluster based on the keywords that SAS produced, and document frequency and percentage of sample statistics. Although there were six identified clusters, these clusters could be further grouped into two broad themes: (1) factors that play a role in the occurrence of mental health experiences in higher education (clusters 1, 2, 3, and 6) and (2) what happens after a mental health experience (clusters 4 and 5). Table 3 depicts these clusters and shows an emphasis on mental health services followed by race as the major themes in the data.

### Qualitative Results

#### Factors in Mental Health Experience

As shown in Table 3, the cluster analysis identified six main foci when discussing themes in mental health experience in higher education. We sought to better understand the clusters via sensemaking from the set of documents linked to the SAS Text Miner results. The quotes provided subsequently are derived from the documents that appeared in the associated clusters rather than from our mere selection of data/quotes from the corpus.

Cluster 1 focused on the ways that age plays a role in mental health experiences in the university environment. The literature in this cluster is primarily focused on younger students and the challenges they experience in the transition from high school to college and during their first year of higher education. Students reported that college preparation focused on academic preparation, often leaving emotional preparation by the wayside. Yet, emotional preparedness was correlated to academic success (“Students who feel...”). The lack of emotional preparation often led to an increase in stress and mental health experiences [24] that colleges are not prepared to handle as discussed in The American Freshman: National Norms [25].
Freshmen often relied on friends, family members, or substance abuse to cope with the stress of the transition from high school to college [25]. Prior research has demonstrated that substance abuse is a contributing factor to further negative mental health experiences [3,24,26], and students without familial support networks might be disadvantaged by the lack of institutional resources, leading to further negative outcomes.

Extant work demonstrated a connection between race and mental health experiences (cluster 2)—namely, minority groups are more likely to have difficulty with the high school to college transition and with the higher education environments as a whole. Black students were shown to feel less emotionally prepared than their white counterparts [7] leading to academic, social, and cultural struggles characterized by minimal diversity and exclusivity [27].

Moreover, although black students are less likely to engage in alcohol consumption, research found that black students were less likely to seek help and act on mental health support or they received less effective support than majority students [24,28], particularly at predominantly white institutions [29]. As Terri Wright, the executive director of Steve Fund, which assists colleges in improving their mental health services for students of color, informed National Public Radio [30], “Stigma is a huge issue in the lives of students of color and what it means to seek services and admit that I need help, when in fact I feel like, as a young person of color, that I’m already being judged differently.”

Cluster 4 (services) emerged as the largest topic found in the corpus. Per the NAMI College Students Speak report [3], appropriate and multiprong delivery of mental health services is essential on today’s university campuses. Health information seeking on the part of students and roles of delivery by counseling centers, in part, influences how services are accessed and provided. The Association for University and College Counseling Center Directors recognizes the revolving needs for mental health services and the broad experiences that students report. Textbox 1 provides the positive and negative experiences associated with on-campus health services per the student participants in the NAMI report [3]. A careful examination of Textbox 1 does not include topics of diversity of services, counselors themselves, location (rural versus urban), and cultural differences, and as researchers [31] concluded in an analysis of the 2007 Virginia Tech tragedy, the need to “connect the dots” among campus stakeholders and faculty, campus police, and counseling center staff.

Higher education institutions also acknowledge that they are not prepared to deal with students’ needs but are attempting to rectify this in various ways. Community colleges, for example, are turning to local partners to outsource the need for mental health services. Some universities are building partnerships with local care providers to bridge the gaps in their support networks. Others are utilizing teletherapy and mobile phone apps to target students in need, databases to track students’ health needs, and self-assessment tools that enable institutions to identify areas for improvement in mental health care services. By 2014, 55 colleges had partnered with the Jed Foundation and Clinton Foundation for a review of their mental health services focused on substance abuse and suicide prevention [32].

From these clusters, it is clear that merely being in college has an impact on the mental health of students, and that there are disparities in the level of these experiences and how universities deliver care to those affected. In addition to these demographic factors (eg, age, race) and the looming needs for additional services, there were external factors that the analysis identified as contributing to mental health experience in the university setting. These were violence and sexual assault (cluster 6) and crime (cluster 3) experiences that students experience while in college.

Although clusters 1 to 4 can be seen as validating what the field has previously reported, clusters 5 and 6 were unanticipated. The findings are absent of any discussion related to institutional staff. Although staff are absent from our findings, they are critical to the delivery and assessment of mental health services on university campuses. Staff are continually in need of mental health training, and this is in light of shrinking institutional budgets [12]. In addition to and despite privacy concerns, more counseling centers are implementing technology applications to assist with increase caseloads and seeking to find effective ways to provide mental health services [12]. Lastly, the increased need for student mental health services is far outpacing the rate of staff and expertise needed to address these issues.

The literature dealing with violence and sexual assault focused primarily on new legal requirements for universities and colleges to compile and report annual statistics about it in the higher education environment. Other articles discussed how to handle these incidents in compliance with federal Title IX regulations. There was no discussion of how to prevent these incidents from occurring or the effects they may have on victims, which is interesting given that research has demonstrated a link between sexual assault and negative mental health experiences [33].

### Table 3. Cluster analysis results.

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Name</th>
<th>Description</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Age</td>
<td>Age factors in mental health experiences</td>
<td>7 (4)</td>
</tr>
<tr>
<td>2</td>
<td>Race</td>
<td>Racial factors in mental health experiences</td>
<td>30 (18)</td>
</tr>
<tr>
<td>3</td>
<td>Crime</td>
<td>Factors related to crime that lead to mental health experiences</td>
<td>3 (2)</td>
</tr>
<tr>
<td>4</td>
<td>Services</td>
<td>What institutions are doing to assist with mental health experiences</td>
<td>113 (68)</td>
</tr>
<tr>
<td>5</td>
<td>Aftermath</td>
<td>What happens after a mental health experience</td>
<td>4 (2)</td>
</tr>
<tr>
<td>6</td>
<td>Violence and sexual assault</td>
<td>Factors that can lead to mental health experiences</td>
<td>8 (5)</td>
</tr>
</tbody>
</table>

What literature did touch on was that universities do not have a legal obligation to protect adult students from third parties. In a California Court of Appeals ruling, it ruled that the University of California system could not be held liable for the attack of a student by a mentally ill student. The dichotomy between these two clusters illustrates a disconnect that exists between theory and practice. Although institutions of higher learning are required to report statistics of violence and sexual assault, they are not required to prevent individuals who might be classified as at-risk from accessing campuses. This points to a clear need to identify gaps in community services, including crisis intervention and case management services [31].

The clusters in this theme demonstrated that higher education is woefully underprepared to assist those who undergo negative mental health experiences. High schools and colleges prepare their students for academic—not emotional—success, leaving young and minority students in danger of suffering negative health outcomes. They also emphasize reporting the prevalence of attacks that might be caused by or cause mental health outcomes but are not required to act on these instances. With the absence of laws and regulations requiring action, it is left to the individual institution to act in a way to benefit their students and minimize risk to the higher education community at their campuses. This lack of standardization leads to an uneven approach to mental health that varies by university; some universities are proactive about their students’ well-being, whereas others simply fulfill the legal requirements. This leads to the aftermath theme (cluster 5) observed in our cluster analysis.

The high number of topics identified stands in stark contrast to the six clusters identified in the literature. This highlights that the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. 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It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. It is limiting to distill the mental health conversation into six clusters. Instead, the discussion of mental health in higher education is a nuanced conversation—each case is different. 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Discussion

Principal Findings

The final cluster analysis yielded six themes in students’ mental health experiences in higher education (ie, age, race, crime, student services, aftermath, victim). These clusters were grouped into two broad categories: (1) factors that play a role in the occurrence of mental health experiences in higher education (age, race, crime, victim) and (2) factors describing what happens after a mental health experience (student services, aftermath). Our data analyses show student services and race are the primary themes in the literature, whereas violence and sexual assault are lesser-covered topics.

Recommendations for Colleges and Universities

The text topic node identified a variety of stressors and traumatizing experiences, such as sexual assault, food scarcity, violence, and racism, that lead students to seek rapid-access mental health support and services. The Center for Collegiate Mental Health [2] reports that participating counseling centers, on average, are providing 28% more “rapid-access” service hours per client but 7.6% fewer “routine” service hours per client over the period from 2010 through 2016. This may suggest a void in the provision of follow-up routine care for students who receive rapid care, university funding models that do not increase treatment capacity, as well as clients terminating their routine care (eg, no shows, appointment cancelations, end of the academic term) before their treatment goals are achieved. We call on higher education institutions to focus on more proactive approaches to mitigate the stressors that can cause mental health episodes among students. A recommendation for moving forward would be to focus on helping students to develop coping skills before they experience a traumatizing event, instead of primarily focusing on the postexperience treatment. In the long run, this proactive shift could enable institutions to reduce demand for rapid-access services, alleviate their overworked mental health practitioners, and lead to a better higher education experience for students.
In addition, unanswered issues remain, namely (1) what happens after a negative mental health occurrence on campus? and (2) what are higher education institutions doing to assist their communities in coping with these experiences? There were several large themes that we observed comprising these clusters. These included subsets of literature that discussed faculty’s role, stigma associated with mental health services, how institutions attempt to help students through tracking mechanisms, technology apps, and counseling centers, and how they are being funded and utilized [12]. Legal and ethical conflicts, however, continue to pose challenges to how higher education does and will approach these unresolved issues.

Literature examining faculty’s role in helping students who experience mental health events was split between two views: (1) faculty should be active in assisting students and (2) faculty involvement should be limited due to a lack of training which might do more harm than good to students in an intervention. This split illustrates the institution-by-institution approach to mental health that the higher education system takes; hence, leaving some universities unprepared or underprepared to deal with their students’ mental health needs. Although some institutions actively fight for better mental health care and individual faculty members weigh the pros and cons of disclosing their own personal mental health issues [34], some institutions instead seek to limit students’ abilities to opt out unless they have a valid medical reason [30]. However, student governments are increasingly advocating for mental health awareness [35] while groups, such as Active Minds [36], are pushing for national reform of the university mental health care services [37]. University administrators, alumni, students, and other stakeholders are recognizing the dramatic increase in utilization of counseling services and are establishing endowments to support mental health services [38]. Students are also addressing the need for better safety nets for young college students and for students who develop serious mental health issues while in college. When a student body comes together, it might frequently expedite a university’s response to an issue [39-41]. Lastly, the role of staff is another vital factor that emerged from our work.

**Recommendations for ICT Interventions**

Our study also offers suggestions for mobile interventions. Prior research has found that individuals with serious mental illnesses own mobile devices at lower rates than the general population. However, despite mobile device ownership or nonownership, people desire mobile services to help cope with their illness [42,43]. In particular, African Americans and Hispanics are using mobile phones to access health information via the internet more frequently than those who classify themselves as white [44]. The higher prevalence of mobile phone use among blacks, along with our finding that race is the dominant theme in discourses about mental health issues on US college campuses, provides unique opportunities for those in public health research and health education to reach these historically underserved populations using mobile health interventions [44].

Our study highlights salient mental health issues for researchers seeking to develop impactful mobile interventions. Additional evidence-based research is needed in this domain. Prior research has identified five existing apps that targeted depression, anxiety, and substance abuse, but noted that these were the only apps that relied on evidence-based research [45]. Researchers went on to note that a majority of commercially available apps do not have scientific evidence backing their efficacy, leaving a gap for research to address with regards to creating better mental health apps.

Although ICT such as teletherapy and mobile phone apps has not yet been the magic bullet to cure health conditions and chronic diseases, it is a promising tool in the field of health promotion and literacy particularly for college-aged technology users. Researchers are reporting health gains in their assessments of mental health mobile apps [46]. For example, Miyamoto and colleagues [45] conducted focus groups with 30 adults and found that mobile health apps can be used to track health data and encourage sustained behavior changes to support health goals. Andersen and colleagues [44] reviewed the scholarly literature and found that mobile apps have the ability to increase prevention and health education in health-disparate communities. Thom et al [47] studied depression, anxiety, and internet use among US teens and found that internet use may mitigate anxiety in adolescents with higher levels of baseline anxiety.

Researchers [48-50] note that mobile technology use supports mental well-being both as an information resource and as a tool for providing interventions and treatments. Mobile apps are used and developed for symptom assessment, psychoeducation, resource location, and tracking of treatment progress. Mobile apps can enable patients, caregivers, and clinicians to assess treatment, mood, stress, anxiety, and location via global positioning system (GPS) tracking. Evidence-based treatments, such as digital diaries, text messaging, video and audio captures, and virtual training for therapeutic skills, are capabilities supported by current mobile apps. Moreover, the mental health mobile apps and digital storytelling can be powerful tools to encourage college students and others to discuss their experiences, provide emotional support, and allow young people mechanisms to explore and artfully share their own stories and thoughts [51].

According to a 2013 survey by the Association for University and College Counseling Center Directors, nearly 6% of the 380 colleges participating in the study now use teletherapy. Although that number might not seem high, it is up from less than 0.5% in 2012. However, legal issues abound for therapists, including college counselors. Current laws require therapists to be licensed in the state in which they practice, so they may not be able to provide mental health services to students in different states. That is especially relevant to students who may be in a different state or enrolled in distance education [37].

**Limitations**

Although this work evaluates mental health among college students via text mining mainstream reports, articles, and academic sources, it is not without limitations. Text analysis is a descriptive method which informs us what but not why—hence underlying patterns are not revealed. Secondly, the analysis is limited by the content used in the corpus. More experimentation via other text mining terms and other databases could provide additional insights to our findings. We use a text mining
approach to analyze the reports and writings, but this study does not focus specifically on how technology can be used to address the issues of mental health among college students. Third, the professoriate is challenged to uncover and address the needs of its students holistically. This, in part, requires attention to who is impacted and unearthing their stories. As reported in The Chronicle of Higher Education by Quintana [52], MIT professor of computer science, Daniel Jackson, calls mental health’s aftermath at the institution the “giant iceberg of unhappiness.”

Our understanding of students’ concerns regarding academic performance, course loads, nontraditional work schedules, food insecurity, family responsibilities, and their mental well-being will paint a holistic picture. The corpus of news articles, foundation reports, and media stories used for this research manuscript do not address the mental health issues using an intersectional lens of clinical technology or student scenarios (context).

Conflicts of Interest
None declared.

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Abbreviations

ICT: information and communication technology
NAMI: National Alliance on Mental Illness
SAMHSA: Substance Abuse and Mental Health Services Administration

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Real-World Technology Use Among People With Mental Illnesses: Qualitative Study

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Abstract

Background: There is growing interest in using technology-based tools to support mental health recovery. Yet, despite evidence suggesting widespread access to technology among people with mental illnesses, interest in using technology to support mental health, and effectiveness of technology-based tools developed by researchers, such tools have not been widely adopted within mental health settings. Little is currently known about how mental health consumers are using technology to address mental health needs in real-world settings outside of controlled research studies.

Objective: This qualitative study examined current practices and orientations toward technology among consumers in 3 mental health settings in the United States.

Methods: Ethnographic observations and semistructured interviews were conducted. Observations focused on if and how technology was salient within the setting and documented relevant behaviors, interactions, and dialogue in fieldnotes. Ethnographic data informed the development of a semistructured interview that inquired into technology use and interest among consumers (n=15) in a community mental health setting. Fieldnotes and interview transcripts were reviewed and coded by multiple researchers. Key concepts and patterns identified were refined by the research team to develop the main findings.

Results: Ownership of technology, although common, was not ubiquitous and was varied across the sites. Participants had varying levels of awareness regarding the key capabilities of modern technologies. Participants used technology for many purposes, but there was limited evidence of technology use to support mental health. Technology-based tools specific to mental health were not routinely used, although some participants found widely available mobile apps to be helpful in recovery.

Conclusions: Qualitative findings suggest that many, but not all, clients will be interested in using technology to support mental health needs. The variability in type and quality of technology owned by participants suggests the need to design for a range of functionality in the development of mental health tools. Findings also suggest thinking broadly about using existing platforms and widely available tools to support consumers in mental health recovery.

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KEYWORDS
qualitative research; technology; mental health; mobile phone

Introduction

People with mental illnesses in the United States and globally have increasing access to mobile technology [1-4], although some are still unable to avail themselves of these resources [5]. As access grows, so does interest in using technology tools to deliver mental health services; thus, mental health apps are quickly becoming available. These apps are designed for many
purposes, from providing information, to self-management, to evidence-based therapies such as cognitive behavioral therapy [6-9]. A few specific tools developed for people with serious mental illnesses (SMIs; ie, schizophrenia, bipolar disorder, and depression) include apps for symptom assessment [10], self-management of psychiatric symptoms [11], remote sensing of behaviors to predict relapse [12], improving medication management through shared decision making [13], and work support [14]. Mental health apps have shown promise in addressing several barriers that exist with traditional mental health services. They offer a platform for increasing access to evidence-based interventions and providing services to underserved populations. [5-8,15,16].

Accumulating evidence on technology use by people with SMI has found that those with SMI use technology in comparable ways to the general population for communication, social connection, and access to information, including health-related information [17-20]. Our research builds on these survey-based findings by applying ethnographic and qualitative methods to elucidate details and nuances of technology use among people with mental illnesses that may be difficult to discern via other modes of inquiry. For example, aggregate numbers tell us that people with mental illness have widespread access to technology, but what is it like for them, and do they experience challenges not yet identified in the literature? What is the range of technologies being used to address mental health needs? How do orientations to, and use of, technologies vary across mental health service delivery settings? With such questions as points of departure, in this qualitative study, we examined current practices and orientations toward technology among service users within 3 mental health settings.

Methods

The study was conducted in 3 mental health settings in the Northeastern United States. Sites were selected to represent a range of service settings (ie, private and community, outpatient and residential) and people from diverse socioeconomic backgrounds and ages. The study sites included a private dual diagnosis clinic for young adults with early psychosis and co-occurring addiction; a private residential treatment program serving a predominantly older adult population with long-term mental disorders; and an academic-affiliated community mental health center serving a broad population with mental illnesses. The location of the mental health centers included urban and rural settings.

Service users at the private clinic are typically young adults of higher socioeconomic status, who are single and employed or pursuing postsecondary education. Service users at the private residential treatment program are typically middle-to-older-aged adults of middle to high socioeconomic status, who are single, unemployed, and long-term recipients of residential or inpatient mental health care. Service users at the community mental health center are typically unemployed, single, and of low socioeconomic status, who vary in age from young to older adults. The two private centers each served 40-50 people at any given time; the community mental health center served approximately 1500 adults with mental illness.

This multimethod study combined ethnographic observation and qualitative interviewing to inquire into use of, and orientations toward, technology. We defined technology broadly to include personal devices such as mobile phones (smartphones and nonsmartphones), computers, and tablets as well as technology made available through mental health organizations such as videoconferencing and public computers. These are examples of technology and not an exhaustive list; we were attuned to a wide range of technology use among participants—from hard-line telephones and cassette players to the latest tablets and mobile phones. The scope of technologies observed was intentionally broad to provide a more complete understanding of the range of technologies currently used by people with mental illnesses.

Data were collected over 1 year, during which we engaged with each site for 3-4 months. The study was approved by our university’s research ethics committee, and participants gave informed consent to participate. Participant observation was the primary method employed in earlier stages of the research in the 2 private treatment settings. Ethnographic methods are particularly well suited for initial explorations into a new area of research. In each of the private centers, most current service users and staff were included in the study, that is, we did not sample at the individual level. Instead, purposive sampling occurred at the site level to a range of settings serving people with mental illnesses who could provide insight into technology use. In these settings, the research team built awareness of the study through Information Sessions in which the research team introduced themselves and provided an overview of the study to service users and staff. Participants could “opt out” of participating, meaning that the research team would not interact directly with them or take notes about their behavior or interactions. No person opted out in either setting.

Ethnographic visits were half-day to daylong visits at each site occurring weekly for 3-4 months. During this time, the ethnographic researcher interacted with key stakeholders, including service users, frontline staff, supervisors, and leadership within the organization, and became familiar with the organizational environment and culture. The potential influence of the researcher on behaviors in the organization was diminished by becoming a regular presence in the setting. During ethnographic visits, the researcher was positioned as both a participant and observer, immersing herself in the setting and sharing the daily lives of participants while also remaining attentive to the aims of the research [21,22]. The researcher observed and interacted with service users and staff at multiple venues, including clinical offices, community-based visits, events and activities, and common areas within the clinic and residential settings. This yielded many opportunities to observe if and how various forms of technology were salient. In addition, informal interviews were conducted with service users and staff that provided a basis for open-ended inquiry about use of, and interest in, technology. Detailed fieldnotes were written following ethnographic visits to systematically document behaviors and interactions in the setting, with particular attention to use of technology and dialogue regarding technology.

As the research progressed, we used the exploratory observations and informal interviews from the ethnography to inform and
design more focused research interactions. In the community mental health center, three of the authors (ECS, VAN, SCA) conducted brief, semistructured interviews with mental health service users. Interviews were conducted until the team felt confident that similar ideas and provisional patterns were recurrent in the dataset, at which point no additional participants were enrolled. The final sample for the interviews included 15 participants. Interviews were organized around the following domains: use of technology, interest in technology, technology in mental health services, and technology and mental health recovery. Interviews were conducted in a private office at the community mental health center, were 15-20 minutes in duration, and were audiorecorded and transcribed.

We reviewed and coded fieldnotes and interview transcripts. Qualitative coding is a process of tagging portions of text with a meaningful label [23]. Coding is the “pivotal link” between data collection and interpreting the meaning of qualitative data [23]. We developed qualitative codes from both researcher-driven categories derived from the research aims and interview questions as well as categories that arose through inductive review of the qualitative data. Coding was done iteratively and involved multiple researchers. Key concepts and patterns were identified through continued immersion in the dataset. The research team met regularly to discuss provisional findings and also received feedback via expert review. The team worked collaboratively to refine and reach consensus on the main findings reported in this article.

Results

Technology Owned

We found variability across mental health service delivery settings by type of technology owned, as well as by awareness of, and interest in, technology; and routine uses of technology. In the private dual diagnosis center that primarily served young adults, participants typically owned several high-end devices, including luxury brand (eg, Apple, Samsung) smartphones, tablets, and computers. In contrast, in the long-term residential care center, a few participants owned modern, high-end devices, but the majority owned outdated technology, for example, old flip phones tucked away in desk drawers and outdated laptops left uncharged or broken. In the community mental health center setting, all participants owned at least one modern device—commonly a smartphone—yet these were typically low-budget, prepaid mobile plans with limited data.

Across all 3 sites, participants’ access to technology was facilitated or constrained by various factors. In some cases, policies at the organization prevented participants from using technology, especially when substance use challenges were present. For other participants, access to technology was mediated by whether family members supported their use of technology. Some family members encouraged using technology, citing reasons ranging from carrying a cell phone for safety to the desire for the participant to develop computer skills. Yet other families had dismissed participants’ desire to own technology stating, “You don’t need it.” Finally, access to technology was facilitated or constrained by whether the participant had adequate financial resources to purchase and maintain technology.

Awareness of, and Interest in, Technology

In both the private dual diagnosis center and the community mental health center, participants had high awareness of the existence of a wide range of technologies even if they did not own the specific devices. They generally were aware of key features and functions of modern technologies (eg, texting; accessing the internet; daily-use apps such as calendar, email, clock, and weather). Similarly, most participants in these 2 settings expressed interest in learning to use technology generally and to support their mental health.

Technological awareness among participants in the long-term residential care center, by contrast, varied. While a few participants in this setting had high awareness, many others were unaware of existing technologies. For example, several people did not know what an iPad was. Similarly, awareness of technological functions was limited in this setting. One older man used the ethnographer’s phone to engage in texting for the first time. Interest in technology among participants in this setting also varied. Some participants expressed interest in learning about and using technology. For example, the participant who texted for the first time was quite enthusiastic about the experience. He immediately saw the potential of texting in making his regular communication (currently via letters) with family and friends much easier. However, for other participants at the long-term residential care center, interest in technology was low as exemplified by the following statements: “I’ve lived my whole life without it” and “I don’t want this.”

Routine Uses of Technology

Across all 3 settings, participants who engaged with technology were using devices for a wide range of purposes. Participants in the private dual diagnosis center were active and regular users of a range of technology for education, research, communication, social networking, relaxation, and entertainment. For example, participants used Web-based videos to learn new skills such as playing the guitar; others were engaged in formal Web-based college courses. Several participants in this setting enjoyed streaming movies, playing video games, and Web-based shopping. Participants in this setting were all familiar with social media, but varied in their engagement with these platforms depending on whether social media was a positive or negative experience for them. Some people found positive, inspirational information and connections on social media, while others had negative reactions to references to partying or the influx of news about troubling current events. With respect to using technology for mental health-related reasons, this was only observed in one participant who used the alarm on his cell phone as a reminder to take his medication.

In the long-term residential care center, the few participants who regularly engaged with technology used their devices for education, relaxation, and entertainment. Participants who owned functioning computers used the internet to access news, email, and stream movies. A few participants in this setting used social media to connect with family and friends and a few enjoyed playing video games. Participants were also observed...
using older forms of technology such as cassette tapes and video home system (VHS) movies for relaxation and entertainment. No participants in the long-term residential center were observed or reported using mental health-related technology, for example, mobile health (mHealth) apps, or used technology for mental health-related reasons such as symptom management.

Participants in the community mental health center all actively used technology for a range of purposes, including education, research, social networking, relaxation, and entertainment. As with participants in the other settings, those at the community mental health center commonly used the internet for email and to access information, including current events, recipes, weather, and health. Some participants searched for jobs via Web-based sources; other participants used social media regularly. Many enjoyed streaming movies and listening to music on their cell phones or laptops. In contrast to the other settings, participants in the community mental health center commonly discussed using technology for health and mental health-related purposes. Accessing health-related websites for information was a common practice, as described by the following participant:

I use [my phone] for internet, looking up prescriptions. I use it for diagnoses...I just google it. And I just type in the type of medicine, or the specific name of the medicine...I look it up for side effects. Basically to see if it coincides with the paper I get through a pharmacy. And like, accidental overdose, any interactions, anything like that. And what exactly the medicine does.

Others reported using technology for psychiatric symptom management and to support recovery. Although some people were aware of or had tried mental health apps, these were not commonly used. Participants described some barriers to using mental health apps, including difficulty understanding some apps:

Well I downloaded a couple. And then. It was like measuring my depression. But see, mine goes up and down. And, I really didn’t understand how to use it.

This participant elaborated that if there were an easy-to-understand app for bipolar disorder, he would “definitely use it.” Another participant described how limited data plans prevented her from exploring available mental health apps:

There have been times I think people have suggested, “Check this app out, check that app out,” and for the most part I don’t think I have. That’s one thing I am limited with the phone. I do only have so much data. So, that does limit me some. Ok, do I really want to waste data on looking this up, or getting this app? Or do I want to be able to listen to music?

Rather than using specific mental health apps, participants in the community mental health center reported using widely available and popular apps in ways that supported their mental health. For example, one woman used Instagram every day to access positive affirmations, expressing that this daily practice supported her mental health recovery:

And it helps. Definitely with my depression. Some with the anxiety. If you really start looking at positive affirmations and really start reading them.

Similarly, another participant described using YouTube videos to manage panic attacks and to help with sleep:

I do use a lot of YouTube [videos]. Like I do progressive muscle relaxation when I’m having panic attacks. I also use it for music. To fall asleep to. I’ve had quite a few apps for anxiety and stuff that haven’t worked.

**Discussion**

**Principal Findings**

We used an ethnographic and qualitative approach in multiple mental health settings to contribute to the growing knowledge base regarding technology and mental health. Our findings are consistent with previous research that has found that people with SMI use technology in a range of ways similar to the general population [17-20]. Previous research has found lower rates of smartphone usage among people with SMI compared with the general population [19,24]. Similarly, we found that although modern technologies, including mobile phones, were commonly owned by participants, ownership was far from ubiquitous in certain settings. Our research contributes to identifying subpopulations that may be less likely to own modern devices and less familiar with the capabilities of modern technology. In particular, our findings suggest that older populations in long-term care settings may need education and support to increase awareness of technology before introducing technology-based supports for mental health. In addition, our findings underscore that access to technology occurs in a social context, and family members may also need some information to become aware that technology may be beneficial for supporting mental health.

Our research extends previous research on technology use among people with mental illnesses by identifying challenges regarding the range of devices owned. We found that owning a device did not necessarily confer full access to available technology-based resources. Many participants owned outdated devices or devices with limited functionality. The low-budget smartphones commonly owned by participants in the community mental health center had limited data plans and storage, which inhibited participants’ ability to download and use mobile apps. These findings hold implications for the development of technology-based mental health supports that are inclusive and can be broadly implemented. Our findings illuminate that mental health app developers should expect—and design for—a range of technological functionality. Facilitating access to technology-based supports in real-world settings will necessitate developing tools that are ecologically valid and take into account limitations posed by outdated or low-budget technology. Current mHealth research may obscure these challenges due to the common practice of providing luxury phones with large data plans to study participants.

In the settings of this study, technology-based tools specific to mental health were not in routine use. This suggests that despite
the vast number of health apps currently available for download [25], at this time, mental health service users may not be routinely seeking out and using such tools. In the community mental health setting, we identified some creative uses of widely available apps to support mental health. Our study suggests thinking broadly about and evaluating a range of apps—including, but not limited to—mental health apps, for example, coloring apps, brainteaser apps, and day planner apps. Prior to recommendation, any app would need to be evaluated because many apps contain information that is inconsistent with current practice guidelines [9] and some contain harmful information [26]. We see potential for applying an evaluation framework [27] to facilitate practical and informed decision making around a range of apps in clinical contexts.

Several strategies have shown promise in addressing barriers to the uptake of technology-based mental health supports. Facilitating the routine use of these supports will likely require a multipronged approach. This approach might include Web-based collections of evidence-based tools to make it easier for people to find high-quality supports [28]; educational or informational interventions to increase the engagement and interest of people regarding technology-based tools [29-31]; and government endorsement, systems of accreditation, and funding to increase the availability of high-quality technology-based tools [31]. Because mental health clinicians and service users are relatively naïve about using technology to support mental health, mental health programs may need to include some form of specific expertise to help the two parties find appropriate, effective tools and learn how to use them, at least over the short run [32].

Qualitative inquiry using multiple methods (ethnographic observations and interviews) at multiple sites over 12 months enhanced the credibility and transferability of our qualitative findings [33]. However, like most qualitative research, our findings are not broadly generalizable. Our study was also limited by a lack of ethnic or racial diversity in our sample.

Conclusions

Many mental health service users currently use technologies but not often in service of addressing mental health needs. Our findings suggest that many, but not all, service users will be interested in using technology to support their recovery. Technology-based mental health education, supports, and interventions should be among the many services offered within mental health centers. Future research should examine the use of technology to support mental health service users and clinicians in real-world settings and also among populations less well connected to services.

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Conflicts of Interest

None declared.

References


Abbreviations

**mHealth**: mobile health

**SMI**: serious mental illness
Desired Features of a Digital Technology Tool for Self-Management of Well-Being in a Nonclinical Sample of Young People: Qualitative Study

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Abstract

Background: Adaptive coping behaviors can improve well-being for young people experiencing life stressors, while maladaptive coping can increase vulnerability to mental health problems in youth and into adulthood. Young people could potentially benefit from the use of digital technology tools to enhance their coping skills and overcome barriers in help-seeking behaviors. However, little is known about the desired digital technology use for self-management of well-being among young people in the general population.

Objective: This is a small, qualitative study aimed at exploring what young people desire from digital technology tools for the self-management of their well-being.

Methods: Young people aged 12-18 years were recruited from the general community to take part in semistructured interviews. Recorded data from the interviews were transcribed and analyzed using inductive thematic analysis.

Results: In total, 14 participants were recruited and completed the study, with a mean age of 14.6 years (female n=3). None of the participants reported using any digital tools specifically designed to manage well-being. However, as indicated through the emerged themes, young people used digital technology to reduce their stress levels and manage their mood, mainly through games, music, and videos. Overall, identified themes showed that young people were keen on using such tools and desired certain facets and features of an ideal tool for self-management of well-being. Themes related to these facets indicated what young people felt a tool should do to improve well-being, including being immersed in a stress-free environment, being uplifting, and that such a tool would direct them to resources based on their needs. The feature-based themes suggested that young people wanted the tool to be flexible and enable engagement with others while also being sensitive to privacy.

Conclusions: The young people interviewed in this study did not report engaging with digital technology specialized to improving well-being but instead used media already accessed in their daily lives in order to self-manage their psychological states. As a result, the variety of coping strategies reported and digital tools used was limited to the resources that were already being used for recreational and social purposes. These findings contribute to the scarce research into young people’s preferred use of digital technology tools for the self-management of their well-being. However, this was a small-scale study and the current participant sample is not representative of the general youth population. Therefore, the results are only tentative and warrant further investigation.

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KEYWORDS
adolescence; young people; well-being; self-management; digital technology; E-health; coping strategies; mental health; help-seeking; qualitative

Introduction
It is estimated that 10-20% of young people experience mental health problems worldwide [1], with 75% of youth being diagnosed with a mental health disorder before the age of 24 [2]. Despite the widely documented reduced well-being levels in youth, there is a lack of research on mental health issues experienced in the general youth population, with most of the literature being focused on youth mental health in clinical groups diagnosed with mood, anxiety, or associated mental health problems [3-9].

There is considerable evidence to suggest that young people’s reduced well-being levels are largely attributed to an inability to cope effectively with stressors stemming from social, physical, and emotionally challenging situations [10,11]. Psychosocial stress, in particular, has been deemed a key factor contributing to high levels of distress in youth, especially during the transitional period from pre-adolescent to adolescent phases when there is increasing accumulation of stressful life experiences, for example, peer, school, and family relationships and events [12,13].

Given that reduced well-being levels in nonclinical youth have been associated with maladaptive coping behaviors [3-9], the use of adaptive coping strategies can play a catalytic role in helping young people manage their stress levels and in reducing the risk of their developing mental health problems in later years [14,15]. Research shows that problem-focused coping strategies (ie, involving directing one’s efforts toward the stressor) can be helpful as they have been associated with positive health outcomes [16]. However, such strategies do not seem to align with the strategies that young people typically use. They frequently adopt either emotion-focused coping techniques in their attempt to regulate their emotions or escape-avoidance strategies by directing their attention away from the problem [11,17,18].

Furthermore, young people tend to show low help-seeking behaviors, often choosing informal offers of support over professional sources of help provision [19-22]. At the same time, mental health services do not have the capacity or resources to sufficiently meet the needs of the young people accessing services [23,24]. In recent years, increased use of digital technology tools has facilitated the provision of health interventions and health-related information through various communication channels and platforms. Self-help digital technology tools have been found to be easily accessible and user-friendly [25] and could therefore help overcome the documented barriers to accessing mental health services [26-28]. However, research into their acceptability by young people is limited.

Findings from a scarce number of studies in nonclinical youth populations have revealed concerns about the use of digital technology tools for the self-management of their well-being, such as the lack of face-to-face support [28-31]. In addition, young people have expressed their desire for these tools to be engaging, interactive, and personable [32], and to provide a variety of online sources of information about self-help on mental health issues rather than directing them to professionals [33]. These findings seem to indicate that the nonclinical youth would find digital technology tools helpful for the management of their well-being if certain desired or disliked tool elements were incorporated or excluded, respectively. To further this understanding, this current qualitative study aimed to explore what features and facets young people would desire from digital technology tools for the purposes of managing their well-being.

Methods
Participants and Recruitment
We recruited 14 young people aged 12-18 years from the community via flyers posted on social media, forums, and through gatekeepers to groups and organizations including youth groups (eg, church, community, government, sports, drama, and charities), local schools, and study participation registers. All participants were recruited from the Nottinghamshire region of East Midlands, United Kingdom, and were in Years 10-13 of secondary school education. The criteria for inclusion required that participants be aged 12-18 years and have previous experience in using digital technology. No exclusion criteria were applied. History of experience or clinical diagnosis of mental health problems was not an exclusion criterion, but participants were asked by the researcher to report on current or previous experience of mental health issues.

Participants did not receive any monetary allowance for participating in the research. This research was approved by, and adhered to the guidelines of, the University of Nottingham Division of Psychiatry and Applied Psychology Ethics Board (United Kingdom).

Study Procedure
Participants contacted the researcher via gatekeepers or directly through the email address provided on the flyers to ask about the study or express their interest in participating in the study. Informed consent forms, and assent forms for participants under 16, were completed electronically. The date and preferred mode of interview (ie, video or voice call) were arranged by email prior to the day of the interview. On the day of the interview, an overview of the study procedure was first provided to participants, reminding them also that they could withdraw from the study at any point and that they should feel free not to answer any questions they felt uncomfortable with. On obtaining verbal consent, in addition to the consent or assent obtained electronically, the researcher proceeded with the interview.

The Mobile Phone Use Survey [34] and previous research into the functions of digital apps [35] helped inform the interview guide and prompts used in the semistructured interviews. Open-ended questions were used to produce in-depth information, followed by a closed or probing format of
questioning, where applicable, to elicit further detail (see Multimedia Appendix 1). Interviews lasted approximately 20 minutes. The initial part of the interview was designed to explore what types of digital technology are used by young people as well as young people’s views and feelings about how their well-being may affect or be affected by their use of this technology. The remaining interview questions centered on the desired features and facets of an ideal tool, that is, exploring youth’s preferences for digital tools aimed at assisting them with nonclinical psychological well-being issues.

Data Analysis

Interview recordings were transcribed verbatim and analyzed using inductive thematic analysis. Express Scribe Transcription software (version 6.0) was used for the organization and development of codes and themes by the researcher (CB). In line with Braun and Clarke’s 6-step recursive process of thematic analysis [36], transcribed interviews were checked against audio recordings for accuracy, then read and re-read by the researcher to ensure familiarization with the data. Following the familiarization stage, initial codes were generated where participants’ responses were relevant to the research question. Codes were subsequently organized into theme categories by CB, which were also reviewed and verified by the co-authors (EN, GMJ) before defining the final themes and subthemes. Both EN and GMJ are experienced in assessing qualitative research. A codebook example can be found in Multimedia Appendix 2, illustrating how themes were generated according to previously proposed codebook guidelines [30,31].

The researcher, CB, is a postgraduate applied psychology student trained in conducting thematic analysis and is conscious that the knowledge gained from thematic analysis and its interpretation is influenced by factors such as the researcher’s previous thoughts on the research subject, cognition, use of language, culture, perceptions, and emotions [36]. To minimize the influence of bias and increase credibility of the research, a self-reflexive approach to the research was used throughout, which included keeping a reflexive journal in line with thematic analysis recommendations [36,37]. These notes were shared with EN and GMJ at the end of the thematic analysis so that they could be reflected on prior to the interpretation of the results.

Results

Participant Recruitment

A total of 14 young people aged 12-18 years were recruited and completed the study (mean age 14.6 years, SD 1.6; 3 females). None of the participants reported having a current or previous clinical diagnosis of mental health problems.

Due to the small-scale nature of this study, a sample of 15 young people was intended to be drawn but recruitment stopped at 14 participants because data saturation was reached for the identified key themes. No more depth could have been achieved due to the limited scope of the digital technology used and of the features and facets reported by the sample. In accordance with thematic analysis guidelines and recent reviews, the final sample was sufficiently sized for the purposes of conducting thematic analysis [38,39].

Overview of Findings

In response to our questions on what young people desire from an ideal digital technology tool designed for managing one’s well-being, none of the participants reported using digital tools specifically designed for the self-management of well-being, such as self-help mobile or Internet apps for managing stress or improving one’s mood. Instead, they tended to refer to the media they would use or expect to use to help them manage their psychological well-being, such as games, music, and platforms for contacting friends. These media were already being used by young people on a daily basis for recreational purposes, but young people reported that they would like to see such media featured in an ideal self-help well-being tool, as well as on other facets and features they would like an ideal tool to incorporate.

The emerged themes concerned the specific facets and features that young people expected to find or desired in a self-help digital technology tool designed to help them improve their well-being. All participants unanimously stated that the applications of such a tool should all be offered on a mobile phone platform due to its accessible and convenient nature. The reported facet-based themes referred to what the ideal tool “should do” in order to improve the young person’s well-being, for example, “The ideal tool should allow oneself to be immersed in a stress-free environment” (Theme 1), “The ideal tool must have an uplifting effect to be helpful” (Theme 2), and “The ideal tool should assess and direct one to resources that match one’s needs” (Theme 3). With regard to the desired features of the tool, young people expressed that, “The ideal tool should be sensitive to privacy” (Theme 4), “Flexibility in choice and resources is a desired feature of the ideal tool” (Theme 5), and “The ideal tool should enable engagement with others” (Theme 6).

Facet-Based Themes

Theme 1 (T1): The Ideal Tool Should Allow Oneself to Be Immersed in a Stress-Free Environment

Young people reported that using music and playing games or talking to others while gaming, on their mobile phones, tablets, and game stations, was a means for them to de-stress.

T1:1 A Means of Distraction From Stressful Thoughts

Participants wanted the tool to offer a relief from the stressors they were experiencing by acting as a distractor, for example, using online games as a means of contact with friends and distraction from stressors.

Because distracting would take your mind off the stress and stuff like that as well and so you eventually forget. [P7, 14 years, male]

Yeah when I’m stressed out and everything like, like some days I’ve been doing a project and it has been annoying me because it’s quite fiddly and when it’s, most of the time I go on that and I play online games, and you’re playing other people and it makes me feel connected. [P6, 13 years, male]
T1:2 A Means of Relaxation or Escape
Participants felt that a purpose of the tool should be to enable one to relax, providing relief from the stressor or to remove oneself from the problematic situation as a means of escape from the stressor. Use of music and games were reported as means to relax and reduce stress-related feelings.

I find music to be very umm, again to be very soothing and easing of me. I am a huge fan of the Beatles. Whenever I feel anxious and stressed or angry, or any kind of negative emotion, listening to them really helps me a great deal, it kind of grounds me and stuff. [P3, 18 years, female]

Umm but, I’d say games are the biggest things that help me destress, I’d say that’s the main thing. Yeah I sort of forget about where I am in the real world. I can engage myself, sort of help you relax and forget about anything that I’m thinking about in real life. [P3, 14 years, male]

Theme 2 (T2): The Ideal Tool Must Have an Uplifting Effect to Be Helpful
Young people stated that the tool ought to produce an uplifting effect in order to boost one’s mood in the short-term.

T2:1 Use of Videos to Motivate or to Make One Feel Better
Videos were considered to have the ability to improve one’s negative mood, for example when featuring inspirational stories or funny scenes.

Yeah…I think it’s hard raising someone’s mood without being there yourself so I think like more videos or, this, it could just be one video or maybe two, it could just be like, TED talks. I know TED talks do loads of videos about how to cope with that, so it could be more about like self-help and distraction in that sense. [P5, 18 years, female]

T2:2 Use of Music to Help Regulate Mood
Participants referred to the use of music as one of the preferred means of mood regulation, in order to improve mood but also to help them reflect on their current emotions: “Yeah, like the type of music can reflect on the mood you’re feeling” (P11, 14 years, male).

Theme 3 (T3): The Ideal Tool Should Assess and Direct One to Resources That Match One’s Needs
It was anticipated by participants that the ideal tool would “know” how one feels and what would make them feel better and direct them to the appropriate resources. Some of these resources should be available within the tool’s features while others could be resources the tool signposts to.

T3:1 Provides Resources to Overcome Negative Emotions
The ideal tool was expected to contain directly supportive functions for dealing with negative emotions. The idea was that after the user informs the tool of their mood, the tool provides the user with information on what to do as well as information about the user’s previously logged preferences.

Like you just tell the app…what you enjoy doing and it kind of picks certain things so you can kind of go, oh get back to what, like if you were stressed out, get back to calm state, just using the app, or tool or whatever and it will kind of use your information that you’ve told it to give you something, like a quiz or something just to feel better. [P2, 15 years, male]

T3:2 Provides Information and Direction for Further Support
Young people expressed a desire for the tool to enable them to improve their knowledge and direct them to external professional sources for dealing with severe issues around their well-being.

Yeah, so I think if someone’s very often clicking like low mood and a certain aspect maybe if the app could just like come a bit more focused and talk about, not brainwashing, but develop itself so that the videos it shows could be of someone being like, about them getting help and external forces as well, just like, giving these ideas and showing that there are other ways to do it as well and talking and stuff. [P5, 18 years, female]

Feature-Based Themes

Theme 4 (T4): The Ideal Tool Should Be Sensitive to Privacy
One of the major concerns young people had about tool use was privacy and exposure of personal data. They had various concerns about social media featuring on the tool and how this would affect their privacy. They also expressed opinions on the degree of parental involvement in the use of the tool.

T4:1 Provides Safeguards as Needed to Limit Disclosure of Personal Data
Young people would prefer not to have to enter personal details on the tool or have site-monitoring features on a tool. Particular concerns were raised around exposure of personal information through social media on current digital technology tools.

Yeah, because like on Snapchat now you can see where people are and I just think that’s a bit over the top. Like I’ve put myself on ghost mode now but I didn’t realize I had that until the app updated itself, which was a couple of weeks later, and when I found it made me quite uncomfortable because I feel like everyone on Snapchat knew what I was doing. [P4, 16 years, female]

T4:2 Parental Involvement Is Acceptable When Necessary
Parental access to the tool was generally not a desired feature, but parental involvement was deemed acceptable when necessary, as in the case of serious risk of self-harm. Young people suggested that the tool should prompt the user to talk to their parents or enable parents to be informed if needed.
Theme 5 (T5): Flexibility in Choice and Resources Is a Desired Feature in the Ideal Tool

A crucial element desired of the tool’s features was flexibility and capacity for personalization so that it would be tailored to an individual’s wide range of needs. The main areas identified as necessitating flexibility included the identification and selection of current emotional state, and selection capacity in games, videos, and music.

T5:1 Choice for Reflecting Different Emotional States

Participants felt the tool should be able to support different emotional states so that the young person has a wide range of options to select from in order to identify the mood that best reflects their current emotional state: “Yeah, umm I think the main thing that would interest me with a tool like that is if it gave you choice. It depends on how I’m feeling and what exactly I feel I’m in the mood for to do” (P13, 14 years, male).

T5:2 Games and Puzzles to Suit Individual Preference

Games were identified as a means of help for managing negative moods and for stress reduction, particularly through distraction. It was deemed necessary for the tool to offer options for different games that suit different people’s tastes in order to enable distraction and hence make one feel better.

It would help if I was stressed out to take my mind off it and you could choose what you want or what your favorite kind of thing is, if you like puzzles, or like quizzes or games and bits, you can just choose whatever you want, that would help a lot. [P2, 15 years, male]

T5:3 Videos Provide a Variety of Resources

Videos were highly desired by participants and were expected to be adaptable and engaging resources expected to serve a variety of functions, including mood boosting and information provision.

T5:4 Music for Individual Preference

Music was often mentioned to be an ideal means of mood self-management, but the tool would have to be able to select the desired music from a range of options that would fit one’s personal taste.

Theme 6 (T6): The Ideal Tool Should Enable Engagement With Others

Communicating with others in order to obtain their support was a highly desired aspect of the tool, but there was a preference for this function to be facilitated through means other than social media.

T6:1 Communication With Friends for Connection

Young people expressed the desire for the tool to enable them to contact friends for improving mood and for maintaining friendships, although it was noted that this should take place outside the context of social media.

I mean having the option to open it out to normal people might be quite interesting because it means that if your friends aren’t able to play then you have the option to open it up to more people but there are risks in that on meeting people that you don’t know well. Normally if I have to do something like that, I would only talk to friends. [P13, 14 years, male]

T6:2 Anonymous Communication for Support

Participants felt that blogs or forums enabling communication with people unknown to the user could offer a type of support that would be different from that offered by friends or other familiar people: “Maybe like blog like a forum, or something, where other people can anonymously put things and ask for advice of other people” (P7, 14 years, male).

Discussion

Principal Findings

This study looked at what young people would like to see featured in an ideal digital technology tool designed to help them cope with nonclinical well-being issues. Despite the small sample size and the relatively limited breadth of theme-related content addressing the research question, our findings showed that young people did not use technology specifically targeted at well-being management. Instead, in their attempt to improve their psychological well-being, they tended to use the same digital technology they would use on a daily basis for recreational or social purposes. Although this meant that the reported range of technology use was unexpectedly limited, hence narrowing the scope of the research question, young people’s accounts still provided an interesting insight into the coping strategies that they tended to seek, such as relaxation and distraction. They also provided some evidence in support of young people’s preferences for an ideal self-help well-being tool that would have to be flexible, interactive, and sensitive to privacy.

Consistent with the reported current technology use patterns of the young people included in this study sample, such self-help tools would be preferred to be implemented as apps on mobile phone platforms, which were reported as the most accessible means. Emerged themes denoted a fundamental expectation that the tool will have to fulfil its intended purpose, that is, to improve well-being levels mainly by boosting mood and reducing anxiety levels. Specifically, the expectation that the ideal tool would improve young people’s mood and motivation levels, particularly through use of music and videos, could be considered as an adaptive approach of mood regulation [14,40]. Moreover, young people wanted the tool to enable them to adopt short-term distraction and escape coping techniques for stress relief purposes, mirroring the techniques adopted in their current use of digital technology. This finding suggests a tendency by young people to direct their attention away from the stressor [11,14,18], an approach that can be of adaptive value in the short-term leading to positive mental health outcomes in youth [16,41]. However, continual use of adaptive distraction has been associated with low levels of well-being and poor mental health outcomes more generally [3-5,11,42,43], perhaps because long-term distraction can hinder appropriate action responses [18] and may reinforce the persistence of avoidance-escape approaches [16]. Such a tendency for short-term distraction is in line with previous literature [3-5] and may be indicative of
young people’s perceived lack of ability to exert control over a stressful situation [44,45].

In line with the assumption that self-management tools provide a means of overcoming barriers to support seeking in young populations [46-48], another desired facet of an ideal well-being tool was the inclusion of pointers to resources for social support as well as psychoeducation about mental health and illness. Support seeking in this context portrays a problem-focused approach given young people’s desire to be directed to resources that match their needs, reflecting their willingness to turn their attention towards the problem, provided that they know where to turn to for help. Notably, the need for psychoeducation may reflect the documented low mental health literacy in adolescent populations [49] and could have important implications for young people’s proactive use of well-being tools. Easy access to information about mental health problems as well as sources for help could equip young people with the knowledge and skills to help them recognize mental health issues and develop effective strategies to optimize their well-being [50]. Flexibility in function and choice was also expected to be featured in an ideal self-help well-being tool, consistent with previous literature [3-5]. An unforeseen finding in our study was that although young people wanted to engage with others, they were not keen on contacting others through social media, mainly because of concerns around privacy. This apprehension has been corroborated in previous research where young people claimed they would not use social media [33] or would prefer face-to-face help [51] when going through a difficult time. Further, contrary to evidence suggesting that young people would want to use a self-management tool independently from their parents, our sample considered parental involvement appropriate if needed, a view that is supported by models of young people accessing health care who found parental encouragement helpful [47,52]. Finally, in light of a reported negative relationship between use of social media and well-being levels in youth [53], our young people’s recommendation for use of forums as a communication platform may pose further concerns regarding risks to the young person around privacy or credibility of source.

Limitations
Although this study helped address a gap in the literature in relation to the elements desired by the youth in a digital technology tool designed for the self-management of well-being, this was a small study with a sample of young people that cannot be regarded as representative of the general youth population. In addition, these findings are limited in breadth given the narrow scope of the participants’ reported digital technology use. Although participants did not report having received a clinical diagnosis of a mental health problem, the presence and nature of current or previous experience of mental health issues cannot be determined. Moreover, the nature of stressors experienced as well as the presence of significant life events could impact on the use of digital technology tools and the perceived need for help with well-being issues and should therefore be factors for consideration in future explorations.

Conclusions
The young people’s preferred features and facets in an ideal self-help well-being tool reflected their desire for these elements to be similar to those readily accessible to them through the technology they use on a daily basis for recreational and social purposes. Young people’s desire to use fit-for-purpose and user-informed self-management tools also highlights the need to embed in such tools pointers for directing young people to appropriate mental health information and support. Such aspects may be important to consider in the refinement of self-help well-being tools with the aim of enhancing their acceptability by the youth population in order to proactively improve psychological well-being levels. However, given the limited scope of this study, these findings warrant further investigation and any conclusions derived from these findings should be tentative.

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Conflicts of Interest
None declared.

Multimedia Appendix 1
The semistructured interview guide.

[PDF File (Adobe PDF File), 25KB - mental_v5i4e10067_app1.pdf ]

Multimedia Appendix 2
Codebook from Themes 3 and 5 using quotes from participants as examples.

[PDF File (Adobe PDF File), 54KB - mental_v5i4e10067_app2.pdf ]

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Computer-Aided Telephone Support for Primary Care Patients with Common Mental Health Conditions: Randomized Controlled Trial

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Abstract

Background: Depression, anxiety, and at-risk drinking are highly prevalent in primary care settings. Many jurisdictions experience geographical barriers to accessing mental health services, necessitating the development and validation of alternative models of care delivery. Existing evidence supports the acceptability and effectiveness of providing mental health care by telephone.

Objective: This analysis assesses patient’s acceptability of computer-aided telephone support delivered by lay providers to primary care patients with depression, anxiety, or at-risk drinking.

Methods: The Primary care Assessment and Research of a Telephone intervention for Neuropsychiatric conditions with Education and Resources study is a randomized controlled trial comparing a computer-aided telephone-based intervention to usual care enhanced by periodic assessments in adult primary care patients referred for the treatment of depression, anxiety, or at-risk drinking; no part of the study involves in-person contact. For this analysis, the following data were obtained: reasons provided for declining consent; reasons provided for withdrawing from the study; study retention rate; and a thematic analysis of a satisfaction survey upon study completion.

Results: During the consent process, 17.1% (114/667) patients referred to the study declined to participate and 57.0% of them (65/114) attributed their refusal to research-related factors (ie, randomization and time commitment); a further 16.7% (19/114) declined owing to the telephone delivery of the intervention. Among the 377 participants who were randomized to the 1-year intervention, the overall retention rate was 82.8% (312/377). Almost no participants who withdrew from the study identified the telephone components of the study as their reason for withdrawal. Analysis of a qualitative satisfaction survey revealed that 97% (38/39) of comments related to the telephone components were positive with key reported positive attributes being accessibility, convenience, and privacy.
Conclusions: Our results suggest that a computer-aided telephone support is highly acceptable to primary care patients with depression, anxiety, or at-risk drinking. In particular, these patients appreciate its accessibility, flexibility, and privacy.


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KEYWORDS
telemedicine; collaborative care; depression; anxiety; at-risk drinking; lay provider; family medicine; general practice; primary care psychiatry

Introduction

Background

In Canada, 1 in 5 individuals report experiencing symptoms of substance abuse and mental health problems each year [1,2], and almost 75% of mental health visits are related to mood and anxiety disorders [3]. The economic impact of depression alone is estimated to be over Can $32 billion, which is twice the amount of money spent on mental health and community care [4]. In Ontario, 15% of adults have consulted a family physician or a psychiatrist about their mental health in the past year, and mental health visits represent 10% of all physician visits [5]. More of these visits occur in the primary care settings than in the psychiatric setting [5,6]. Despite the increased focus on mental health, an estimated 1.6 million Canadian citizens report that their needs for mental health were unmet with 36% reporting that their needs for counseling services were either unmet or partially met [7]. In a recent survey, wait times to see a psychiatrist ranged from 15 to 59 weeks, and wait times to start psychotherapy ranged from 3 to 22 weeks [8].

Prior Work and Rationale

With long wait times and unmet needs for mental health service, alternative approaches to service delivery have been proposed and evaluated. A literature search was conducted to identify relevant examples of studies that investigated the feasibility and impact of using lay coaches to provide mental health management and support over the phone [9-18]. These studies conducted in the United States or Canada used telephone coaching to provide a range of interventions as follows: self-help resources, symptom tracking, promotion of behavioral activation and self-management, or treatment adherence. Their main findings are summarized in Table 1. Collectively, these studies suggest the acceptability and efficacy of offering support and care via telephone to primary care patients with depression, anxiety, or at-risk drinking. These studies were identified with PubMed using the following keywords: “lay coach,” “telephone support,” “mental health,” “depression,” “anxiety,” and “alcohol use.” We included studies that were judged to be most relevant and met the following criteria: use of a telephone component; use of a lay coach; and focus on depression, anxiety, or alcohol use. Not all interventions described in these studies were successful for all patients. Thus, we are conducting a study to assess the feasibility and impact of a computer-aided telephone-based intervention for primary care patients with depression, anxiety, or at-risk drinking: the Primary care Assessment and Research of a Telephone intervention for Neuropsychiatric conditions with Education and Resources study (PARTNERs; ClinicalTrials.gov Identifier: NCT02345122). PARTNERs utilizes Mental Health Technicians (MHT; coaches) who provide mental health support to patients over the telephone with the help of standardized questionnaires and assessment reports available on the Behavioral Health Laboratory (BHL) software (Capital Solutions, PA, USA). This paper evaluates the acceptability of this intervention and potential limitations from the patient’s perspective.
Table 1. Summary of most relevant published studies of telephone-based support for depression, anxiety, or at-risk drinking.

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<thead>
<tr>
<th>Study and location</th>
<th>Study design</th>
<th>Main findings</th>
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<tr>
<td>Simon et al (2000) [9], United States (n=613)</td>
<td>Patients starting antidepressant trial randomized to 3 groups: (1) usual care; (2) telephone contacts every 3 months with feedback only; and (3) telephone contacts every 3 months with feedback and support.</td>
<td>- Patients who received telephone feedback and support were more likely to receive an adequate antidepressant dosage; have lower depression scores; and have a lower likelihood of persistent major depression. - Feedback only had no significant effect on the outcomes.</td>
</tr>
<tr>
<td>Oslin et al (2003) [10], United States (n=97)</td>
<td>Veteran participants (n=97) with depression and at-risk drinking were assigned to 2 groups: (1) usual care and (2) TDM by a behavioral health specialist. Patients in the TDM received regular follow-ups for 24 wk. Symptomatic outcomes were assessed at 4-months.</td>
<td>- TDM was associated with improved outcomes for depression and at-risk drinking: response rates were 39% in the TDM group and 18% in the usual care group.</td>
</tr>
<tr>
<td>Brown et al (2007) [11], United States (n=819)</td>
<td>Open, noncontrolled design. Participants with comorbid depression and chronic physical illness received self-care tools and telephone support by a lay coach for 6 months.</td>
<td>- The telephone intervention was found to be feasible and acceptable: 91% (57/63) of the participants completed the 2-month follow-up; 63% (mean 5.7/9) of possible calls were completed. - Participants experienced significant improvement in depression symptoms at 6 months.</td>
</tr>
<tr>
<td>Mello et al (2013) [13], United States (n=285)</td>
<td>Injured adults screening positive for alcohol use and discharged from an emergency room randomized to 2-call phone intervention or usual care. Outcomes were measured after 12 months.</td>
<td>- Alcohol-related injuries were lower in the phone intervention group with no difference in consumption and other alcohol-related consequences.</td>
</tr>
<tr>
<td>Pickett et al (2014) [14], United States (n=124)</td>
<td>12-wk randomized trial of telephone-facilitated depression care and usual care in recently discharged primary care patients.</td>
<td>- No significant difference in outcomes between facilitated and routine care.</td>
</tr>
<tr>
<td>McCusker et al (2012) and Simco et al (2015) [12,17], Canada (n=63)</td>
<td>Open, noncontrolled design. Participants with comorbid depression and chronic physical illness received self-care tools and telephone support by a lay coach for 6 months.</td>
<td>- The telephone intervention was found to be feasible and acceptable: 91% (57/63) of the participants completed the 2-month follow-up; 63% (mean 5.7/9) of possible calls were completed. - Participants experienced significant improvement in depression symptoms at 6 months.</td>
</tr>
<tr>
<td>Rollman et al (2017) [18], United States (n=329)</td>
<td>Patients with anxiety randomized to a telephone-delivered CC intervention or usual-care referral. Participants in the CC group received help from a nonmental health professional for 12 months.</td>
<td>- Patients randomized to CC had improved mental health-related quality of life, anxiety symptoms, and mood at the 12-month follow-up compared with usual care.</td>
</tr>
</tbody>
</table>

aTDM: telephone disease management.
bPHQ-9: Patient Health Questionnaire-9 [19].
cCC: collaborative care.

Methods

Setting

PARTNERs is a randomized controlled trial that aims to assess the feasibility and impact of computer-aided telephone monitoring and support for primary care patients with depression, anxiety, or at-risk drinking using an integrated care model. As of April 30, 2017, the project has been implemented at 18 primary care sites, comprising 189 primary care providers (PCPs; ie, family physicians and nurse practitioners) in urban, suburban, and rural settings across Ontario.

Participants Eligibility and Recruitment

Starting in November 2014, PCPs identified adult patients with symptoms of depression, anxiety, or at-risk drinking; obtained their verbal permission to refer them to the study; and completed a brief referral form including the patient’s phone number and preferred time of contact. Research associates (RAs) called these patients within 5 business days and obtained their consent...
to participate via phone, following a process approved by the Research Ethics Board of the Centre for Addiction and Mental Health (CAMH). Starting with this call and at the beginning of each call, participants were asked to confirm their date of birth to verify their identity. Participants were then scheduled for a baseline assessment to confirm that they met all the inclusion criteria (receiving care from a PCP; referred to the study by their PCP because of depression, anxiety, or at-risk drinking; age 18 years and older; access to a telephone; willingness and ability to converse in English by telephone; willingness and ability to provide informed consent). Participants were excluded if they met one of the following exclusion criteria: psychotic disorder; bipolar disorder; obsessive-compulsive disorder; post-traumatic stress disorder; current substance use disorder except for alcohol use disorder; cognitive impairment as defined by a score of 16 or higher on the Blessed Orientation Memory Concentration test [20]; high risk for suicide; physical condition requiring hospitalization; or expected to die during the next 6 months.

Assessments

Participants were called by an RA at baseline and after 4, 8, and 12 months and completed a comprehensive assessment using the BHL software. Additional data were obtained regarding reasons for declining to participate in the study, reasons for withdrawing from the study, and satisfaction with participation. Patients who declined consent were asked for their reason(s) and their answers were recorded in a tracking log. Patients who consented but subsequently withdrew before completing the baseline assessment were also asked for their reason(s). When participants withdrew later during the study, reasons were similarly obtained and recorded.

During the 12-month follow-up assessment, participants completed a satisfaction survey including 5 open-ended questions (“Do you have any comments about access or entry to services?”; “Please comment on aspects of your experience with this treatment or support service that were particularly helpful to you”; “Please comment on aspects of your experience with this treatment or support service that you feel could be improved”; and “Any additional comments?”) and one 4-point global rating of the services provided (ie, poor, fair, good, and very good). The satisfaction survey was completed by telephone using a REDCap (Vanderbilt University, Nashville, Tennessee with ongoing support from the US National Institutes of Health) database.

Intervention

After completing the baseline assessment, eligible participants were randomized to either usual care plus research assessments and telephone support (“the intervention”) or usual care enhanced by the research assessments (“enhanced usual care”).

Using electronic faxes, PCPs were provided with the results of the 4 research assessments for all participants and were contacted as needed clinically (eg, if a participant reported some suicidality). In addition, participants randomized to the intervention received telephone calls from an MHT; typically, these phone calls took place weekly at the initiation of the intervention and tapered off to monthly as participants improved. This decision was based on remission of symptoms as defined by a score of <10 on Patient Health Questionnaire-9 or a decrease of 50% compared with the baseline score; after remission was maintained for at least 1 month, the frequency of the calls was reduced from weekly to biweekly; after remission was maintained for at least another month, the frequency of the calls was decreased to monthly. The first phone call lasted about 1 hour and the subsequent phone calls lasted 20-30 minutes; all calls were scheduled at times convenient to the participant, including evenings but not weekends. MHTs were bachelor-level trained lay providers. Their main role was to support participants’ self-management by monitoring symptoms and treatment adherence, providing education on contributory lifestyle factors, facilitating healthy lifestyle, and communicating updates and recommendations to their PCP [21]. MHTs also facilitated goal setting using a stages-of-change model and motivational interviewing techniques to set Specific; Measurable; Attainable; Relevant; Timely goals. MHTs received weekly supervision from the project psychiatrist.

Data Analysis

This analysis is based on all data collected until April 30, 2017. Descriptive statistics characterize the participants.

For this analysis, the main measures of acceptability of the telephone-based intervention were as follows: the proportion of referred patients who declined to consent or withdrew before completing the baseline and identified telephone services as their reason for doing so and the overall retention rate. In addition, a content analysis of the qualitative information in the consent tracking log and the satisfaction survey was conducted to characterize the intervention acceptability. Reasons for declined consent and withdrawal prior to completing the baseline were combined. Responses to the overall satisfaction rating and the 4 open-ended questions from the satisfaction survey were analyzed; responses that included comments related to the telephone component of the project were categorized and counted.

Results

Flow and Characteristics of Participants

Figure 1 summarizes the flow of the 667 patients who were referred to the study: of these, 10.3% (69/667) could not be contacted, 0.1% (1/667) had been deemed incompetent to consent; 14.8% (99/667) declined to consent, and an additional 2.2% (15/667) consented but withdrew before completing the baseline. Moreover, 4.8% (32/667) could not be contacted to complete the baseline assessment, resulting in 64.3% (429/667) who completed the baseline assessment. The demographic and clinical characteristics of these 429 participants are presented in Table 2. Of the participants who completed their baseline assessment, 87.9% (377/429) were randomized, of whom 2 died, 44 withdrew before completing the study, and 19 could not be reached for their 12-month assessment, yielding an overall retention rate of 82.8% (312/377).
Of the participants who declined consent (n=99) or withdrew prior to the baseline assessment (n=15), 15 did not provide any reasons for their refusal. Of the 121 reasons provided by the other participants that are presented in Table 3, only 15.7% (19/121) were explicitly related to concerns with the telephone component of the project or to a preference to see a therapist in person.

Reasons Provided for Withdrawing from the Study
Of the 44 participants who withdrew from the study after being randomized, 10 did not provide a reason for their withdrawal. The 41 reasons provided by other participants are shown in Table 4; none were attributed to the telephone intervention.

Satisfaction Survey
The overall satisfaction ratings are presented in Figure 2. In open-ended responses, 39 participants made 45 comments on the use of the telephone in the study (Table 5). Moreover, 16% (7/45) of these comments were negative and 84% (38/45) were positive, emphasizing the accessibility and convenience of telephone calls (ie, being able to speak with someone from their home) or the privacy and relative anonymity of the calls.
Table 2. Characteristics of the 429 participants who completed the baseline assessment.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>41.7 (15.8)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>38 (18-90)</td>
</tr>
<tr>
<td>Q1-Q3</td>
<td>29-54</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>294 (68.5)</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>344 (80.2)</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>29 (6.8)</td>
</tr>
<tr>
<td>Native Canadian</td>
<td>16 (3.7)</td>
</tr>
<tr>
<td>Black/African Canadian</td>
<td>15 (3.5)</td>
</tr>
<tr>
<td>Other/Mixed</td>
<td>25 (5.8)</td>
</tr>
<tr>
<td><strong>Self-reported general health, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>24 (5.6)</td>
</tr>
<tr>
<td>Very good</td>
<td>86 (20.0)</td>
</tr>
<tr>
<td>Good</td>
<td>188 (43.8)</td>
</tr>
<tr>
<td>Fair</td>
<td>98 (22.8)</td>
</tr>
<tr>
<td>Poor</td>
<td>33 (7.7)</td>
</tr>
<tr>
<td><strong>Education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>35 (8.2)</td>
</tr>
<tr>
<td>High school graduation</td>
<td>88 (20.5)</td>
</tr>
<tr>
<td>Some college or university</td>
<td>163 (38.0)</td>
</tr>
<tr>
<td>University degree</td>
<td>102 (23.8)</td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>34 (7.9)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (1.6)</td>
</tr>
<tr>
<td><strong>Employment, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>162 (37.8)</td>
</tr>
<tr>
<td>Part-time</td>
<td>63 (14.7)</td>
</tr>
<tr>
<td>Not working</td>
<td>204 (47.6)</td>
</tr>
<tr>
<td><strong>Marital status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Married or partnered</td>
<td>186 (43.4)</td>
</tr>
<tr>
<td>Never married</td>
<td>166 (38.7)</td>
</tr>
<tr>
<td>Divorced or separated</td>
<td>57 (13.2)</td>
</tr>
<tr>
<td>Widowed</td>
<td>20 (4.7)</td>
</tr>
<tr>
<td><strong>Patient Health Questionnaire-9</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14.0 (6.0)</td>
</tr>
<tr>
<td>Minimal (0-4), n (%)</td>
<td>19 (4.4)</td>
</tr>
<tr>
<td>Mild (5-9), n (%)</td>
<td>84 (19.6)</td>
</tr>
<tr>
<td>Moderate (10-14), n (%)</td>
<td>130 (30.3)</td>
</tr>
<tr>
<td>Moderately severe (15-19), n (%)</td>
<td>106 (24.7)</td>
</tr>
<tr>
<td>Severe (20-27), n (%)</td>
<td>90 (21.0)</td>
</tr>
<tr>
<td><strong>Generalized anxiety disorder</strong></td>
<td></td>
</tr>
<tr>
<td>Characteristic</td>
<td>Value</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>11.6 (5.5)</td>
</tr>
<tr>
<td>Minimal (0-4), n (%)</td>
<td>45 (10.5)</td>
</tr>
<tr>
<td>Mild (5-9), n (%)</td>
<td>115 (26.8)</td>
</tr>
<tr>
<td>Moderate (10-14), n (%)</td>
<td>130 (30.3)</td>
</tr>
<tr>
<td>Severe (15-21), n (%)</td>
<td>139 (32.4)</td>
</tr>
</tbody>
</table>

**Alcohol use**

- At-risk drinker:<sup>a</sup> 156 (36.4)
- Number of weekly standard drinks, mean (SD) 7.2 (12.8)
- Median (range) 2 (0-113)
- Q1-Q3 0-9

<sup>a</sup>At-risk drinker: males with 15 or more drinks per week or 5 or more in a given day; females with 10 or more drinks per week or 4 in a given day; or participants endorsing 2 or more symptoms of The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Alcohol Use Disorder.

Table 3. Reasons given for declining consent or withdrawing prior to completing the baseline assessment.

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Number of times reason was given (n=121)&lt;sup&gt;a&lt;/sup&gt;, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns with telephone components or prefers in-person assessment and treatment</td>
<td>19 (15.7)</td>
</tr>
<tr>
<td><strong>Concerns with other research components</strong></td>
<td></td>
</tr>
<tr>
<td>Time commitment (30)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Not a good fit (11)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Privacy concerns (9)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Concerns with research participation or design (8)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Communication and logistic barriers (7)&lt;sup&gt;b&lt;/sup&gt;</strong></td>
<td></td>
</tr>
<tr>
<td>Moving (4)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Language or hearing problems (2)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Unavailable during study times (1)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Prefers or already pursuing other treatment</td>
<td>18 (14.9)</td>
</tr>
<tr>
<td><strong>Does not believe treatment is needed</strong></td>
<td></td>
</tr>
<tr>
<td>Feeling better (14)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Not interested in seeking help (1)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Other reasons</td>
<td>4 (3.3)</td>
</tr>
</tbody>
</table>

<sup>a</sup>121 reasons provided by 99 patients who declined consent and 15 who withdrew prior to completing the baseline assessment (some provided multiple responses).

<sup>b</sup>The number of patients who provided “time commitment” as the reason.

<sup>c</sup>N/A: not applicable.
Table 4. Reasons given for withdrawal after randomization.

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Number of times reason given (n=41)(^a), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study not helpful</td>
<td>19 (46)</td>
</tr>
<tr>
<td>Time commitment</td>
<td>9 (22)</td>
</tr>
<tr>
<td>Uncomfortable with assessments</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Prefers pursuing other treatment</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Feeling better</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Expected counseling</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Other reasons</td>
<td>2 (5)</td>
</tr>
</tbody>
</table>

\(^a\)41 reasons provided by 44 participants who withdrew after randomization (some provided multiple reasons; some provided no reasons).

Figure 2. Distribution of responses to the question “overall, how would you rate the services you received?”(n=121).

Table 5. Major topics related to use of phone from the satisfaction survey.

<table>
<thead>
<tr>
<th>Topics</th>
<th>Number of comments (n=45)(^a), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive comments</td>
<td></td>
</tr>
<tr>
<td>Accessibility and convenience of calls</td>
<td>21 (47)</td>
</tr>
<tr>
<td>Flexibility</td>
<td>7 (16)</td>
</tr>
<tr>
<td>Privacy and anonymity</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Liked phone calls</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Text reminders</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Negative comments</td>
<td></td>
</tr>
<tr>
<td>Would prefer in-person services</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Barriers associated with telephone use</td>
<td>3 (7)</td>
</tr>
</tbody>
</table>

\(^a\)45 comments provided by 39 participants (some provided multiple comments).
Discussion

Principal Findings
We assessed the acceptability of computer-aided telephone assessments and support for primary care patients with depression, anxiety, and at-risk drinking. Telephone services were highly acceptable, as demonstrated by high consent and retention rates and overall positive feedback. Only a small proportion of referred patients cited the use of telephone as their main reason for declining to participate and none cited this as a reason for withdrawing after randomization.

Comparisons with Prior Work
Our results are congruent with those of several previous studies that have demonstrated telephone as an effective means of engaging some patients in mental health screening and interventions [9-13,18]. Several of our findings deserve further comment. First, we were unable to reach and engage approximately 10.3% (69/667) of the patients referred to the study despite attempting to call them up to 10 times over a period of 1 month. Similarly, despite multiple attempts, we could not complete the baseline assessment in 6.7% (32/476) of the participants who consented. Although these rates are low, they illustrate the decreased engagement opportunities of a telephone intervention compared with an intervention embedded in a practice setting. Also, although PCPs were informed about this inability to contact their patients, we do not know what happened to these patients.

Only a small proportion of those who were contacted declined to participate. The main reason cited was the time commitment required to participate in the study. The second reason was a preference for other treatment, typically counseling or psychotherapy. By contrast, only a few specifically mentioned being uncomfortable with telephone assessments and intervention. A few patients also explicitly indicated a preference for speaking with a trained professional. Thus, although lay providers may facilitate access to mental health care by increasing the supply of providers and decreasing costs, they may not be accepted by all patients.

The retention rate was over 80%, higher than the retention rate in most 12-month or shorter randomized studies of mental health interventions [22]. Previous studies of telephone interventions have shown similar high retention rates [9,12,14-17]. The use of cellular phones by almost all participants, in combination with appointment text reminders, may have contributed to the high retention rate because it facilitated participants’ availability. Taken together, these results support the acceptability of computer-aided telephone-based mental health support in primary care. Furthermore, our high retention rate in a study in which half of the participants were randomized to a low intensity condition (ie, telephone assessments every 4 months) suggests that frequent calls may not be needed to promote retention. In some prior studies, the retention rate was negatively correlated with the length of the study (as would be expected) and with the frequency of contacts [9,12,14,15,17]. This suggests that many patients prefer a shorter time commitment. After randomization, none of the relatively small number of participants who withdrew cited the use of telephone as their reason. The main reported reason was that “participation was not helpful,” but about one-fifth did not provide a reason for withdrawal. We did not identify specific characteristics (eg, age, gender, mental health condition) associated with withdrawal from the study (data not shown).

Finally, the satisfaction survey responses were almost universally positive and highlighted several advantages of a telephone intervention. As expected, participants identified accessibility and convenience. Access is particularly important in rural areas where resources are scarce [9]. A telephone intervention can also be used to engage those people for whom driving or other aspects of mobility are issues, such as older adults [9]. Participants also appreciated being contacted promptly and the flexible call times, obviating the need to take time off work or school. Some participants also identified privacy and anonymity as advantages of the telephone intervention. Thus, we believe it helped alleviate the stigma that remains attached to accessing mental health services. Similarly, some participants reported that the relative anonymity of telephone calls made it easier to disclose and discuss sensitive issues such as suicidal ideation, self-harm, or past traumas not previously disclosed to their PCP.

Limitations
The main limitations are owing to our study not being designed to directly assess the acceptability of the phone intervention. First, some patients declined the referral to the study, and we did not collect the number of, or reasons for, these refusals. Though we believe that most were owing to concerns about participating in a randomized trial, some may have been because of the telephone intervention. Thus, our results may overestimate the acceptability of this type of service. A different study eliciting preference for an in person versus a telephone intervention, followed by randomization to one of these interventions, would be needed to compare the acceptability and adherence to these 2 types of interventions in the general patient population. However, the high retention rate supports the acceptability of the telephone intervention in those who consented to the study. Second, the satisfaction survey was completed during the last assessment and it is possible that we would have obtained less positive feedback from the small number of participants who discontinued the study early.

Conclusion
Many patients in primary care settings cannot access traditional mental health care. Fully automated interventions (eg, Web-based therapy) offer potential innovative and cost-effective solutions to this problem [23,24]. Although these more advanced technologies are being developed, “plain-old telephone” can be combined with computer-based assessments and support. This approach seems to be highly acceptable to a large number of primary care patients. Furthermore, even when in-person or fully automated services are available, computer-aided telephone-based mental health services may have unique advantages for some subgroups of patients. We envision a future mental health system that optimizes access and quality by integrating multiple modes of service delivery—in person, by phone, and via Web-based and mobile platforms.

http://mental.jmir.org/2018/4/e10224/
Acknowledgments

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Authors' Contributions

BHM, AP, and DO conceptualized and designed the study. VG and SZ were the Mental Health Technicians who delivered the intervention. JC conducted structured assessments. DR, AP, and BHM provided supervision to the Mental Health Technicians and Research Associates. SZ, VG and JC analyzed the data and conducted the literature search. SZ and BHM drafted the manuscript. All authors provided critical input and reviewed the final manuscript.

Authors' roles in the PARTNERs Study Group: Principal Investigator: BHM; Project Psychiatrist and Co-investigator: DR; Project Director: AP; Co-investigators: AC, RG, AL, BM, NS; Mental Health Technicians: VG, SZ; Research Associate: JC; Consultant: DO.

Conflicts of Interest

BM receives compensation from the following: the Department of Psychiatry, University of Toronto, Toronto, Ontario; CAMH, Toronto, Ontario; and the University of Pittsburgh, Pittsburgh, Pennsylvania. He belongs to the Board of Trustees of CAMH, Toronto, Ontario. He currently receives research support from Brain Canada, the Canadian Institutes of Health Research, the CAMH Foundation (funding of the study described in this paper with a gift from Bell Canada), the Patient-Centered Outcomes Research Institute, the US National Institute of Health (NIH), Capital Solution Design Limited Liability Corporation (software used in the study described in this paper), and HAPPYneuron (software used in a study founded by Brain Canada). Within the past 5 years, he has also received research support from Bristol-Myers Squibb (medications for a NIH–funded clinical trial), Eli-Lilly (medications for an NIH–funded clinical trial), and Pfizer (medications for an NIH–funded clinical trial). He directly owns stocks of General Electric (less than Can $5000).

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2MB - mental_v5i4e10224_app1.pdf ]

References


20. Koenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [Medline: 11556941]


Abbreviations

BHL: Behavioral Health Laboratory
CAMH: Centre for Addiction and Mental Health
MHT: Mental Health Technicians
NIH: National Institute of Health
PARTNERs: the Primary care Assessment and Research of a Telephone intervention for Neuropsychiatric conditions with Education and Resources study
PCP: primary care provider
RA: research associate

http://mental.jmir.org/2018/4/e10224/
Predicting Change in Posttraumatic Distress Through Change in Coping Self-Efficacy After Using the My Trauma Recovery eHealth Intervention: Laboratory Investigation

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Abstract

Background: Technology offers a unique platform for delivering trauma interventions (ie, eHealth) to support trauma-exposed populations. It is important to evaluate mechanisms of therapeutic change in reducing posttraumatic distress in eHealth for trauma survivors.

Objective: This study evaluated a proactive, scalable, and individually responsive eHealth intervention for trauma survivors called My Trauma Recovery. My Trauma Recovery is an eHealth intervention aiming to support trauma survivors and consisting of 6 modules: relaxation, triggers, self-talk, professional help, unhelpful coping, and social support. It was designed to enhance trauma coping self-efficacy (CSE). We tested 3 hypotheses. First, My Trauma Recovery would decrease posttraumatic stress symptoms (PTSS). Second, My Trauma Recovery would increase CSE. And last, changes in CSE would be negatively correlated with changes in PTSS.

Methods: A total of 92 individuals exposed to trauma (78/92, 85% females, mean age 34.80 years) participated. Our study was part of a larger investigation and consisted of 3 sessions 1 week apart. Participants completed the baseline online survey assessing PTSS and CSE. Each session included completing assigned modules followed by the online survey assessing CSE. PTSS was remeasured at the end of the last module.

Results: PTSS significantly declined from T1 to T9 ($F_{1,90}=23.63, P<.001, \eta^2_p=.21$) supporting the clinical utility of My Trauma Recovery. Significant increases in CSE for sessions 1 and 2 ($F_{8,83}=7.51, P<.001$) were found. No significant change in CSE was found during session 3 (N=92). The residualized scores between PTSS T1 and T9 and between CSE T1 and T9 were calculated. The PTSS residualized score and the CSE residualized score were significantly correlated, $r=-.26, P=.01$. Results for each analysis with a probable PTSD subsample were consistent.

Conclusions: The findings of our study show that participants working through My Trauma Recovery report clinically lower PTSS after 3 weeks. The results also demonstrate that CSE is an important self-appraisal factor that increased during sessions 1 and 2. These improvements are correlated with reductions in PTSS. Thus, changes in CSE may be an important mechanism for reductions in PTSS when working on a self-help trauma recovery website and may be an important target for eHealth interventions for trauma. These findings have important implications for trauma eHealth interventions.

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KEYWORDS
eHealth; posttraumatic stress disorder (PTSD); coping self-efficacy (CSE); trauma triggers; relaxation; digital behavior change interventions (DBCI); internet

Introduction
Mechanisms of Change for eHealth Interventions
eHealth interventions have demonstrated successful outcomes in reducing posttraumatic stress symptoms (PTSS) [1]. A meta-analytic study showed that eHealth interventions had medium to large effect sizes in reducing PTSS and trauma-related panic disorder, and the efficacy of the interventions was comparable to face-to-face therapy [2]. Amstadter and colleagues [1] argued that features such as psychoeducation, goal setting, exposure, and theoretical basis (eg, cognitive behavioral therapy) enhanced the efficacy of eHealth interventions in reducing symptoms. Most importantly, the more extensively eHealth interventions are developed based on a theory, the better their outcomes [2]. eHealth interventions that are based on theoretical models provide the opportunity to evaluate mechanisms of change that are predicted based on the theory. Understanding mechanisms of change through empirical experimental analysis provides important information for enhancing eHealth interventions. My Trauma Recovery (MTR) is a theoretically designed eHealth intervention for trauma survivors. The focus of this paper is to evaluate coping self-efficacy (CSE) as a key theoretically based mechanism of empowerment for users of MTR.

Benight and Bandura [3] suggested that social cognitive theory (SCT) provides a useful framework to understand trauma adaptation. Trauma recovery requires that individuals manage both extreme internal (eg, intrusive thoughts, hyperarousal) and external (eg, on-going posttraumatic stressors) demands putting a spotlight on self-regulation. SCT posits that self-regulation is managed through bidirectional interactions among environmental conditions, coping behaviors, and person factors [4]. Human beings use self-evaluation to determine success or failure in attaining valued goals (eg, regaining a sense of normalcy), thereby making coping adjustments based on environmental feedback. CSE perceptions are a primary factor in this self-evaluation feedback system predicting empowered perseverance or resigned giving up [4].

Previous studies have investigated effects of trauma and a posttrauma recovery process within the SCT framework. These studies examined the effects of trauma-specific CSE on PTSS. CSE appraisals were negatively associated with PTSS among survivors of natural disasters [5,6], terrorist attacks [7], motor vehicle accidents [8,9], and childhood sexual abuse [10]. In addition, CSE has shown to be a strong mediator between trauma-related distress variables (eg, negative cognitions) and negative outcomes [5,10]. It is important to note that a meta-analytic review of CSE in trauma adaption demonstrated effect sizes for longitudinal studies ranging from $r=-.55$ to $r=-.62$ with negative psychological outcomes [11]. These effect sizes are much stronger than other predictors often cited in posttraumatic outcome studies (eg, dissociation, $r=.35$; previous psychopathology, $r=.17$; or social support, $r=-.28$) [12]. Thus, CSE perceptions provide a useful target for evaluation as a mechanism of change that has shown to be significantly related to important posttraumatic outcomes. Our study examined the importance of CSE changes in psychological improvement while working through modules of the MTR website.

My Trauma Recovery Description and Evaluation
MTR offers 6 self-directed modules (relaxation, triggers, social support, professional help, self-talk, and unhelpful coping; see Figure 1 for the homepage of the website) based on SCT and underlying cognitive behavioral principles of self-management. The interactive website uses video and audio segments for modeling, feedback on progress to promote mastery, verbal persuasion through encouraging text, and physical arousal management through relaxation training [4]. Evidence for the clinical effectiveness of MTR is based on a study in the United States and a set of studies in China [13,14]. A randomized controlled trial (RCT) of the disaster recovery version of MTR showed that the website, compared to an information-only website, significantly reduced worry among survivors of Hurricane Ike (partial $\eta^2=.11$, large effect size) [14]. In this study, CSE perceptions increased in the intervention group ($\eta^2=.05$, medium effect size), although the effect was not statistically significant due to limited statistical power. An RCT of the Chinese version of MTR showed a significant reduction in PTSS after 1 month with a large effect size (Cohen $d=0.81$) and remained strong at the 3-month follow-up (Cohen $d=0.87$) in an urban sample. The effect was even stronger in a rural sample both at posttest (Cohen $d=1.34$) and at the 3-month follow-up (Cohen $d=0.99$) [13]. However, CSE did not significantly increase in this RCT. Thus, early studies suggest that MTR can help improve mental health following traumatic exposure. However, it remains unclear how important CSE perceptions are as a mechanism of change in PTSS when working with these eHealth interventions. This study provides evidence to help fill this void.
This Study

This study analyzed changes in CSE perceptions throughout the sessions and how these changes related to changes in PTSS between pre- and post-sessions. The module order manipulation also allowed us to evaluate the importance of differential skill building in relation to changes in CSE and PTSS. Collectively, these data provide critical information to evaluate the importance of changes in CSE perceptions as a mechanism of change in the reduction in PTSS among trauma-exposed populations working on an eHealth intervention. This study was a part of a larger project to develop learning-based computer models mapping from sensory and facial/voice data to engagement, arousal, and self-efficacy states. The larger study used machine learning to develop a smart system to help maximize user benefit from the site.

Hypotheses

The following hypotheses were generated for this study:

- **Hypothesis 1**: We hypothesized that PTSS would decrease from baseline to completion of all 3 sessions because previous studies have demonstrated a positive effect for trauma survivors using the site.
- **Hypothesis 2**: We hypothesized that CSE would increase as users engaged in the website because the site was designed based on SCT with specific interactive features to promote greater CSE (ie, personal empowerment).
- **Hypothesis 3**: We predicted that changes in CSE would be positively associated with reductions in PTSS.

Methods

Participants

Overview

A large diverse sample was purposively recruited in order to gather a wide range of responses to the MTR website to assist the machine learning aspect of the larger study. This also provides greater external validity for our study. Participants were survivors of domestic violence recruited from a local shelter, patients at local mental health clinics, people listed on a study registry at a trauma clinic, and undergraduate students who were enrolled in psychology courses at a university in the Mountain region of the United States. The inclusion criteria for this study were that participants must be aged 18 years or older and have had a traumatic experience within the past 2 years. In total, 93 trauma-exposed individuals completed session 1. One participant was excluded because that person worked on a different module from the one assigned, resulting in 92 individuals exposed to trauma (78/92, 85% females, mean age 34.80 years, SD 14.15) in session 1. Among these participants, 82 completed session 2, and 76 participated in all 3 sessions.

Table 1 shows demographic information of participants. Participants reported exposure to a wide range of traumatic events in the past 2 years including intimate partner abuse (35/92, 38%), sudden death of a close friend or loved one (27/92, 29%), threat of death or serious bodily harm (26/92, 28%), motor vehicle accidents (19/92, 21%), adult sexual abuse or assault (19/92, 21%), other accidents (14/92, 15%), severe assault by acquaintance or stranger (14/92, 15%), life-threatening illness (12/92, 13%), witness to family violence (12/92, 13%), miscarriage (12/92, 13%), natural disasters (9/92, 10%), witness to a severe assault of acquaintance or stranger (7/92, 8%), combat (5/92, 5%), life-threatening or permanently
disabling illness of a loved one (5/92, 5%), childhood physical abuse (4/92, 4%), robbery involving a weapon (2/92, 2%), childhood sexual abuse by someone at least 5 years older (2/92, 2%), abortion (1/92, 1%), and other (6/92, 7%).

Posttraumatic Stress Symptoms

Posttraumatic stress disorder (PTSD) Checklist Version 5 (PCL-5) was used to assess 4 symptom clusters of PTSD (intrusion, avoidance, negative alterations in cognitions and mood, and alterations in arousal and reactivity) corresponding to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, symptom criteria [15,16]. The PCL-5 is a 20-item measure assessing how bothersome each symptom was in the past month on a 5-point scale ranging from 0 (not at all) to 4 (extremely). Respondents were asked to complete each item with the stem “In the past month, how much were you bothered by...” Sample items included “Repeated, disturbing, and unwanted memories of the stressful experience” and “Trouble remembering important parts of the stressful experience.” Scores range between 0 and 80. Cronbach alpha coefficients were .95 at the baseline and .96 at the end of session 3.

Trauma Coping Self-Efficacy

The Trauma Coping Self-Efficacy Scale was used to assess coping self-efficacy appraisals for dealing with posttrauma challenges [17]. The scale comprises 9 items assessing the perception of capability to deal with internal and external demands on a 7-point scale ranging from 1 (not at all capable) to 7 (totally capable). Respondents answered each question with the stem “I am capable to...” Sample items included “Get my life back to normal” and “Not ‘lose it’ emotionally.” Total scores range between 1 and 49 and overall mean scores from 1 to 7. Overall mean scores are offered for ease of interpretation. Internal reliability coefficients were .89 at the baseline (T1), .92 after module 1 in session 1 (T2), .93 after module 2 in session 1 (T3), .92 at the beginning of session 2 (T4), .92 after module 1 in session 2 (T5), .93 after module 2 in session 2 (T6), .92 at the beginning of session 3 (T7), .93 after module 1 in session 3 (T8), and .95 after module 2 in session 3 (T9).

Trauma History

Traumatic Life Events Questionnaire was used to assess whether respondents have had a traumatic experience in the past 2 years [18]. It is a list of 22 traumatic events where respondents answer with “yes” or “no” depending on whether or not they have experienced the event. Sample items included natural disasters, intimate partner abuse, and robbery involving a weapon.

Procedures

Qualified participants were invited to the laboratory for 3 sessions, each 1 week apart (see Figure 2 for the study design). Upon arrival to the lab, participants were asked by a research assistant to wash their hands to ensure accurate measurement of skin conductance. Participants then completed the baseline online survey assessing PTSS, CSE, and demographics. After participant completion of the baseline online survey (T1), a research assistant attached the respiration band and electrodes for the electrocardiogram and skin conductance.

Participants watched an introductory video that described an overview of the website. Immediately following the video, participants were asked to close their eyes and relax for 1 minute in order to gather baseline physiological assessments. Next, participants worked on the randomly assigned first module (either triggers or relaxation) followed by the online survey assessing CSE (T2). This procedure was repeated for the second module (T3). One week later participants repeated the same process except they completed the CSE before they began the module (T4). The order of the modules was counterbalanced as they completed the 2 modules again. CSE was assessed after each module (T5 and T6). The final session included the same procedures used in sessions 1 and 2, except for the modules participants completed. Two modules were randomly selected from the remaining 4 modules (ie, seeking professional help, social support, unhelpful coping, self-talk). CSE was again assessed before they worked on the modules (T7) and after they finished each module (T8, T9). The participants also completed the PCL-5 at the end of the last module. Participants received US $25 after each session. Local and national mental health resources were provided to all participants after the study.

Statistical Analysis

First, we performed a 2 (module order) × 2 (assessment period) mixed multivariate analysis of variance (MANOVA) on PTSS to test whether PTSS improved after the use of MTR (hypothesis 1). Dependent variables were PTSS at baseline and the end of the study. Significant effects were followed up with post hoc follow-up tests using the Fisher least significant difference method.

Similarly, we conducted a 2 (module order) × 3 (session) × 3 (assessment period) MANOVA on CSE across all time points to analyze whether CSE increased as participants continued to use the website (hypothesis 2). SPSS Statistics version 24 (IBM Corp) was used for the analysis. Dependent variables included CSE at baseline, after module 1, and after module 2 for all 3 sessions.

The effect of change in CSE on changes in PTSS was evaluated using a bivariate correlation between the residualized change score for CSE from T1 to T9 and the residualized change score for PTSS T1 to T9.

Missing Data Treatment

Missing data were imputed using the maximum likelihood estimation in analysis of a moment structures. The assumption of the maximum likelihood imputation is that missing data must be at least missing at random. Because there is no procedure to assess missing at random, we performed a test of Little missing completely at random for all study variable items (χ² = 442.98, P = .62). Thus, all missing data were imputed. In total, 1.85% of the session 1 values, 11.27% of the session 2 values, and 17.41% of the session 3 values were imputed.
Table 1. Descriptive statistics for demographics (some percentages do not add up to 100% due to missing data; N=92).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) mean (SD)</td>
<td>14.15 (34.80)</td>
</tr>
<tr>
<td>Age (years), range</td>
<td>18-79</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>78 (84.8)</td>
</tr>
<tr>
<td>Male</td>
<td>14 (15.2)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
</tr>
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<td>68 (73.9)</td>
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<tr>
<td>African American</td>
<td>14 (15.2)</td>
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<tr>
<td>Hispanic/Latino</td>
<td>9 (9.8)</td>
</tr>
<tr>
<td>Native American/Alaskan</td>
<td>7 (7.6)</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>5 (5.4)</td>
</tr>
<tr>
<td>Other/prefer not to answer</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Intimate relationship, n (%)</td>
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<tr>
<td>Single</td>
<td>32 (34.8)</td>
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<tr>
<td>Divorced</td>
<td>21 (22.8)</td>
</tr>
<tr>
<td>Married</td>
<td>17 (18.5)</td>
</tr>
<tr>
<td>Separated</td>
<td>13 (14.1)</td>
</tr>
<tr>
<td>Widowed</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Other</td>
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<tr>
<td>Highest education, n (%)</td>
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<td>High school</td>
<td>24 (26.1)</td>
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<tr>
<td>Some college</td>
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<tr>
<td>Associates degree</td>
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<tr>
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<tr>
<td>Master’s degree</td>
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</tr>
<tr>
<td>Other</td>
<td>4 (4.3)</td>
</tr>
<tr>
<td>Income (USD), n (%)</td>
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<td>$25,001-$70,000</td>
<td>21 (22.8)</td>
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<td>&gt;$100,000</td>
<td>10 (10.9)</td>
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<tr>
<td>Seeing mental health provider, n (%)</td>
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<tr>
<td>Yes</td>
<td>50 (54.3)</td>
</tr>
<tr>
<td>No</td>
<td>40 (43.5)</td>
</tr>
</tbody>
</table>
Results

Descriptive Data

Attrition analysis revealed there were no significant differences between session 1 and session 2 and session 2 and session 3 in sex, age, education, and baseline PTSS and CSE. There were no significant differences in baseline PTSS \((t_{90}=1.94, P=.06)\) or CSE \((t_{90}=1.46, P=.18)\) between the 2 module order conditions. Multimedia Appendix 1 displays bivariate correlation coefficients, means, and standard deviations for the study variables. Out of 92 participants, 54 (59%) reported PTSD scores greater than or equal to 33, which is considered a probable diagnostic level. Overall, CSE levels showed negative correlations with PTSS across study time points.

Hypothesis 1: Posttraumatic Stress Symptoms Would Decrease From Baseline to Completion of All 3 Sessions

Findings of a 2 (module order) \(\times\) 2 (assessment periods) MANOVA on PTSS showed that assessment periods were significant, indicating PTSS significantly declined over time \((F_{1,90}=23.63, P<.001, \eta^2_p=.21)\); see Figure 3. Participants' T1 PTSS scores (mean 38.01, SD 19.56) suggested they had on average relatively high initial symptoms of PTSD. Scores above 33 are recommended for diagnosable PTSD [19]. The drop in average PTSS scores at T9 (mean 29.89, SD 17.17) was close to 10 points suggesting a clinically significant reduction of PTSD symptoms according to Weathers et al [19]. The main effect of the module order \((F_{1,90}=3.10, P=.08, \eta^2_p=.03)\) and the interaction between the module order and the assessment periods \((F_{1,90}=1.16, P=.29, \eta^2_p=.01)\) were not significant.

Results from a 2 (module order) \(\times\) 2 (assessment period) MANOVA with participants with probable PTSD diagnosis showed consistent, yet stronger, results. The assessment period was significant \((F_{1,52}=39.07, P<.001, \eta^2_p=.43)\) demonstrating that levels of PTSS declined across the study. The module order \((F_{1,52}=0.13, P=.73, \eta^2_p=.002)\) and the interaction effect between the assessment period and the module order \((F_{1,90}=23.63, P<.001, \eta^2_p=.21)\) were not significant.

Hypothesis 2: Trauma Coping Self-Efficacy Will Increase as Users Engage in the Website

Results of a 2 (module order) \(\times\) 9 (assessment periods) mixed model MANOVA on CSE showed that CSE levels significantly improved across study time points \((F_{8,83}=7.51, P<.001, \eta^2_p=.42)\); see Figure 4, supporting hypothesis 2. Results of the follow-up tests with the least significant difference showed that from T1 to T3 (session 1; \(t_{91}=3.30, P<.001\), T4 to T6 (session 2; \(t_{91}=4.31, P<.001\), and T1 to T9 (all sessions; \(t_{91}=3.70, P<.001\), there were significant increases in CSE on average. There was no significant change in CSE from T7 to T9 (session 3; \(t_{91}=0.41, P=.68\)), CSE did not significantly change from T3 to T4 \((t_{91}=0.38, P=.70)\) and from T6 to T7 \((t_{91}=0.03, P=.97)\). These results of the follow-up tests indicated that CSE significantly increased within sessions 1 and 2 but not within session 3 and between sessions. There was no significant effect of the module order \((F_{1,90}=0.81, P=.37, \eta^2_p=.01)\), and no significant interaction effect between the module order and the assessment periods \((F_{8,83}=1.96, P=.06, \eta^2_p=.16)\).
The 2 (module order) × 2 (assessment period) MANOVA on CSE with participants with probable PTSD showed consistent results (N=54). The assessment period was significant ($F_{8,45}=4.13$, $P<.001$, $\eta^2_p=.42$, Cohen $d=1.70$). Follow-up tests showed that CSE was higher at T3 than T1 ($t_{53}=2.05$, $P=.045$) and at T6 than T4 ($t_{53}=2.02$, $P=.049$). There was no significant difference between T3 and T4 ($t_{53}=0.46$, $P=.65$), T6 and T7 ($t_{53}=0.01$, $P=.99$), or T7 and T9 ($t_{53}=1.27$, $P=.21$). The module order was not significant ($F_{1,52}=1.86$, $P=.18$, $\eta^2_p=.04$), and the interaction effect of the module order and the assessment period was not significant ($F_{8,45}=0.76$, $P=.63$, $\eta^2_p=.12$).
Hypothesis 3: Overall Improvement in Trauma Coping Self-Efficacy Would Predict Decreases in Posttraumatic Stress Symptoms

The bivariate correlations between the overall change in CSE and change in PTSS (using residualized change scores for both variables) demonstrated a significant negative correlation ($r = -0.26, P = 0.01$), explaining approximately 7% of the variance. Among participants with probable PTSD, the correlation between the overall change in CSE and change in PTSS was slightly stronger and also significant ($r = -0.32, P = 0.02$), accounting for 10% of the variance.

Discussion

Principal Findings

Our study provides important information on the clinical utility of MTR in reducing PTSS and the importance of changes in CSE perceptions as a mechanism of change in the reduction in PTSS. Results were supportive of study hypotheses. PTSS significantly decreased from baseline to the end of session 3 ($\eta^2 = 0.27$, Cohen $d = 1.66$), accounting for approximately 7% of the variance. This effect size is consistent with a therapist-assisted cognitive behavior therapy internet intervention for a variety of trauma survivors ($\eta^2 = 0.27$) and with an internet intervention for Iraqi people exposed to war ($\eta^2 = 1.57$) [20,21]. It should be noted that the Web-based intervention used in Iraq includes therapist assistance and exposure-based methods that MTR does not employ.

Notably, self-appraisals of coping capability to manage trauma recovery (CSE) increased across the first 2 study sessions. This implies that trauma survivors working on a self-help trauma recovery website may get the biggest boost to their confidence early when they initially use the relaxation and triggers management modules (hypothesis 2). Significant increases in CSE were also observed during both session 1 and session 2 for the overall sample and the clinical subsample. This is important in that the survivors were working through the same modules they had seen the week before. Thus, the initial boost in self-efficacy was enhanced with further exposure to skills designed to manage hyperarousal and triggering environmental stimuli.

CSE levels did not significantly change during session 3. The lack of continued improvement in self-efficacy perceptions from session 3 is difficult to interpret. It is possible that the first 2 sessions provided the maximum benefit for efficacy change. Indeed, CSE was close to maximum values by the end of session 3. Among participants with probable PTSD, the correlation between the overall change in CSE and change in PTSS was slightly stronger and also significant ($r = -0.32, P = 0.02$), accounting for 10% of the variance.

In a study on the MTR, Wang et al [13] did find reductions in PTSS compared to a control group. They also reported results on CSE change compared with a wait-list group after working on the Chinese version of the MTR. They found that CSE was not significantly different between the treatment and comparison groups after 1 month even though CSE slightly increased from
the baseline to 1-month follow-up in the treatment group. In comparison, Steinmetz et al. [14] did find increases in CSE following use of the My Disaster Recovery site (a sister site to MTR) after Hurricane Ike demonstrating a moderate effect size, although it should be noted that this effect was not statistically significant due to the low statistical power for this study. These inconsistencies between our study and the study conducted by Wang et al. [13] might be due to cultural differences. An RCT of the English version of the MTR needs to be conducted to directly compare changes in CSE with the Chinese version.

**Clinical Implications**

The first clinical implication is the possible value of the MTR website for reducing PTSS. As a standalone website, this provides a useful tool to assist survivors in their recovery. The CSE findings also have important implications for clinical interventions. Coping self-efficacy often serves a crucial role in other clinical interventions. For example, a group intervention for veterans with PTSD demonstrated increases in self-efficacy as a therapeutic target [27]. Wiedenfeld et al. [28], in an experiment with spider phobics, showed that enhancing self-efficacy directly related to improvements in immune functioning. Therapeutic improvements in coping self-efficacy following a group intervention for HIV-positive patients mediated reductions seen in stress and burnout [29]. In another study with patients who contracted HIV, high CSE was related to adherence to antiretroviral treatment [30,31]. Last, changes in self-efficacy perceptions as well as baseline levels predicted both physical and psychological improvements in a sample of patients with multiple sclerosis [32]. Although these medical disorders are different than coping with trauma, these findings suggest that strong perceptions of capability to manage challenging demands are important in predicting important behavioral outcomes. Indeed, significant research with trauma survivors demonstrates the importance of CSE perceptions in healthy and unhealthy adaptation [3,11].

**Limitations**

Several limitations should be considered when interpreting the findings in this study. First, the research design limits the causal interpretation of our data. A nontreatment control condition was not included, making the changes in PTSS or CSE difficult to interpret relative to the website versus general improvement over time. An RCT with an appropriate control condition is needed to more effectively evaluate the effect of MTR on PTSS and CSE. Second, we only examined the order effect for 2 of the 6 modules. The influence of order with the rest of the 4 modules was not investigated. Future studies must evaluate the order effects of the remaining 4 modules. Last, the use of the modules was in a controlled laboratory environment, which may have influenced our findings due to demand effects, interactions with laboratory personnel, and payment for participating versus a more natural use of the website.

**Conclusions**

Our study examined whether using MTR resulted in significant reductions in PTSS, whether levels of CSE changed throughout the 3 study sessions over 3 weeks, and whether the changes in CSE predicted changes in PTSS after using the website. The findings confirmed that PTSS symptoms went down using MTR over the study period, trauma survivor CSE improved, and change in CSE correlated with changes in posttraumatic distress. Our study offers support for the clinical value of the standalone MTR and offers initial evidence for a therapeutic mechanism for the reduction in PTSS after working on a trauma recovery website.

**Acknowledgments**

This study was supported by the National Science Foundation Smart and Connected Health program (IIS-1418520).

**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**

Correlations, means, and standard deviations of posttraumatic stress symptoms and coping self-efficacy.

[PDF File (Adobe PDF File), 41KB - mental_v5i4e10309_app1.pdf ]

**References**


Abbreviations
CSE: coping self-efficacy
MANOVA: multivariate analysis of variance
MTR: My Trauma Recovery
PCL-5: Posttraumatic Stress Disorder Checklist version 5
PTSD: posttraumatic stress disorder
PTSS: posttraumatic stress symptoms
RCT: randomized controlled trial
SCT: social cognitive theory

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Original Paper

Interaction and Engagement with an Anxiety Management App: Analysis Using Large-Scale Behavioral Data

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Abstract

Background: SAM (Self-help for Anxiety Management) is a mobile phone app that provides self-help for anxiety management. Launched in 2013, the app has achieved over one million downloads on the iOS and Android platform app stores. Key features of the app are anxiety monitoring, self-help techniques, and social support via a mobile forum (“the Social Cloud”). This paper presents unique insights into eMental health app usage patterns and explores user behaviors and usage of self-help techniques.

Objective: The objective of our study was to investigate behavioral engagement and to establish discernible usage patterns of the app linked to the features of anxiety monitoring, ratings of self-help techniques, and social participation.

Methods: We use data mining techniques on aggregate data obtained from 105,380 registered users of the app’s cloud services.

Results: Engagement generally conformed to common mobile participation patterns with an inverted pyramid or “funnel” of engagement of increasing intensity. We further identified 4 distinct groups of behavioral engagement differentiated by levels of activity in anxiety monitoring and social feature usage. Anxiety levels among all monitoring users were markedly reduced in the first few days of usage with some bounce back effect thereafter. A small group of users demonstrated long-term anxiety reduction (using a robust measure), typically monitored for 12-110 days, with 10-30 discrete updates and showed low levels of social participation.

Conclusions: The data supported our expectation of different usage patterns, given flexible user journeys, and varying commitment in an unstructured mobile phone usage setting. We nevertheless show an aggregate trend of reduction in self-reported anxiety across all minimally-engaged users, while noting that due to the anonymized dataset, we did not have information on users also enrolled in therapy or other intervention while using the app. We find several commonalities between these app-based behavioral patterns and traditional therapy engagement.

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KEYWORDS
anxiety; mobile phone; eMental health; mHealth

Introduction

Background

Anxiety is one of the most common mental health problems; in 2013, there were 8.2 million cases of diagnosed anxiety disorders reported in United Kingdom [1]. The cost of anxiety—treatment, health care, and indirect costs such as loss of employment and productivity—was estimated at €11.6 billion [2]. The current demands on mental health services are considerable [3] and at the same time, there may be a lack of help seeking among young people [4,5]. Digital self-help and education tools are seen as possible ways to help alleviate both demand and lack of support seeking and have shown potential...
to be effective in anxiety reduction [6,7]. The development of SAM (Self-help for Anxiety Management) was driven by a desire to produce a generic, flexible tool for anxiety self-help that provided ease of access and embodied high standards of usability. A report on the development, structure, and functions of the app is available [8]. Although there has been significant uptake, 1,007,469 downloads users in over 100 countries with an average of 40,000 regular users each month as of October 2017, it is important to understand how users are engaging with it, what features are most used, and whether logs of usage and self-reporting measures can provide insights as a first step in evaluating its therapeutic impact. In general, there has been insufficient work on mHealth app engagement and its associations with intended outcomes [9].

This paper reports on the analysis of user data and its therapeutic implications from the first 3 years of SAM’s availability to a global population of users. In this introduction, we will first position this study in terms of approaches to understanding engagement and present related work on behavioral engagement with mHealth apps. Next, we present the overall design philosophy and main features of the app. Based on these reference points, we will then outline our aims for the research.

**Approaches to Engagement**

Engagement can be seen to be constituted as the relationship between a consumer and an individual product or service. A rounded view should incorporate emotional, usability, and behavioral factors [10]. Behavioral engagement can be defined in terms of users’ interactions with different app functions and features, both quantitative and longitudinal.

Although our qualitative impact data (eg, from user reviews) provide evidence of usability and emotional engagement and will be the subject of future investigations, this study focuses on behavioral engagement through analysis of app interaction data over time.

**Related Work**

We know of no previous work that has looked at user engagement specifically with eMental Health tools. Previous similar work focusing on behavioral aspects of engagement with other kinds of service has looked at recognizable subgroups of users, engagement periods, and correlates of engagement with mHealth apps. Next, we present the overall design philosophy and main features of the app. Based on these reference points, we will then outline our aims for the research.

In terms of usages modalities, the app was designed with flexible pathways of navigation so that users could choose to engage either in organic or more structured processes of self-help for anxiety management. This is in line with the “snowflake” model of cognitive-behavioral therapy and “reciprocal interaction” model which empowers patients to manage their own condition [15,16].

Self-monitoring is a core skill in effective self-help [17-19] and SAM provides a function to self-report on 4 dimensions of anxiety (feelings, thoughts, physiological reactions, and avoidance) and to report trends in these dimensions over time.

The app was intended to help people with moderate levels of anxiety to learn to manage that anxiety and to this end, SAM offers users a range of self-help options categorized by modality, level of challenge, and media format. This was to provide an opportunity for users to experiment and determine what works best for them [20].

Given the potential value of mobile peer connection for informational and emotional support [21,22], SAM includes a social forum—the Social Cloud—which users can join to (pseudonymously) share support and advice while learning to manage anxiety.

**Study Aims**

Our enquiries in this study were therefore organized around the following core components of SAM that can be used to assess behavior: user engagement with the app, experience of anxiety as self-reported, user stated context for anxiety, use of self-help options, and peer support. In summary, our aims were as follows:

1. **User engagement with the app and user profiles over time**: To quantify engagement in terms of behavioral signatures and to characterize the user base into behavioral personas through users’ interactions with different app features.
2. **Self-reported experience of anxiety**: To establish the nature and extent of self-monitoring activity by users; to understand the perceived relationships among our dimensions of anxiety used in self-monitoring; to investigate whether engagement with SAM was associated with a meaningful reduction in users’ self-reported levels of anxiety

3. **User stated context for anxiety**: To survey events and situations that users associate with anxiety and which are therefore potential foci for self-help actions

4. **Use of self-help options**: To determine whether user choice and ratings of options indicate any preferences for specific options

5. **Peer support**: To assess the extent of peer support within this community and identify gradations in the amount of support between different Social Cloud users

### Methods

#### Ethics and Data Protection

Ethical approval for this project was granted by the University of the West of England, Bristol, Research Ethics Committee, Faculty of Health and Applied Sciences, Reference No. HAS.16.07.177. Use of anonymized data from the app for academic research purposes is allowed under the app’s terms of service [23].

#### Dataset

The data were a snapshot of application program interface (API; cloud-based) data for the app taken in January 2017 and covering the period from July 2013 to January 2017. This included data from the activity of 105,380 registered users. Because registration with the cloud services is not mandatory in the app, this represents an estimated 15% of the total user base (based on total downloads and allowing for some redownloads by the same users).

#### Data Analysis

**Engagement Coding**

Patterns of user engagement were informed by user data on anxiety monitoring, ratings of self-help options, and Social Cloud activity.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequent monitor?</strong></td>
<td>True if a person has recorded anxiety levels an average of once a day or more frequently through the “How’s my anxiety right now?” feature</td>
</tr>
<tr>
<td><strong>Significant monitor?</strong></td>
<td>True if a person has recorded at least 20 updates of anxiety levels</td>
</tr>
<tr>
<td><strong>Long-term monitor?</strong></td>
<td>True if a person’s anxiety tracking has spanned 14 days or more</td>
</tr>
<tr>
<td><strong>Technique rater?</strong></td>
<td>True if a person has rated a self-help technique, otherwise false</td>
</tr>
<tr>
<td><strong>Social poster?</strong></td>
<td>True if a person has ever posted to the “Social Cloud” forum</td>
</tr>
<tr>
<td><strong>Significant social poster?</strong></td>
<td>True if a person has posted at least 20 times to the “Social Cloud” forum</td>
</tr>
<tr>
<td><strong>Anxiety reducer?</strong></td>
<td>True if there was a reduction of at least 20% between the mean of the first 5 and last 5 anxiety tracking updates on 0-10 scales (mean of the “feelings of anxiety” and “worrying thoughts” scales)</td>
</tr>
<tr>
<td><strong>Long-term social poster?</strong></td>
<td>True if a person’s “Social Cloud” posts span at least 14 days</td>
</tr>
</tbody>
</table>

### Anxiety Monitoring

Users’ experience of anxiety was derived from their self-reports of anxiety on the anxiety monitoring facility (“How’s my anxiety right now?”). Data from the 4 dimensions used, Feelings of anxiety and tension, Worrying thoughts, Avoiding things I fear, and Unpleasant physical sensations, were rated on a 0-10 scale and stored along with a timestamp for the record. We used this to derive users’ monitoring timelines and then for aggregating multiple timelines to visualize mean changes over time.

The minimum clinically important difference (MCID) is the minimum change in symptoms that is considered meaningful to the client. From reviews of its application to other mental health issues [24], we selected a criterion level for MCID of a 20% reduction in anxiety ratings, parameters as defined in Table 1, above for the “Anxiety Reducer” group.
Anxiety Causes and Triggers

The “Things that make me anxious” feature of the app enables the user to identify anxiety triggers in a short piece of text, together with associated anxiety levels. This was used for automated content analysis.

Peer Support

We analyzed Social Cloud posts in terms of number of replies received, filtering to remove self-replies and extracting a complete years’ worth of data (2016). Next, to investigate the profiles of users who reply to other posts, we enumerated the number of distinct users that people had replied to.

Results

As described in the dataset section above, we analyzed results from 105,380 registered users for whom data were logged via the app’s cloud services. Results use this entire dataset unless otherwise specified.

User Engagement and User Profile Subgroups

Table 2 summarizes engagement levels for each of our behavioral variables. We divided anxiety monitoring into 3 variables relating to the duration and frequency of logging. Only 5% (5822/105,380) of the users were found to log anxiety levels more than once a day on average and only 2.5% (2721/105,380) made 20 or more monitoring logs and 14.9% (15,713/105,380) monitored for at least 14 days.

According to our stringent MCID defined above, 2.2% (2327/105,380) of the user base could be said to be anxiety reducers.

In terms of the rating of self-help techniques, 5.5% (5,862/105,380) submitted at least one rating. On the Social Cloud functions, 25.6% (2781/105,380) posted at some point in their usage of the app with only 0.4% (522/105,380) posting 20 or more times and 3.7% (3973/105,380) posting over an extended period.

Our dimensionality computation using MCA on these behavioral variables gave the 7 dimensions shown in Table 3. The first 2 dimensions explained 50% of the variance and the first 5 explained 85%. The relatively low initial 2 eigenvalues and percentage variance explained indicate that the dimension reduction is only partially successful and is explained by the large dataset and the fact that only small percentages of users show “extreme” specialized engagement and a larger percentage show more moderate and mixed engagement.

Figure 1 illustrates the variable values against the first 2 MCA dimensions, indicating a bifurcation at the more extreme ends by social engagement and monitoring engagement. Anxiety reducers were most closely correlated with significant monitors. Long-term social posters also posted significant levels of content.

Figure 2 illustrates the cluster membership against the 2 principle MCA dimensions. Multimedia Appendix 1 shows the cluster statistics for each variable value.

Table 2. Engagement levels by activity (N=105,380).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Users that answered yes, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent monitor?</td>
<td>5,822 (5.52)</td>
</tr>
<tr>
<td>Significant monitor?</td>
<td>2,721 (2.58)</td>
</tr>
<tr>
<td>Long-term monitor?</td>
<td>15,713 (14.91)</td>
</tr>
<tr>
<td>Anxiety reducer?</td>
<td>2,327 (2.21)</td>
</tr>
<tr>
<td>Technique rater?</td>
<td>5,862 (5.56)</td>
</tr>
<tr>
<td>Social poster?</td>
<td>27,081 (25.70)</td>
</tr>
<tr>
<td>Significant social poster?</td>
<td>522 (0.50)</td>
</tr>
<tr>
<td>Long-term social poster?</td>
<td>3,973 (3.77)</td>
</tr>
</tbody>
</table>

Table 3. Components with percentage of variance explained.

<table>
<thead>
<tr>
<th>Multiple correspondence analysis dimension</th>
<th>Eigenvalue</th>
<th>Percentage of variance</th>
<th>Cumulative percentage of variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.30</td>
<td>29.54</td>
<td>29.54</td>
</tr>
<tr>
<td>2</td>
<td>0.21</td>
<td>20.55</td>
<td>50.09</td>
</tr>
<tr>
<td>3</td>
<td>0.14</td>
<td>14.24</td>
<td>64.33</td>
</tr>
<tr>
<td>4</td>
<td>0.11</td>
<td>11.48</td>
<td>75.80</td>
</tr>
<tr>
<td>5</td>
<td>0.09</td>
<td>9.29</td>
<td>85.09</td>
</tr>
<tr>
<td>6</td>
<td>0.08</td>
<td>8.24</td>
<td>93.33</td>
</tr>
<tr>
<td>7</td>
<td>0.07</td>
<td>6.67</td>
<td>100.00</td>
</tr>
</tbody>
</table>
Figure 1. Multiple correspondence analysis-variable map. Dim: dimension.

Figure 2. Cluster analysis: groups (jittering added to points, ellipses show 95% normal confidences). coord.Dim: dimension coordinates.
The 4 cluster categories appear to have the following characteristics supported by the data in Multimedia Appendix 1 (see Multimedia Appendix 1 for group membership and statistics from the MCA output, as defined in [25]).

- **Cluster 1: Brief Users** (65% of sample) monitor their anxiety more than once a day for a short period of time. They do not post on the Social Cloud.
- **Cluster 2: Social Monitors** (30% of sample) are defined by low levels of anxiety monitoring and Social Cloud posts over a longer period of time.
- **Cluster 3: Persistent Monitors** (3.5%) engage in high levels of anxiety monitoring over time with a low level of posts on the Social Cloud.
- **Cluster 4: Socialites** (1.5%) are defined by a high level of Social Cloud posts over time with low levels of anxiety monitoring.

**Experience of Anxiety**

In terms of self-monitoring using the “How’s my anxiety” app feature, Table 4 summarizes their use of this facility. Out of our 105,380 users, less than half monitored their anxiety at least once and only 2.5% monitored it 20 times or more.

Correlations between the anxiety monitoring dimensions are shown in Table 5. All correlations were significant at $P<.001$. There were moderate to high correlations (0.4 to 0.7) between each of the user-rated dimensions of anxiety. Feelings of anxiety and tension were most strongly associated with both worrying thoughts and unpleasant physical sensations. Avoidance was most strongly associated with worrying thoughts and least strongly with unpleasant physical sensations. Although there was some differentiation, the equivalence of correlations might indicate that some users were not discriminating between the 4 components of anxiety.

**Change in Levels of Anxiety**

Anxiety monitoring over time is shown in Figure 3. This covers the first 6 weeks of monitoring by all monitoring users.

The graphs in Figure 3 show a downward trend on all 4 dimensions of anxiety over the measurement period of 40 days. There is a marked dip in aggregated mean anxiety within the first 5 days of using the app; following that, there is variability in the mean anxiety levels across all 4 dimensions with no return to the initial level of anxiety.

**Meaningful Change**

Of the sample (2327 users), 2.2% met our MCID criterion for anxiety reduction. Because this group is of interest in terms of our primary outcome for the app, we also looked in more detail at the behavioral characteristics of the group. Figure 4 summarizes the monitoring and Social Cloud activity for this group. As indicated by our earlier clustering, the anxiety reducers tended not to post on the Social Cloud and typically had a relatively low monitoring count dispersed over a relatively long period of time.

**Causes of Anxiety**

In addition to the self-reported anxiety levels, we also investigated self-reported triggers and causes. In total, there were 105,898 triggers recorded by 35,700 (33.88%) of the registered users with 6072 (5.76%) users making 5 or more entries. The frequency of occurrence of a sample of significant key words is shown in Figure 5.

The corpus of anxiety triggers was further analyzed for common bigrams (2-word phrases) and an association graph between these was constructed, as seen in Figure 6.

**Use of Self-Help Options**

We aggregated the ratings that had been made for the self-help techniques across all users. Table 6 shows the ordering of the most popular self-help options by mean user ratings, showing the number of times each was rated and the self-help category to which each technique belongs. We find highly rated (> 4/5 star) techniques across all of our content categories though, as noted below, the most frequently-rated techniques were associated with the quick-access “Help for anxiety now” screen. We note that mental and motivational information and techniques were among the most highly rated, gaining an average of 4.2 out of 5 and above.
Figure 3. Anxiety levels over the first 6 weeks of monitoring (235, 286 observations with generalized additive model-GAM-smoothing), 95% CI shading. Ratings on 0-10 scale where 10 is highest. Updateday is the days elapsed since the user began monitoring.

Figure 4. Activity summary for the "anxiety reducers" group (N=2327). Boxes and whiskers show quartiles with outliers as individual points.
Looking at how many techniques different users have rated, we note that most people have rated only a small number of those available (Table 7).

**Peer Support**

Table 2 shows that one quarter of users (27,081) posted at least one message on the Social Cloud with less than 4% posting for more than 50 days. A very small group (0.4%, 522 users) posted more than 50 times. In terms of replies to social posts, we firstly observed that a large proportion of posts (in the sense of “new threads”) received at least one reply from another app user, as seen in Figure 7.

In terms of who is doing the replying, when graphed on a log scale (frequency vs users replied to), we observed an approximate inverse power law trend, as seen in Figure 8, indicating that a small percentage of profiles are responsible for a very large number of Social Cloud replies.

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**Figure 5.** Frequency of a sample of key words occurring in “Things that make me anxious” entries.

**Figure 6.** Network of bigram associations for most common bigrams in user anxiety causes (bigrams with 30 or more occurrences).
### Table 6. Top 12 most popular self-help options ordered by mean rating (most popular first), N=15,437 ratings by 5862 app users.

<table>
<thead>
<tr>
<th>Self-help option</th>
<th>Description</th>
<th>Section</th>
<th>Ratings, n</th>
<th>Mean rating&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop that thought</td>
<td>A self-help intervention based on the idea that persistent worrying thoughts can be suppressed or diverted by forceful inner speech or external actions</td>
<td>Mental relaxation</td>
<td>528</td>
<td>4.26</td>
</tr>
<tr>
<td>You can do it</td>
<td>Encourages positive thinking about making changes using personal examples from survey interviews</td>
<td>Small steps</td>
<td>124</td>
<td>4.25</td>
</tr>
<tr>
<td>You’re biased!</td>
<td>Provides a digest of research-based information on how cognitive biases influence our experience of anxiety</td>
<td>Information</td>
<td>530</td>
<td>4.24</td>
</tr>
<tr>
<td>Examples of anxious thinking</td>
<td>Describes common patterns of thought derived from practice-based research in cognitive therapy</td>
<td>Thinking</td>
<td>527</td>
<td>4.24</td>
</tr>
<tr>
<td>Picture peace</td>
<td>Uses contemplation of and physical contact with selected visual images to shift attention away from anxious experience</td>
<td>Mental relaxation</td>
<td>2222</td>
<td>4.21</td>
</tr>
<tr>
<td>Checklist</td>
<td>Provides a summary reminder of the key principles of learning to manage anxiety using SAM&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Small steps</td>
<td>239</td>
<td>4.20</td>
</tr>
<tr>
<td>A simple meditation</td>
<td>Uses well-established meditation guidance to clear the conscious mind of thoughts and sensations</td>
<td>Mental relaxation</td>
<td>190</td>
<td>4.13</td>
</tr>
<tr>
<td>Calm breathing</td>
<td>Uses a well-established breathing exercise to achieve a basic level of physical and mental calm</td>
<td>Physical relaxation</td>
<td>2186</td>
<td>4.08</td>
</tr>
<tr>
<td>Ground yourself 2</td>
<td>Uses associative learning to establish links between positive memories and low arousal</td>
<td>Physical relaxation</td>
<td>231</td>
<td>4.06</td>
</tr>
<tr>
<td>Symptoms of anxiety</td>
<td>A graphic which aims to show the diversity of anxiety symptoms within 4 psycho-physical categories</td>
<td>Information</td>
<td>617</td>
<td>4.06</td>
</tr>
<tr>
<td>A cycle of anxiety</td>
<td>A graphic to show how feelings, sensations, beliefs, and behavior interact to create and maintain anxiety</td>
<td>Information</td>
<td>604</td>
<td>4.06</td>
</tr>
<tr>
<td>Read this twice, slowly</td>
<td>A self-help module whose instructions and linked content are intended to provide some immediate relief from anxiety</td>
<td>Help for anxiety now</td>
<td>467</td>
<td>4.03</td>
</tr>
</tbody>
</table>

<sup>a</sup>Out of 5, where 5 is highest.  
<sup>b</sup>SAM: Self-help for Anxiety Management [app].

### Table 7. Number of users giving ratings, by number of techniques rated (N=5862 users).

<table>
<thead>
<tr>
<th>Number of options</th>
<th>Number of users, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>5304 (90.48)</td>
</tr>
<tr>
<td>5-10</td>
<td>362 (6.18)</td>
</tr>
<tr>
<td>10-15</td>
<td>113 (1.93)</td>
</tr>
<tr>
<td>15-20</td>
<td>27 (0.46)</td>
</tr>
<tr>
<td>20-25</td>
<td>26 (0.44)</td>
</tr>
<tr>
<td>25-30</td>
<td>17 (0.29)</td>
</tr>
<tr>
<td>30-35</td>
<td>13 (0.22)</td>
</tr>
</tbody>
</table>
Figure 7. Social Cloud activity by month for 2016, showing total posts and the replies received.

Figure 8. Extent of replying to others' posts (log10 scales).
Discussion

Principal Findings

This study aimed to enlarge our understanding of how people use a self-help app for anxiety management. We analyzed user data on anxiety-provoking events, self-monitoring of anxiety, ratings of self-help options, and social network posts.

Our main findings, in summary, were as follows:

1. There was an inverted pyramid or “funnel” of anxiety monitoring with decreasing numbers of users making increasing use of the facility. Out of 105,380 users in our sample, fewer than half monitored their anxiety at least once and only 2.5% monitored it 20 times or more. Our persona profiling showed significantly different subgroups based on engagement levels and the extent of monitoring and social activity with very active social users tending not to monitor extensively and vice versa.

2. Anxiety monitoring by all users showed an initial dip in mean aggregated anxiety ratings over the first few days of use, followed by a more mixed profile subsequently. There was a partial correlation between our anxiety component scales.

3. Anxiety triggers were varied but centered on those more associated with early adolescence.

4. The most highly rated self-help options were those associated with our “Help for anxiety now” screen, though physical relaxation and informational options also featured highly in the ratings.

5. Activity on the Social Cloud showed a similar funneling to monitoring with only one quarter of registered users posting at least one message, less than 4% posting for more than 50 days, and a very small group (0.4%) posting more than 50 times. A similarly small group contributed to a large amount of the social support through providing replies to others’ posts.

We feel that findings are consistent with stage-based models of help seeking (eg, [26]) and with a consumer choice ethos where consumers and clients felt entitled to explore and evaluate their health care options. Exploration of its functions helps people to decide whether they wish to persist with a particular self-help device. It is these “visitors” to SAM who populate the top layer of the inverted pyramid. We will now explore the findings in these different areas in more detail.

Engagement patterns were overall similar to those noted in other mHealth user populations [11,12] with a high number of low engagers and a long tail of more active users. The attributes of our 4 clusters (Brief Users, Social Monitors, Persistent Monitors, and Socialites) offered some clues to user engagement with SAM.

There are help-seeking preferences in that Socialites value social sharing, whereas Persistent Monitors prefer tasks such as self-monitoring and self-help activities. Further work is needed to understand if these differences have a link to gender, as suggested by Pedersen [27]. Certainly, systematic reviews and phased models (eg, [28-33]) provide evidence that matching therapy to client preferences has a positive impact on therapeutic engagement and therapy outcomes.

For anxiety reduction, the graphical summaries of anxiety monitoring showed a downward trend on all 4 dimensions of anxiety over the measurement period of 40 days. There was a marked dip in anxiety within the first 10 days of using the app; following that, there was variation in anxiety levels across all 4 dimensions with no return to the initial level of anxiety. The data were consistent with several perspectives on personal development.

Frank and Frank [34] proposed that people seek help because they are demoralized by being unable to manage their problems. Contacting a source of help instilled hope that change could occur and reduced anxiety. We have suggested previously [8] that “common factors” in psychotherapy [35,36] such as hope, credibility, and autonomy might also apply to digital mental health devices including a self-help app. If true, one would expect some reduction in anxiety in the initial period of anxiety monitoring.

Studies of change without professional help, for example [37], indicated that change is a gradual process, sometimes emotionally turbulent, and takes months rather than weeks. For those receiving psychotherapy, initial severity of symptoms, individual differences, and the ongoing challenges of emotion regulation contribute to variations in the pattern of change [38]. A recent large-scale study of counseling clients with varying levels of psychological well-being [39] also indicated that trajectories of change are diverse. Researchers on the dose-effect relationship in psychotherapy concur that around 50% of patients are measurably improved after 8 weekly sessions, a treatment period of 56 days [40,41]. Thus, our users’ 40-day monitoring period may be a small but revealing slice of a longer process.

Only a small percentage of users achieved a criterion reduction in anxiety. With medians of 18 anxiety updates and 41 days anxiety monitoring (upper quartile over 100 days), reductions in anxiety were associated with sustained anxiety monitoring. They were not associated with Social Cloud activity where the median number of posts was zero. Whatever external support the Social Cloud users in the other clusters received, it was not associated with criterion reductions in reported anxiety.

While noting that this study did not exclude people who might concurrently have been enrolled in a therapeutic program or intervention, this group might indicate a larger population of users learning to manage their anxiety; if the percentages are scaled up for 1 million downloads (SAM’s approximate uptake at September 2017), there would be 37,300 users. This is similar in magnitude to 10.7% of the 346,412 annual referrals to United Kingdom’s National Health Service Improving Access to Psychological Therapies service for anxiety or stress-related disorders (p24, Figure 10) [42].

For causes of anxiety, Figures 5 and 6 indicate the main areas of anxiety for the user sample. There are many references to social relations—people, talk, meeting, and touching. They include evaluative aspects of those relations such as public speaking, watching, judging, and hating. The situations described and other references suggested a user group in the...
adolescent to young adult stage of development, including school, parents, authority, class, grades, and interviews. With a user group in middle to late adulthood, one would expect more references to jobs and careers, family and children, and finances and health care contexts [43]. Some of these midlife anxieties were noticeably limited in this user group.

We also looked at user of self-help options. The app was designed to offer a range of self-help options for anxiety management, differentiated by presentation mode and psycho-educational focus. The fact that all 34 options were given ratings suggests that each was potentially meeting a need for some portion of the user sample.

Although user ratings indicated a moderate to high level of satisfaction with the self-help options, they were provided by only 5.5% of the sample and over 90% of those users gave ratings to no more than 5 out of 34 available options. Users were encouraged to explore the range of self-help options and it was assumed that they may not rate them unless engaged with them over time.

Based on the frequency of user ratings, 3 of the top 5 options were “Calm Breathing,” “Picture Peace,” and “Change the Focus.” These were accessed from the “Help for anxiety now” module which is intentionally prominent on the app’s main menu page; it is likely that these options for managing immediate anxiety or panic will attract users. All 4 of the “Information about Anxiety” options featured in the top 10 of the frequency list and 2 of them in the top 5 with the “Help for anxiety now” options. In contrast, 6 of the 8 options in the “Making Changes” module featured in the bottom 10 of the frequency list.

These rankings suggest that actions to contain immediate anxiety with information and directed self-help are primary uses of the app and are preferred over sustained self-help activity involving a range of options. They support the view of many users being in the early stages of commitment to a personal change process, as outlined above.

A complementary view is that SAM is being used to provide what users expect apps to provide. In a content analysis of app store descriptions, the most commonly stated purpose of apps was symptom relief and information about mental health; the most frequently mentioned self-help options were those for mild anxiety, such as relaxation [44].

From an interaction design perspective, these ratings provide excellent evidence for future iterations of the self-help techniques and the addition of new tools into the app. In this way, the available self-help techniques might be allowed to evolve based on user preferences.

As far as social peer support is concerned, three quarters of the users who registered for the Social Cloud did not take part in its interactions but may have nonetheless logged in to absorb the views and experiences of others. For them and for those users who were more socially active, there are therapeutic factors in group psychotherapy which may apply in Web-based forums [45], such as learning that others have similar concerns, raising hope that things can change, and gaining information that is helpful in dealing with personal concerns. These factors are supported by recent studies of Web-based support which have identified information exchange, sharing experiences, emotional support, and encouragement as the most common interactions [46,47].

Overall, the low levels of sustained engagement with the Cloud in our sample (less than 5%) and the number of registrations as a proportion of total downloads (15%) indicate that the Social Cloud appeals to a subset of users rather than to the majority of those who download the app.

User attributions for causes of their anxiety (above) suggest an adolescent or early adulthood user group, a developmental period which is associated with higher levels of social-evaluative anxieties. The limited appeal of the Social Cloud tends to support that view. Being anxious may be experienced as shameful [48], and this will discourage social sharing.

Limitations

The dataset was based on a sample of users who downloaded SAM and also registered with its Social Cloud. Our findings may not apply to the greater proportion that downloaded but did not register.

The research quoted on the duration and trajectories of change in personal development processes indicates that from a large dataset covering a short period of user activity, we should be cautious in our generalizations about patterns of engagement and change.

Where the findings are based on self-reporting by users, as in monitoring of anxiety levels or rating self-help options, there was no standard guidance for users on how to make those assessments. In this absence, self-monitoring of anxiety will be guided by subjective criteria and individual baselines. Further research should aim to confirm reductions in anxiety using a validated measure of anxiety.

Our reflections on the statistical analyses, hypothesizing links between user behavior and psychological processes, could not be contextualized by qualitative data from users. The value and meaning of the user experience with SAM remains a matter for further investigation.

Conclusions

The analysis suggests a scenario of initial downloads by a large body of prospective users, followed by successive withdrawals from engagement, leaving a small core of committed and effective users—an inverted pyramid of engagement. Within this process of narrowing engagement, there are clusters of users, notably those focused differently on the self-monitoring and peer support functions of the app.

Causal attributions for anxiety suggest a user group in adolescence and early adulthood who have particular anxieties about self and social relations. The indications from rating and frequency data on the app’s self-help options indicate that help for immediate anxiety might be a primary motive for using the app.

Anxiety reduction is most associated with persistence in change.
Newman et al [20] concluded that self-help interventions for anxiety are most effective with motivated users.

**Recommendations**

Our analyses of users’ patterns of engagement with the app as presented here will be of value to other mHealth apps offering self-help for common mental health concerns. Reflections on these patterns will inform practitioners seeking to engage with clients using self-help apps. Service managers will need to take account of how client populations respond to mHealth opportunities to promote them appropriately. App developers may wish to consider how engagement can best be supported through in-app guidance and external prompts. They will need to work closely with practitioners to increase the validity of self-monitoring and rating systems and consider how a more guided usage approach might be built into the app as an implicit aspect of its design.

Suler [49] has researched and written extensively about how people use social media, their forms of engagement, and the interaction between personality types and Web-based engagement. He is clear that the architecture of Web-based life offers many routes to personal development; media references such as “a therapist in your pocket” [50] applaud the immediacy and accessibility of apps without recognizing the varieties of user engagement shown in this study.

User motivation and personalization of therapy resources are critical to engagement with the therapeutic program [51]. We propose that there is a task for therapeutic practitioners and organizations who wish to promote digital mental health, that is, matching the digital support to the individual user with regard to patterns of and preferences for mobile engagement as they would in face-to-face therapy. For autonomous self-help by large, diverse user populations, this will mean comprehensive in-app guidance, links to Web-based support in a range of formats, and options for integrating mobile self-help with offline therapy.

Practitioners working with app users will need to adopt a flexible role in matching therapeutic needs to digital options. They can offer encouragement for persistence with autonomous self-help activities; be active in helping their clients make best use of their apps; and collaborate to select self-help options in support of a program of face-to-face therapy. There is a parallel with art therapy where interaction between client, therapist, and image is employed to facilitate personal understanding and options for change [52]. Practitioners will want to consider the benefits and the challenges of their clients and users having attachments to, and communications between, both person and digital device.

**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**

Characteristics of user clusters.

[PDF File (Adobe PDF File), 37KB - mental_v5i4e58_app1.pdf]

**References**


46. McCormack A, Coulson N. Individuals with eating disorders and the use of online support groups as a form of social support. J Psychosoc Res Cybersp 2009;3(2).


**Abbreviations**

MCA: multiple correspondence analysis  
MCID: minimum clinically important difference  
SAM: Self-help for Anxiety Management
Online Positive Affect Journaling in the Improvement of Mental Distress and Well-Being in General Medical Patients With Elevated Anxiety Symptoms: A Preliminary Randomized Controlled Trial

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Abstract

Background: Positive affect journaling (PAJ), an emotion-focused self-regulation intervention, has been associated with positive outcomes among medical populations. It may be adapted for Web-based dissemination to address a need for scalable, evidence-based psychosocial interventions among distressed patients with medical conditions.

Objective: This study aimed to examine the impact of a 12-week Web-based PAJ intervention on psychological distress and quality of life in general medical patients.

Methods: A total of 70 adults with various medical conditions and elevated anxiety symptoms were recruited from local clinics and randomly assigned to a Web-based PAJ intervention (n=35) or usual care (n=35). The intervention group completed 15-min Web-based PAJ sessions on 3 days each week for 12 weeks. At baseline and the end of months 1 through 3, surveys of psychological, interpersonal, and physical well-being were completed.

Results: Patients evidenced moderate sustained adherence to Web-based intervention. PAJ was associated with decreased mental distress and increased well-being relative to baseline. PAJ was also associated with less depressive symptoms and anxiety after 1 month and greater resilience after the first and second month, relative to usual care.

Conclusions: Web-based PAJ may serve as an effective intervention for mitigating mental distress, increasing well-being, and enhancing physical functioning among medical populations. PAJ may be integrated into routine medical care to improve quality of life.

Trial Registration: ClinicalTrials.gov NCT01873599; https://clinicaltrials.gov/ct2/show/NCT01873599 (Archived by WebCite at http://www.webcitation.org/73ZGFzD2Z)

(JMIR Ment Health 2018;5(4):e11290) doi:10.2196/11290

KEYWORDS
adult; anxiety; depression; emotions; expressed emotion; internet; stress, psychological/physiopathology; surveys and questionnaires; treatment outcome; writing
Introduction

Background
At present, 60% of all people living in the United States have at least one chronic health condition, and 42% have multiple chronic conditions [1]. As advances in the treatment of disease continue to prolong life and the overall population continues to age, these numbers are likely to increase. The significant costs associated with managing medical conditions are well known. The majority of diseases hold the potential to worsen the overall health of patients by limiting their functional capacity, productivity, and health-related quality of life and are a major contributor to health care expenditures [2-4]. Patients with medical conditions face several challenges and often need to modify life aspirations, daily routines, and employment. Although some patients experience periods of grieving and adjustment after a diagnosis, many others experience sustained distress that can further impact physical and mental health and quality of life [4]. Given the link between severe or chronic medical conditions and psychological distress, it is not surprising that comorbidity between medical and mental health conditions is the rule rather than the exception [5]. The 2001 to 2003 National Comorbidity Survey Replication, for example, found that more than 68% of adults with a mental health disorder reported having at least one general medical illness and that 29% of people with a medical condition also had a comorbid mental health problem [6,7]. Stressful life events often precede anxiety and mood disorders [8], and the accompanying psychological strain associated with the diagnosis of, and living with, a major medical illness places these patients at risk for comorbidity and worse health outcomes overall. Stress and dysphoric mood generally may worsen the prognosis and progression of disparate diseases [9,10] and is a major contributor to many of the leading causes of death in the United States such as cancer, coronary heart disease, respiratory disorders, and suicide, among others [11]. In light of evidence that stress and dysphoria might be a modifiable risk factor for the development and progression of medical illnesses, finding ways to reduce distress in patients with one or more existing medical conditions is a major public health concern.

Psychological interventions (eg, cognitive behavioral therapy, CBT) have been shown to reduce psychological distress in chronic disease populations [12-14]. Although psychological interventions are increasingly desirable among patients [15], there are several barriers to accessing face-to-face psychological care among people with chronic health conditions (eg, cost or insurance coverage, access, and stigma) [15-18]. The internet has emerged as an effective tool for disseminating efficacious mental health interventions [19] and may serve to overcome some of these barriers to accessing mental health services. For example, a meta-analysis of internet-based CBT interventions observed that they are effective for reducing depression and anxiety [20], and a study by Farrer et al [21] observed a 44% reduction in depressive symptoms over 6 months among those randomized to internet-based CBT versus only 11% among controls. To date, however, these evidence-based internet interventions are either not readily accessible or widely disseminated among the general population and, therefore, do not address the problem of access to psychological services.

Relative to internet-based therapeutic or counseling interventions, positive affect journaling (PAJ), a simple intervention that is cost-efficient and easily disseminated to patients, is becoming increasingly popular. PAJ is a modified version of the traditional expressive writing paradigm [22,23] wherein the participants write about a traumatic experience for approximately 15- to 20-min intervals, often across a period of 3 to 5 days. Reviews of expressive writing suggested that it was modestly effective in improving a number of physical and mental health outcomes [24,25] although large heterogeneities in efficacy have been documented.

For example, several studies have found clinical benefits tied to expressive writing in patients with autoimmune and inflammatory conditions such as arthritic conditions, lupus, and asthma [25-29], fibromyalgia [30,31], irritable bowel syndrome [32], and HIV or AIDS [33,34]. In addition, expressive writing has been found to have beneficial effects on blood pressure [35] and on several health-relevant outcomes following the experience of a heart attack such as reduced numbers of medical appointments and prescription medications, increased self-care behaviors, improved cardiac symptoms [36], and improved health-related quality of life [37]. Expressive writing has also been associated with small, but consistent, improvements to well-being among diverse cancer groups—especially breast, renal, and prostate cancer patients [38]. Finally, a relatively small study of 40 people diagnosed with major depressive disorder found that those writing about their deepest thoughts and feelings related to emotional events had significant reductions in depression immediately after writing and over 1 month thereafter [39].

A number of efforts have been made to modify the original expressive writing approach to be better suited for use across several contexts and populations. One stream of this process is reflected in the integration of positive psychology, a large and growing area of research that has linked positive psychological and emotional dispositions and states of being (eg, optimism, happiness, subjective well-being, and positive affect) to various beneficial outcomes. Some of the reported benefits of these positive dispositions include fewer physical symptoms [40], faster wound healing [41], healthier functioning biological processes (eg, neuroendocrine, inflammatory, and cardiovascular activity) [42], better interpersonal relationships [43], higher quality of life [44], increased longevity [45], and decreased morbidity [46,47]. As such, the expressive writing paradigm has been adapted to have participants write about positive aspects of their lives and themselves (eg, making meaning out of or finding benefit in past experiences [48,49] and focusing on positive aspects of one’s self [50]) under the notion that this would yield similar benefits to those observed in the positive psychology literature. As a whole, we refer to this array of positive-focused writing approaches as PAJ.

Positive affect interventions among both patients and healthy individuals have led to improvements in a number of health outcomes. In 2 studies comparing an educational control (ie, educational workbook and behavioral contract) with a positive
affect intervention (ie, self-affirmation inducement over bimonthly telephone sessions with staff and unexpected gifts before calls), positive affect improved medication adherence in hypertensive African American patients [51] and physical activity in patients following a percutaneous coronary procedure [52]. In addition, Stanton et al [53] found that 4 sessions of written expressive disclosure or benefit finding resulted in lower physical symptom reports and medical appointments among breast cancer patients at 3-month follow-up. In healthy samples, Armitage et al [54] found beneficial effects of completing a self-affirmation questionnaire or self-affirming implementation intention on alcohol intake at 1-month follow-up, whereas Burton and King [55] observed that participants randomized to write only 2 min for 2 consecutive days in a laboratory about a recent positive event showed moderate reductions in physical symptoms (Cohen $d=0.65$) at 4- to 6-week follow-up.

**Objectives**

The goal of this randomized controlled trial was to examine whether a 12-week internet-based PAJ intervention could reduce mental distress (primary outcome) and positively influence psychological, interpersonal, and physical well-being (secondary outcomes), relative to usual care, in a heterogeneous sample of patients with elevated anxiety symptoms. It was hypothesized that participants randomized to the intervention would experience decreases in mental distress (ie, Hospital Anxiety and Depression Scale score; HADS) and improvements in psychological well-being (eg, perceived stress and resilience), interpersonal well-being (ie, social support), and physical well-being (eg, days during which pain inhibited usual activities) over the 12-week intervention period. It was also hypothesized that participants randomized to receive the intervention would report less mental distress and greater levels of psychological, interpersonal, and physical well-being than those in the control condition at each assessment period.

**Methods**

**Sample and Recruitment**

All study procedures were approved by the Pennsylvania State Hershey Medical Center’s (PShMC) institutional review board, and all participants provided written informed consent before engaging in any research-related activity. This study was registered on ClinicalTrials.gov (reference number NCT01873599), with recruitment and active intervention occurring from June 2013 to February 2014.

Potential participants were recruited through flyers placed around the PShMC campus and advertisements placed in PShMC media and local community newspapers in central Pennsylvania. In addition, oncology patients at The Pennsylvania State University Hershey Cancer Institute with an Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 to 3 (not completely disabled) were identified through registry review and sent a letter describing the study. Participants were provided with a toll-free number to call if they were interested in participating, as well as an opt-out card that could be mailed back by those who were uninterested. Individuals who did not respond were contacted through phone by a research staff member within 2 weeks to determine their interest in participating.

Eligibility for inclusion was based on (1) English fluency, (2) between 21 and 80 years of age, (3) internet access, (4) self-report of moderate to significant stress during the last month, (5) not currently pregnant and no plans to become pregnant within the next 3 months, (6) no plans to move within the next 6 months, (7) no hospitalization for a psychiatric condition in the last year, (8) not a high risk for suicidality as assessed by selected questions from the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders [56]. Although not an explicit requirement, it was assumed that potential participants be familiar with using a computer and accessing websites.

Individuals interested in participation and who met the initial inclusion criteria were invited for a laboratory visit and further assessed for eligibility. Eligible participants: (1) reported a score of 8 to 15 on the anxiety subscale of the HADS [57] and (2) had an ECOG performance status of 0 (fully active) through 3 (limited self-care) [58]. Participants who met all inclusion criteria were invited to participate.

**Random Assignment**

Randomization (1:1) was done through sealed envelopes prepared by someone other than the research staff conducting the study visits and opened by participants during the baseline visit after completing informed consent. See Figure 1 for flow diagram of recruitment procedure.

**Procedure**

Eligible participants met the research staff during a scheduled baseline visit to discuss study procedures and provide written informed consent. During the baseline visit, all participants completed baseline surveys and were randomized (through computer-generated sequences provided in sealed envelopes) to 1 of the 2 conditions. Participants assigned to the intervention condition received an introduction and training session to orient them to the intervention website where they would complete the writing sessions. All participants completed self-report survey assessments on the Web at the end of months 1, 2, and 3 using a secure data capture system (REDCap Penn State). Participants received gift cards following the completion of each survey (ie, US $40 compensation for completing all 3 assessments).
Intervention

Participants in the PAJ intervention condition were asked to complete Web-based writing sessions for 15 min on 3 days each week for the duration of the 12-week study. The amount of time spent writing at each session is similar to prior expressive writing studies although the duration of the intervention in this study was longer than many other prior studies [23,25,59] to ensure the potential for adequate dose of intervention. This was the first version tested of this intervention; the intervention content was frozen during the trial and not adjusted. During each Web-based writing session, participants logged onto the study website and wrote a journal entry on 1 of the 7 commonly used positive affect prompts (eg, What are you thankful for? What did someone else do for you?; full details available upon request) [60]; all entries were saved on a secure server. During the study, journal entries of participants in the intervention condition were screened by research staff to monitor content. Participants who did not complete a journal entry within any given 7-day period were sent an email reminder (this email reminder also included reminders of how study staff could help them resolve any technical difficulties, in case, any existed). As there is no clinical standard of care treatment for medical patients with mild to moderate anxiety symptoms, participants randomized to the wait-list control group received their usual care for the duration of the study. After they had completed all study procedures, participants in the control condition were given access to the PAJ intervention.

Measures

Sociodemographics and Health Behaviors

Participants’ age, gender, race, ethnicity, marital status, and educational level were obtained at baseline. During this time,
participants self-reported basic information related to their specific disease and health behaviors (ie, smoking, physical activity, and alcohol use) using standard self-report items from the Behavioral Risk Factor Surveillance System [61].

Primary Outcome

The HADS [57] consists of 2 scales, anxiety and depression, with each consisting of 7 items rated on a scale from 0 through 3. Items are aggregated for each subscale (range=0-21), with higher scores indicating greater anxiety or depressive symptom severity, and for a total HADS score (range=0-42), with higher scores indicating greater mental distress. Various cut-off scores are available for the HADS. A score of 8 or greater on the anxiety subscale (HADS-A) has a specificity of 0.78 and sensitivity of 0.9 for clinically significant anxiety, whereas scores below 8 indicate noncases [62]; the inclusion criterion of a HADS-A score of 8 to 15 was intended to include participants with mild to moderate symptoms, whereas those with nonsignificant or severe symptoms (HADS-A scores of 15-21) were excluded as the PAJ intervention was expected to have limited benefit for those individuals. In this study, Cronbach alpha at baseline was .65 for anxiety, .86 for depression, and .85 for HADS total score.

Secondary Outcomes

The Brief Resilience Scale (BRS) [63] is a 6-item measure of perceived resilience, including items such as “It does not take me long to recover from a stressful event.” Each item is rated on a scale from 1 (strongly disagree) to 5 (strongly agree). All items are aggregated for a total score (range=6-30); higher scores indicate greater resilience. The BRS has high levels of internal consistency, with Cronbach alpha ranging from .80 to .91 [63]. In this study, Cronbach alpha was .90 at baseline.

The Healthy Days Measure [61] assesses self-reported physical health and functioning. Respondents answered 4 items to indicate (1) general health (ie, “Would you say that in general your health is ‘poor’–‘excellent’”), (2) days during which pain inhibited their usual activities (ie, “During the past 30 days, for about how many days did pain make it hard for you to do your usual activities...?”), (3) sleep quality (ie, “During the past 30 days, for about how many days have you felt you did not get enough rest or sleep?”), and (4) number of days they felt healthy and full of energy (ie, “During the past 30 days, for about how many days have you felt very healthy and full of energy?”). The Perceived Stress Scale [64] consists of 10 items that assess perceived stress rated on a scale from 0 (never) to 4 (very often). A sample item includes “In the last month, how often have you felt nervous and stressed?” Items are combined for a total score, with higher scores indicating greater stress. The measure demonstrates strong internal consistency. In this study, Cronbach alpha was .91 at baseline.

The Positive and Negative Affect Schedule (PANAS) [65] consists of 2 subscales, each including 10 items. Respondents indicate the extent to which they felt specific positive emotions (eg, excited and proud) and negative emotions (eg, upset and afraid) over the last month on a scale from 1 (not at all) to 5 (extremely). Subscales are scored separately (range=10-50); higher scores indicate greater positive affect and greater negative affect. Internal consistencies are high (Cronbach alpha=.85-.88) [65]. In this study, Cronbach alpha for the positive affect subscale was .90 and negative affect subscale was .90 at baseline.

The Satisfaction with Life Scale (SWLS) [66] is a 5-item scale that assesses overall life satisfaction with items such as “In most ways my life is close to my ideal” and “I am satisfied with my life.” Each item is rated on a scale from 1 (strongly disagree) to 7 (strongly agree), and a total score is calculated using all items (range=5-35); higher scores indicate greater satisfaction with one’s life. The SWLS has a test-retest reliability of 0.82 [66]. In this study, Cronbach alpha was .93 at baseline.

The Social Provisions Scale [67] assesses various dimensions of social support. The scale consists of 24 items that make up 6 components, each consisting of 4 items pertaining to attachment, social integration, reassurance of worth, reliable alliance, guidance, and opportunity for nurturance. The respondent rates the extent to which each statement describes their current social network on a scale from 1 (strongly disagree) to 4 (strongly agree). Items are aggregated separately for each component (range=4-16) and for a total perceived support score (range=24-96); higher scores indicate a greater degree of perceived support provisions. In this study, Cronbach alpha for attachment was .76, .88 for social integration, .72 for reassurance of worth, .84 for reliable alliance, .83 for guidance, .79 for opportunity for nurturance, and .93 for total perceived support at baseline.

Adherence

Adherence generally describes the extent to which individuals are exposed to the content of the intervention. For this study, participants were asked to complete Web-based PAJ sessions an average of three 15-min sessions per week, over 12 weeks, for a total of 36 journaling sessions throughout the course of the study. Overall PAJ adherence rate was calculated using 2 methods: (1) weekly journaling counts for each participant—derived from Web-based user log-in counts—were recoded into a binary variable (ie, yes or no) based on journaling >1 time per week. The journaling counts for all weeks were then summed, divided by 12, and multiplied by 100 to calculate the overall 12-week adherence rate and (2) total journaling counts for all participants were summed for all weeks of the study, divided by 36, and multiplied by 100. Although it would be desirable to count actual time (minutes per session) spent engaged in the PAJ intervention, the website was not capable of accurately tracking this information (eg, if a person left the computer to complete another task).

Sample Size

The sample size was calculated based on an anticipated baseline mean of 11.0 (SD 3) on the HADS-A. This anticipated value was derived from a study of 273 medical patients participating in a Web-based educational program. Using G*Power, we assumed treatment condition SDs similar to those reported by Yun et al [68] and a 5% type-I error rate for a two-sided hypothesis test, concluding that 31 subjects per group would provide 80% power to detect a difference in the HADS-A at 3 months (10.0 vs 8.0). This effect size is based on a clinical trial...
of CBT for distressed medical patients wherein the CBT arm decreased their HADS-A score by 3.1 points more than controls [7], and a Web-based CBT intervention by Farrer et al [21] observed a 44% reduction in depression scores over 6 months. This study estimated a reduction of 2.0 in the HADS-A measure (18% reduction). Anticipating a dropout rate of <10%, we planned to recruit 70 subjects at baseline.

**Analytic Plan**

All analyses were conducted using SAS Software version 9.4 (SAS Institute, Cary, NC). First, descriptive statistics were calculated for all variables at baseline and at each of the 3 follow-up assessments, and response rates were calculated using the Web-based user log-in tracking logs. Categorical variables were summarized with frequencies and percentages, and continuous variables were summarized with means, SDs, medians, and quartiles. The distribution of continuous variables was checked using box plots, histograms, and normal probability plots. For demographic variables and other characteristics measured at baseline, comparison tests were conducted between the intervention and control groups using a two-sample t test or Wilcoxon rank-sum test with means for continuous variables and using a chi-square test with percentages for categorical variables. A Fisher exact test was used as needed when cell counts were too small for the chi-square test to be valid.

Second, in making comparisons of the differences from baseline to each of the 3 months within and between groups, we used 2 approaches depending on the type of outcome variable. For continuous outcome variables, we first found the change from baseline at each subsequent month. A linear mixed-effects model was then employed, which included factors for group (intervention vs control), month, the interaction between the intervention group and month, and the baseline measurement for adjustment, and the differences between groups were quantified with means. For binary outcome variables, a generalized estimating equations model was used that included factors for group, month, and the interaction between the group and month, and differences between groups were quantified with percentages and odds ratios. All comparisons were adjusted for age, sex, income, and preexisting journaling—reflecting self-reported frequency (ie, “Never,” “Less than once per month,” “1-3 times per month,” and “At least once per week”) of writing in a diary or journal in the year leading up to the study—by including these factors as additional covariates in the models. Missing data were not a significant problem for the primary outcome variable (at less than 5%) or for the secondary outcome variables (at less than 10% at most) and were not an issue for any independent variables.

**Results**

**Participants**

A total of 99 people were assessed for eligibility, of which 88 patients were interested in participating. After further screening, 70 people were eligible, consented, and randomized to the intervention (n=35) or usual care (n=35) condition (Figure 1). A total of 3 participants were lost to follow-up during the 12-week assessment period and all participants were included in analyses. No unanticipated harms were reported, and there were no privacy breaches or major technical problems during the trial. Participants in this study had a broad range of chronic health conditions, including arthritic conditions (eg, rheumatoid arthritis, gout, lupus, and fibromyalgia: 19/69, 27%), diabetes (type 1 or type 2: 12/70, 17%), asthma (12/70, 17%), cancer (13/70, 11.1%-19%, all cancer types combined), prediabetes (4/70, 6%), kidney disease (not including kidney stones, bladder infection, or incontinence: 3/69, 4%), chronic obstructive pulmonary disease (1/69, 1%), heart disease (1/70, 1%), and stroke (1/69, 1%). Demographic and other baseline characteristics are shown in Table 1. There were no significant differences between the intervention and control groups on any baseline characteristics (demographics, primary, or secondary outcomes).

**Within-Group Differences**

Our initial analyses examined changes over time within each group. All results for the within-group differences across the 3-month study period are shown in Multimedia Appendix 1. Results indicated that the PAJ intervention reduced mental distress and improved well-being. Specifically, the intervention group reported lower HADS-A at all 3 assessments (at the end of months 1 through 3), more resilience at the end of month 2, less perceived stress at all 3 assessment points, and a greater percentage (ie, 56.3% vs 31.3%) of participants reported better mental health at the end of the first month, relative to baseline. No other within-group differences were observed in the intervention group. Compared with the baseline, the control group reported less social integration at the end of month 3, more days in pain inhibiting usual activities at the end of month 2, and a greater percentage (ie, 41.4% vs 20%) of participants reported better mental health at the end of month 3, relative to the previous month. No other within-group differences were observed in the control group.

**Between-Group Differences**

We next examined differences between the groups over time. Results for the between-group differences across the 3-month study period are also indicated in Multimedia Appendix 1. Compared with the control group, the intervention group exhibited lower anxiety at the end of month 1, lower mental distress at the end of months 1 and 2, greater resilience and lower perceived stress at the end of month 1, greater self-reported social integration at the end of month 2, and at the end of month 2, they reported fewer days in which pain prohibited usual activities.

**Adherence**

We also examined patient adherence to suggested journaling frequency (or dose). Overall adherence to the intervention, operationalized by dividing the mean amount of completed sessions by the maximum amount of sessions, was moderate in the sample from this study (mean 47.8% with a range of 2.8%-172.2%; 1 participant journaled 62 times with the remainder having rates at or below the expected 100%). When operationalizing adherence as completing at least one journaling session per week, a level consistent with the broader expressive writing literature [23], the adherence rate was 66.4% (range of 41.7%-100%). After the first week of journaling, participants...
journaled an average of 0.94 times with a peak of 2.3 times per week in week 2. Overall, the number of journaling sessions generally decreased as time progressed (see Figure 2).

Adherence to PAJ sessions was largely unrelated to outcomes (data not shown; results available upon request).

Table 1. Participant and baseline characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N=70)</th>
<th>Control (n=35)</th>
<th>Intervention (n=35)</th>
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<td>30 (85)</td>
<td>30 (88)</td>
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<td>0 (0)</td>
<td>.99</td>
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<tr>
<td>Married, n (%)</td>
<td>44 (64)</td>
<td>25 (71)</td>
<td>19 (56)</td>
<td>.18</td>
</tr>
<tr>
<td>Education (college 4+ years), n (%)</td>
<td>41 (59)</td>
<td>18 (51)</td>
<td>23 (68)</td>
<td>.17</td>
</tr>
<tr>
<td>Employed for wages, n (%)</td>
<td>53 (77)</td>
<td>26 (74)</td>
<td>27 (79)</td>
<td>.61</td>
</tr>
<tr>
<td>Income (&lt;US $50,000), n (%)</td>
<td>21 (33)</td>
<td>9 (30)</td>
<td>12 (35)</td>
<td>.65</td>
</tr>
<tr>
<td>Current smoker, n (%)</td>
<td>3 (4)</td>
<td>1 (3)</td>
<td>2 (6)</td>
<td>.99</td>
</tr>
<tr>
<td>General health (excellent or very good), n (%)</td>
<td>34 (49)</td>
<td>14 (41)</td>
<td>20 (57)</td>
<td>.19</td>
</tr>
</tbody>
</table>

Hospital anxiety and depression scale, mean (SD)

<table>
<thead>
<tr>
<th></th>
<th>Total (N=70)</th>
<th>Control (n=35)</th>
<th>Intervention (n=35)</th>
<th>P valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>14.3 (6.6)</td>
<td>14.3 (7.1)</td>
<td>14.3 (6.1)</td>
<td>.74</td>
</tr>
<tr>
<td>Depression</td>
<td>9.8 (3.4)</td>
<td>9.5 (3.4)</td>
<td>10.1 (3.4)</td>
<td>.44</td>
</tr>
<tr>
<td></td>
<td>4.6 (4.0)</td>
<td>4.9 (4.2)</td>
<td>4.3 (3.7)</td>
<td>.68</td>
</tr>
<tr>
<td>Perceived stress scale, mean (SD)</td>
<td>19.9 (7.2)</td>
<td>20.4 (6.7)</td>
<td>19.4 (7.7)</td>
<td>.55</td>
</tr>
<tr>
<td>Brief resilience scale, mean (SD)</td>
<td>20.1 (5.3)</td>
<td>20.8 (4.3)</td>
<td>19.5 (6.1)</td>
<td>.37</td>
</tr>
<tr>
<td>Satisfaction with life scale, mean (SD)</td>
<td>19.0 (8.0)</td>
<td>19.7 (7.3)</td>
<td>18.3 (8.6)</td>
<td>.48</td>
</tr>
</tbody>
</table>

Social provisions scale, mean (SD)

<table>
<thead>
<tr>
<th></th>
<th>Total (N=70)</th>
<th>Control (n=35)</th>
<th>Intervention (n=35)</th>
<th>P valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>79.0 (12.0)</td>
<td>78.6 (10.9)</td>
<td>79.3 (13.1)</td>
<td>.55</td>
</tr>
<tr>
<td>Attachment</td>
<td>12.5 (2.6)</td>
<td>12.6 (2.4)</td>
<td>12.5 (2.8)</td>
<td>.94</td>
</tr>
<tr>
<td>Social integration</td>
<td>13.2 (2.7)</td>
<td>13.3 (2.4)</td>
<td>13.1 (2.9)</td>
<td>.94</td>
</tr>
<tr>
<td>Reassurance of worth</td>
<td>12.9 (2.2)</td>
<td>12.8 (1.9)</td>
<td>12.9 (2.4)</td>
<td>.41</td>
</tr>
<tr>
<td>Reliable alliance</td>
<td>13.6 (2.6)</td>
<td>13.4 (2.6)</td>
<td>13.8 (2.6)</td>
<td>.47</td>
</tr>
<tr>
<td>Guidance</td>
<td>13.3 (2.7)</td>
<td>13.1 (2.6)</td>
<td>13.5 (2.9)</td>
<td>.35</td>
</tr>
<tr>
<td>Opportunity for nurturance</td>
<td>13.6 (2.5)</td>
<td>13.7 (2.2)</td>
<td>13.5 (2.7)</td>
<td>.96</td>
</tr>
</tbody>
</table>

Positive and negative affect scale, mean (SD)

<table>
<thead>
<tr>
<th></th>
<th>Total (N=70)</th>
<th>Control (n=35)</th>
<th>Intervention (n=35)</th>
<th>P valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive affect</td>
<td>31.9 (8.2)</td>
<td>33.4 (7.8)</td>
<td>30.4 (8.4)</td>
<td>.15</td>
</tr>
<tr>
<td>Negative effect</td>
<td>16.0 (6.6)</td>
<td>16.7 (6.9)</td>
<td>15.3 (6.2)</td>
<td>.20</td>
</tr>
<tr>
<td>Days pain inhibited usual activities, mean (SD)</td>
<td>3.5 (6.9)</td>
<td>3.7 (6.1)</td>
<td>3.4 (7.6)</td>
<td>.08</td>
</tr>
<tr>
<td>Days not getting enough sleep, mean (SD)</td>
<td>12.3 (9.7)</td>
<td>13.1 (10.3)</td>
<td>11.5 (9.2)</td>
<td>.68</td>
</tr>
<tr>
<td>Days felt healthy and full of energy, mean (SD)</td>
<td>14.0 (10.0)</td>
<td>12.8 (9.4)</td>
<td>15.3 (10.5)</td>
<td>.30</td>
</tr>
<tr>
<td>Better mental health than 1 month ago, n (%)</td>
<td>17 (25)</td>
<td>6 (18)</td>
<td>11 (31)</td>
<td>.18</td>
</tr>
</tbody>
</table>

P values for variables based on means are from a two-sample t test or Wilcoxon rank-sum test; P values for variables based on percentages are from a chi-square test; Fisher exact tests were used as needed.
Discussion

Principal Findings

The primary aim of this study was to examine whether a 12-week Web-based PAJ intervention could reduce mental distress and improve psychological, interpersonal, and physical well-being in a heterogeneous sample of medical patients with significant anxiety symptoms. Compared with the patients receiving standard care, patients randomized to the PAJ intervention exhibited reduced mental distress, anxiety, and perceived stress; greater perceived personal resilience and social integration; and fewer days on which pain inhibited usual activities. The PAJ intervention was not associated with improvements in depressive symptoms, satisfaction with life, other indices of social support (ie, attachment, reassurance of worth, reliable alliance, guidance, opportunity for nurturance, and overall perceived support), or positive and negative affect. Overall, the findings from this study suggest that PAJ has potential utility as an intervention for managing mental distress, particularly elevated anxiety symptoms, and other aspects of well-being among general medical patients. This is consistent with, and extends, prior research on positive writing interventions as a way to improve aspects of health and well-being [55,69,70,71].

Effects on Well-Being

This study demonstrates that PAJ can improve several factors associated with psychological well-being among patients with mild to moderate anxiety, each of which may have implications for long-term health outcomes. Some of the most notable findings from this study were that the PAJ intervention was associated with better mental health, including lower anxiety, mental distress, and perceived stress after only 1 month of the intervention and was associated with reduced mental distress across time (eg, continued reduction in anxiety and perceived stress across the 12-week intervention period). As such, PAJ may be an effective way to improve mental well-being and potentially increase longevity through improvements in these outcomes in a variety of patient populations. In addition, PAJ was associated with higher perceived resilience. Although PAJ may be a useful intervention for improving this outcome, more work is needed to understand why the beneficial effects of PAJ on resiliency appear to taper off over time and whether the initial increase in resiliency may serve as a mechanistic pathway between PAJ and disease outcomes across a variety of medical conditions.

Another aspect of psychological well-being with potential implications for health outcomes are perceptions of one’s social environment such as perceived social integration. For example, perceived social isolation, which is conceptually the opposite of perceived social integration, is known to contribute to increased risk for early mortality [72]. This study indicates that PAJ may be beneficial to this end as the results demonstrate greater self-reported social integration in the intervention group relative to controls at the end of the second month. Moreover, more work is needed to understand why the effects of PAJ on perceived social integration do not appear to hold over time and whether these benefits can be prolonged.

Surprisingly, 1 indicator of improved well-being (ie, percent of patients who self-reported “somewhat” or “much better” mental health compared with the previous month) was observed in the control group. This indicates that patients receiving usual care will fluctuate in their perceived well-being (ie, have occasional upswings in self-reported mental health). In addition, PAJ was not observed to improve all indices of well-being (ie, we did not...
not see beneficial effects on depression, satisfaction with life, indices of social support other than perceived integration, or positive and negative affect). This indicates that this intervention may be effective for improving some but certainly not all aspects of well-being. To explore the robustness of PAJ for enhancing additional indices of well-being, future studies would benefit from exploring ways to modify the expressive writing methods used in this study to increase their effectiveness (eg, across more well-being outcomes, for longer durations of time, or both). For example, the writing schedule in this study was fairly dense (3 writing sessions per week for 12 weeks). Perhaps, patients would benefit from a less dense writing schedule or greater variability in the topics offered. It may also be possible to optimize benefit by tailoring PAJ instructions (overall or adaptively over time) to individual patient needs. Furthermore, the writing task used in this study was a modified version of that developed by Pennebaker et al [23], particularly in terms of the number of overall sessions; it is possible that writing in a manner more consistent with earlier expressive writing studies would be preferable.

**Timing Effects**

Regarding the timing effects as a whole, the first month of the PAJ intervention provides a considerable number of improvements in quality of life that are still observed 2 and 3 months later, albeit to a lesser degree. For example, PAJ was associated with decreased mental distress and improved well-being in the first month, but the number of benefits and between-group differences diminished over time. Perhaps, the benefits of PAJ are largely observed within only at the start of the intervention and do not provide sustained improvements in mental distress and well-being over time. However, other studies have demonstrated that longer-lasting positive psychology interventions are effective at improving subjective and psychological well-being among cancer patients [73], and the short-term improvements in cancer patients’ mental well-being observed in this study may translate into longer-term health benefits. As such, future studies are needed to determine whether PAJ beyond 3 months would provide additional upswings in well-being. Conducting longer investigations of expressive writing in clinical populations may be particularly important as previous work has found the benefits to dissipate after several months of discontinuation [28]. It is worth noting that the sample size of our study was modest, and even after just 3 months, improvements were observed that favor the PAJ group. Although a portion of the effect sizes for these significant improvements were small (ie, Cohen $d$ or $h$: 0.5-0.49), there were also several effect sizes of moderate size (ie, Cohen $d$ or $h$: 0.51-0.64; see Multimedia Appendix 1). Given the potential for cost-efficiency and reach of this Web-based intervention, we view these preliminary results as promising and supportive of a larger follow-up study examining the clinical utility of PAJ interventions.

**Feasibility of Intervention**

An important aspect of this study is the demonstrated feasibility of the Web-based writing task intervention. First, participants generally enjoyed the intervention (ie, 39.4% reported that the journaling activity made them feel “somewhat better” and 18.2% reported that it made them feel “much better”). A total of 67 out of 70 consented and randomized participants completed the study for an overall excellent completion rate of 95%; this compares favorably with other randomized expressive writing interventions in chronic illness samples (eg, 73% [74] and 81% [53]). Overall adherence to the intervention was moderate in the sample of this study (mean 47.8%). However, when operationalizing adherence as completing at least one journaling session per week, the adherence rate rose to 66.4% (range of 41.7%-100%). Once-weekly sessions are common in therapeutic practice and are frequently used in randomized trials of CBT [75]. Although these adherence rates are acceptable, it remains unclear why adherence was not even higher, given the relative ease through which Web-based PAJ modules could be accessed. Generally, the number of completed journaling sessions decreased over the course of the intervention. The reasons for this decrease are uncertain but several plausible explanations exist. One possibility, although unassessed in this study, is that participants began the journaling process with enthusiasm in the early weeks but experienced reduced interest or increased fatigue with the intervention over time. Another possible explanation is that participants believed there were diminishing returns on therapeutic benefit as journaling sessions increased; a single weekly journaling session could have been deemed therapeutically equivalent to multiple sessions, for example. Web-based interventions are becoming more prevalent [76] as they can be administered at lower costs and disseminated to more people. Future work should investigate factors that drive adherence to Web-based PAJ interventions and explore opportunities to improve the interventions themselves, given the benefits observed in this study.

**Limitations**

Given the preliminary nature of investigating this novel Web-based intervention, we included several outcomes and conducted a large number of statistical tests, and the small sample size reduced our power to detect some effects (especially when contrasting between groups); together, these decisions may have contributed to spurious and/or missed associations. As such, care should be taken in interpreting any specific effect, and replication of these effects is warranted before strong conclusions can be made about potential efficacy. In addition, the length of the study was relatively short, and it remains unclear whether longer-term interventions would be sustainable or show similar improvements in various indices of well-being. Evidence from some clinical populations (eg, patients with asthma [29]) suggests that expressive writing may offer the most benefit for those with moderate level of disease—patients who are relatively healthy do not have much room for improvement, and those with very severe illness may require a more powerful treatment alternative. A large percentage (44.3%) of patients in this study reported excellent or very good health at baseline, possibly limiting the therapeutic benefit that could be observed from journaling; less healthy patients may have greater gains to make in well-being from baseline relative to their healthier counterparts, and future studies may consider testing this intervention in a sample of patients with greater disease severity. Finally, the homogenous nature of our small study sample (95.5% white and 87.0% female), combined with...
the relatively brief study time frame, limits the generalizability of our findings to more diverse patient samples.

Conclusions
The results of this randomized controlled trial provide preliminary evidence that PAJ is a feasible and well-accepted intervention that can be implemented on the Web for effectively reducing some aspects of mental distress and improving aspects of well-being among medical patients with mild to moderate anxiety symptoms. Moreover, PAJ is likely to be a more pleasant and uplifting treatment for patients compared with the traditional expressive writing interventions that focus on writing about deeply distressing and traumatic experiences from the past; this may promote acceptability and treatment engagement relative to other treatments. Thus, this relatively simple and cost-effective intervention may represent a low-risk way to improve a variety of well-being domains, particularly among underserved patients.

Acknowledgments
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Conflicts of Interest
None declared.

Multimedia Appendix 1
Outcome variables over time.

[PDF File (Adobe PDF File), 78KB - mental_v5i4e11290_app1.pdf ]

Multimedia Appendix 2
CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 572KB - mental_v5i4e11290_app2.pdf ]

References


20. Smyth et al. JMIR MENTAL HEALTH


Abbreviations

- **BRS**: Brief Resilience Scale
- **CBT**: cognitive behavioral therapy
- **ECOG**: Eastern Cooperative Oncology Group
- **HADS**: Hospital Anxiety and Depression Scale
- **PAJ**: positive affect journaling
- **PANAS**: Positive and Negative Affect Schedule
- **PSHMC**: Pennsylvania State Hershey Medical Center
- **SWLS**: Satisfaction with Life Scale
Attitudes and Preferences Toward a Hypothetical Trial of an Internet-Administered Psychological Intervention for Parents of Children Treated for Cancer: Web-Based Survey

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Abstract

Background: Clinical trials are often challenged with issues of recruitment and retention. Little is known concerning general attitudes and preferences toward trial design and willingness to participate among parents of children treated for cancer. Furthermore, willingness to participate in internet-administered psychological interventions remains unexplored. In this study, we examined attitudes and preferences of the population regarding study procedures for a hypothetical trial of an internet-administered psychological intervention. In addition, differences in the response rate between modes of study invitation and willingness to engage in internet-administered interventions were examined.

Objective: The primary objective of this study was to examine attitudes and preferences toward participating in an internet-administered psychological intervention. The secondary objective was to examine the response rates and help-seeking behavior among parents of children treated for cancer.

Methods: A cross-sectional, Web-based survey was conducted with parents of children who had completed cancer treatment. This Web-based survey examined self-reported emotional distress, prior help-seeking and receipt of psychological support, past research participation, attitudes toward research, preferences concerning recruitment procedures, and attitudes toward different types of trial design.

Results: Of all the parents invited, 32.0% (112/350) completed the survey, with no difference in response rate between modes of study invitation ($\chi^2=0.6, P=.45$). The majority (80/112, 71.4%) of parents responded that they had experienced past emotional distress. Responses indicated high (56/112, 50.0%) or somewhat high trust in research (51/112, 45.5%), and the majority of parents would accept, or maybe accept, internet-administered psychological support if offered (83/112, 74.1%). In addition, responses showed a preference for postal study invitation letters (86/112, 76.8%), sent by a researcher (84/112, 75.0%) with additional study information provided on the Web via text (81/112, 72.3%) and video (66/112, 58.9%). Overall, parents responded that trials utilizing a waiting list control, active alternative treatment control, or a patient-preference design were acceptable.

Conclusions: Parents of children treated for cancer appear willing to participate in trials examining internet-administered psychological support. Findings of this study will inform the design of a feasibility trial examining internet-administered psychological support for the population.

doi:10.2196/10085

KEYWORDS

anxiety; cancer; clinical trial; depression; eHealth; parents

http://mental.jmir.org/2018/4/e10085
Introduction

Background

Due to marked treatment advances across the developed world, the overall 5-year survival rate of children diagnosed with cancer is now >80% [1]. However, a number of negative impacts of living with childhood cancer persist long term, for both parents [2] and childhood cancer survivors [3,4]. In the case of parents, negative impacts include financial difficulties [5,6], uncertainty regarding future prognosis [7], and poor quality of life [8]. Furthermore, a considerable proportion of parents report elevated levels of long-term psychological distress [9-11]. However, despite increased psychological distress, parents have reported substantial unmet health care needs concerning the receipt of psychological support in Sweden [12] and Australia [13,14]. Potential reasons for these unmet psychological needs include the high costs of delivering psychological treatment, alongside a lack of qualified therapists [15]. Indeed, research indicates psychological support is not routinely offered to parents in Sweden [11,12]. Furthermore, parents may experience additional barriers to accessing psychological support such as lack of time, guilt, and putting their child’s health first [16].

Electronic mental health interventions (eMental Health) may represent a way of increasing access to psychological support [17] for parents of childhood cancer survivors. One example of an eMental Health intervention is internet-administered cognitive behavioral therapy (ICBT) [18]. ICBT is a clinically and cost-effective psychological intervention for a range of mental health difficulties [19] and has been demonstrated to be as effective as face-to-face psychological interventions [20]. Furthermore, ICBT may overcome barriers to accessing psychological support, such as parental guilt, considering its increased anonymity in comparison with face-to-face treatment [21]. In addition, as treatment provision is not confined to specific locations or times, practical barriers (eg, lack of time) may be overcome [21]. Given the potential of ICBT as a solution, a research program, informed by the Medical Research Council (MRC) framework for complex interventions [22], has been undertaken to develop an ICBT intervention tailored to the needs of parents of children treated for cancer [10,23].

This study builds upon the previous MRC phase I development [24] work [10,23] by recognizing the necessity to examine the feasibility of methodological and study procedures before conducting definitive controlled trials [25]. Successful recruitment, retention, and data completeness are essential for clinical trials to reach power and maximize generalizability [26]. However, recruitment difficulties in psychological treatment trials are common [27], including ICBT trials [28]. Indeed, in our previous research, we encountered difficulties with recruitment and attrition into a randomized controlled trial (RCT) examining an ICBT intervention for parents of children currently receiving treatment for cancer [29,30]. While trial design can contribute to poor recruitment [31] and attrition [32], understanding attitudes and preferences toward trial design may improve acceptability and, subsequently, recruitment and retention [33]. However, the existing literature is scarce on attitudes and preferences toward ICBT trial design, as well as willingness to participate among parents of children treated for cancer. As such, a survey study was conducted to examine attitudes and preferences regarding the design of a hypothetical trial of an internet-administered psychological intervention, alongside study response rates, past and present emotional distress, and help-seeking behavior. Results will be used to inform the design of a planned phase II feasibility trial (MRC) of the ICBT intervention previously developed for parents of children treated for cancer [10,23].

Aims and Objectives

The primary study aims were to examine (1) attitudes and preferences toward trial design and (2) willingness to participate in a hypothetical trial of internet-administered psychological intervention for parents of children treated for cancer. Secondary study aims were to investigate (1) overall response rates and differences in the response rate between two modes of study invitation and (2) current and past emotional distress and help-seeking behavior. The following outcomes were examined:

1. Overall response rate
2. Number of study invitation reminders required to recruit
3. Differences in the response rate between two modes of study invitation (standard letter and professionally illustrated postcard)
4. Self-reported current and past emotional distress
5. Prior help-seeking and receipt of psychological support
6. Willingness to receive internet-administered psychological support
7. Past experience of research participation and attitudes toward research
8. Attitudes and preferences concerning the delivery of initial study invitations and presentation of full study information
9. Attitudes toward participation in different trial designs (waiting list control, alternative active treatment, and patient-preference).

Methods

Study Design

A cross-sectional, Web-based, self-report survey was conducted from April 2017 to June 2017 with parents of children treated for cancer and recruited across Sweden.

Eligibility Criteria

In this survey study, Swedish-speaking parents of children treated for cancer (aged 0-16 years at study commencement) residing in Sweden were eligible. Parents were included if the child had (1) completed successful cancer treatment 3 months to 5 years earlier at study commencement and (2) been treated for cancer and recruited across Sweden. As such, a survey study was conducted to examine attitudes and preferences regarding the design of a hypothetical trial of an internet-administered psychological intervention, alongside study response rates, past and present emotional distress, and help-seeking behavior. Results will be used to inform the design of a planned phase II feasibility trial (MRC) of the ICBT intervention previously developed for parents of children treated for cancer [10,23].

Recruitment and Study Procedures

Potential participants were identified using a two-step screening process:

1. Childhood cancer survivors, meeting the inclusion criteria, were identified via the Swedish Childhood Cancer Registry (National Quality Registry, initiated in 1982).
2. Children’s personal identification numbers were linked to parents’ personal identification numbers via the SPAR-Registry (“Statens personadressregister” by Swedish acronym) held by the Swedish Tax Agency to obtain parent contact information.

Although the SPAR-Registry includes all currently registered residents in Sweden, at the time of the study, it was only possible to access parent information for children aged ≤16 years. Therefore, the current age-span of children, whereby it was possible to identify parents, was restricted to 0-16 years.

From identified parents, an in-house computer program was used to randomize to the mode of invitation (letter vs postcard), with a 1:1 allocation, stratified by cohabitation status (cohabiting parents, noncohabiting parents, one parent registered). Prior to posting invitations, the most up-to-date information concerning whether children were currently living, or deceased, was checked via the telephone by a member of the research group with the Swedish Tax Agency.

Parents were sent an invitation either via a postcard (Figure 1) or a letter (Figure 2). Each mode of invitation contained identical text (see Multimedia Appendix 1 for the English translation), providing brief study information, a link to a Web portal (the U-CARE-portal), and an individual log-in code. The study invitation letter followed a standard plain letter format and was sent in the post using an envelope. The study invitation postcard was designed by a professional illustrator, including color illustrations representing the intervention and population. Invitation letters or postcards, with a “post-stick” reminder note, were resent at 1 week and 2 weeks postinitial study invitation to parents who did not respond.

Figure 1. Study invitation postcard.
**Forskning med föräldrar**

Hej!

Vi är en grupp forskare vid Uppsala universitet som tillsammans med föräldrar till cancerdubbade barn utvecklar en internetbaserad psykologisk behandling för föräldrar. Om du vill vara delaktig i att undersöka hur forskning om programmet ska bedrivas och har 20 minuter över, gå in på [www.studie.u-care.se](http://www.studie.u-care.se) och svara på frågorna i formuläret.

Din studiekod är:

Tack för hjälpen!

Vänliga hälsningar,

Professor Louise von Essen, ansvarig forskare
Kontaktuppgifter: Professor Louise von Essen, ansvarig forskare
Tel: 070-4250714
E-post: louise-von.essen@kth.uu.se
Institutionen för kvinnors och barns hälsa
Uppsala universitet

**UPPSALA UNIVERSITET**

Vår forskning finansieras av

Cancerfonden

Vetenskapsrådet

Parents were provided full study information via the U-CARE-portal (Multimedia Appendix 2), and informed consent was provided through Web (Multimedia Appendix 3). After the provision of Web-based consent, parents gained access to the survey. Prior to completing the survey, parents were able to view a brief informational video (5 minutes and 23 seconds) presenting the background of the study. The brief informational video covered the following topics: (1) psychological distress in parents of children treated for cancer; (2) what is internet-administered psychological support; and (3) general psychological support.
information on clinical trials (eg, randomization and different types of control condition). Multimedia Appendix 4 provides the full video, and Multimedia Appendices 5 and 6 provide an English transcript of the video and translation of PowerPoint used in the video, respectively.

Ethical approval was obtained from the Regional Ethical Review Board in Uppsala (DNR: 2015/426/3).

**Sample Size**

Sample size calculation indicated that a minimum of 340 participants would be required to detect a difference of 15% in the response rate between groups (ie, those who responded vs those who did not respond), with a power of 0.8 and \( P < .05 \) (two-tailed).

**Measures**

**Sociodemographics**

The following sociodemographic data were collected for parents via the SPAR-Registry: (1) date of birth; (2) gender; and (3) marital status. Sociodemographic data for children were collected via the Swedish Childhood Cancer Registry: (1) cancer diagnosis; (2) date of diagnosis; (3) date of treatment completion; (4) date of birth; and (5) gender.

**Web-Based Survey**

A Web-based survey, consisting of 20 items and written in Swedish, was designed for the study and comprised 4 subsections as follows: (1) sociodemographics (3 items); (2) emotional distress and psychological support (6 items); (3) experience of participation in research and attitudes toward research (2 items); and (4) attitudes toward proposed trial procedures (9 items). The survey was administered on the U-CARE-portal, an internet research platform, designed to support both data collection and the provision of complex eMental Health interventions [34]. Multimedia Appendix 7 provides an English translation of the survey.

**Statistical Analysis**

Study recruitment and flow are reported using an adapted version of the Consolidated Standards of Reporting Trials Statement [35]. Descriptive statistics were used to describe the study sample and compare those who responded and those who did not respond regarding key sociodemographic and clinical variables for parents and children. Descriptive data are reported in terms of numbers (\( n \)) and percentages (\( \% \)) or means and SDs. Chi-square tests were used to assess differences between those who responded and those who did not concerning categorical data, and independent-sample \( t \) tests were used to assess differences regarding continuous variables (\( P < .05 \)). Furthermore, chi-square tests were used to assess differences in response rate between parents invited via postcard and those invited via study invitation letter. Descriptive statistics are used to present the responses to the Web-based survey. All data analyses were performed using SPSS statistics for Windows, version 24.8.

**Results**

**Study Recruitment and Participant Flow**

Figure 3 presents study recruitment and flow. Of 1241 children identified in the Swedish Childhood Cancer Registry, 430 met the eligibility criteria. The parents’ contact information could be identified for 416 of these children via the SPAR-Registry, totaling 813 parents eligible for inclusion. A stratified random sample (\( n = 352 \)) was drawn for randomization to the mode of invitation proportional to the number of cohabitating, noncohabitating, and single parents among potentially eligible parents identified. The distribution of the sample was as follows: 81.8% (288/352) cohabitating parents; 15.9% (56/352) noncohabitating parents; and 2.3% (8/352) single parents (status of other parent unknown) listed on the SPAR-Registry. Due to incorrect contact information listed in the SPAR-Registry, 2 eligible parents did not receive the study invitation and were excluded. Of the invited parents (174 via study invitation letter and 176 via study invitation postcard), 34.6% (121/350) provided Web-based consent and 32.0% (112/350) completed the Web-based survey. Before completing the Web-based survey, 45.5% (51/112) parents watched over 3 minutes, 26.8% (30/112) watched 2-3 minutes, and 27.7% (31/112) watched less than 2 minutes of the informational video.

**Sociodemographic and Clinical Variables**

The majority of parents who responded were female, cohabiting, with a mean age of 43.2 years. Children were predominantly male, had experienced leukemia, with a mean current age of 9.3 years, and had finished cancer treatment an average of 2.9 years ago. No significant differences were noted regarding parent or child sociodemographic and clinical variables between those who responded and those who did not (Table 1).

Figure 3. Study recruitment and flow.
Table 1. Baseline characteristics of those who responded versus those who did not respond (N=350).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Parents who responded (n=112)</th>
<th>Parents who did not respond (n=238)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td>.13</td>
</tr>
<tr>
<td>Female</td>
<td>63 (56.3)</td>
<td>113 (47.5)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49 (43.7)</td>
<td>125 (52.5)</td>
<td></td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td>.75</td>
</tr>
<tr>
<td>Cohabiting</td>
<td>90 (80.4)</td>
<td>196 (82.4)</td>
<td></td>
</tr>
<tr>
<td>Living apart</td>
<td>20 (17.8)</td>
<td>36 (15.1)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (1.8)</td>
<td>6 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>43.2 (7.3)</td>
<td>43.1 (6.6)</td>
<td>.87</td>
</tr>
<tr>
<td><strong>Child</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td>.73</td>
</tr>
<tr>
<td>Female</td>
<td>51 (45.5)</td>
<td>113 (47.5)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>61 (54.5)</td>
<td>125 (52.5)</td>
<td></td>
</tr>
<tr>
<td>Cancer diagnosis category, n (%)</td>
<td></td>
<td></td>
<td>.55</td>
</tr>
<tr>
<td>Leukemia</td>
<td>76 (67.9)</td>
<td>156 (65.5)</td>
<td></td>
</tr>
<tr>
<td>Central nervous system tumor</td>
<td>22 (19.6)</td>
<td>58 (24.4)</td>
<td></td>
</tr>
<tr>
<td>Solid tumor</td>
<td>14 (12.5)</td>
<td>24 (10.1)</td>
<td></td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>9.3 (2.8)</td>
<td>10.0 (3.0)</td>
<td>.63</td>
</tr>
<tr>
<td>Years since end of treatment, mean (SD)</td>
<td>2.9 (1.4)</td>
<td>2.9 (1.4)</td>
<td>.43</td>
</tr>
</tbody>
</table>

Mode of Study Invitation and Number of Reminders

No difference was noted between the mode of invitation and response rate (letter: 59/112, 52.7%, vs postcard: 53/112, 47.3%; \(\chi^2 = 0.6, P = .45\)). Among those who responded, 18.8% (21/112) responded to the first invitation (letter: 15/21, 71.4%; postcard: 6/21, 28.5%), 48.2% (54/112) responded following one reminder (letter: 27/54, 50.0%; postcard: 27/54, 50.0%), and 33.0% (37/112) responded after 2 reminders (letter: 17/37, 45.9%; postcard: 20/37, 54.1%).

Emotional Distress and Psychological Support

Table 2 presents results pertaining to emotional distress and psychological support. Current distress was commonly reported, and the majority of parents reported past experience of emotional distress. Of those parents who had sought help for their distress, the majority had received help. Help for emotional distress had been received from a variety of health professionals, with the majority receiving support from a psychologist, therapist, or physician. For those currently experiencing emotional distress, internet-administered psychological support, with guidance from a psychologist, was deemed appropriate by the majority (see Table 2). Furthermore, the majority parents (regardless of current emotional distress) reported that they would definitely or maybe accept internet-administered psychological support if offered.

Past Experience of Research Participation and Attitudes Toward Research

Almost half of the parents had previously participated in research, and the majority responded that they held either very high or somewhat high trust in research (Table 3).

Attitudes Toward Trial Procedures

Table 4 presents results regarding attitudes toward trial procedures. For receiving initial study information, the largest number of parents considered a postal letter as acceptable. In addition, the majority responded they would find presentation of further study information on a study website via text or video acceptable. While a researcher was most widely considered as an acceptable sender of study invitations, other professionals, including psychologists and nurses, were also considered acceptable by some parents (see Table 4). Furthermore, just under one-third of parents responded that they would find it acceptable to receive a study invitation from a parent of a child previously treated for cancer.

The majority of parents responded that they would either accept, or maybe accept, participation in a hypothetical RCT of an internet-administered psychological intervention utilizing a waiting list control condition. Little difference in the preference was found regarding an acceptable length of waiting list time; however, a slightly higher acceptance was reported for a waiting list length of 1-2 months (see Table 4). Moreover, the majority responded that they would accept, or maybe accept, participation in a hypothesized alternative active treatment and participant-preference trial.
Table 2. Emotional distress and preferences for psychological support (n=112).

<table>
<thead>
<tr>
<th>Emotional distress and preferences</th>
<th>Value, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emotional distress</strong></td>
<td></td>
</tr>
<tr>
<td>Current self-reported emotional distress</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>41 (36.6)</td>
</tr>
<tr>
<td>No</td>
<td>70 (62.5)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td><strong>Past emotional distress</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>80 (71.4)</td>
</tr>
<tr>
<td>No</td>
<td>32 (28.6)</td>
</tr>
<tr>
<td><strong>Psychological support</strong></td>
<td></td>
</tr>
<tr>
<td>Sought help for emotional distress</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (42.8)</td>
</tr>
<tr>
<td>No</td>
<td>33 (29.5)</td>
</tr>
<tr>
<td>Not applicable (no past or current emotional distress)</td>
<td>31 (27.7)</td>
</tr>
<tr>
<td><strong>Help received for emotional distress (of those who sought help)</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>39 (81.2)</td>
</tr>
<tr>
<td>No</td>
<td>8 (16.7)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td><strong>Type of help received for emotional distress</strong>&lt;sup&gt;a,b,c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Psychologist</td>
<td>14 (29.2)</td>
</tr>
<tr>
<td>Therapist</td>
<td>13 (27.1)</td>
</tr>
<tr>
<td>Physician</td>
<td>12 (25.0)</td>
</tr>
<tr>
<td>Counselor</td>
<td>7 (14.6)</td>
</tr>
<tr>
<td>Health care center</td>
<td>6 (12.5)</td>
</tr>
<tr>
<td>Church</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>Stress management self-help program</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Mindfulness Exercises</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td><strong>Preferences for psychological support for parents currently self-reporting distress</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Other (unspecified)</td>
<td>13 (31.7)</td>
</tr>
<tr>
<td>Internet-administered psychological treatment with support from a psychologist</td>
<td>11 (26.8)</td>
</tr>
<tr>
<td>Internet-administered psychological treatment and to see a psychologist in person</td>
<td>11 (26.8)</td>
</tr>
<tr>
<td>Internet-administered psychological treatment without support from a psychologist</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>See a psychologist in person</td>
<td>2 (5.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td><strong>Accept internet-administered psychological support if offered</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>47 (42.0)</td>
</tr>
<tr>
<td>Maybe</td>
<td>36 (32.1)</td>
</tr>
<tr>
<td>No</td>
<td>28 (25.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.9)</td>
</tr>
</tbody>
</table>

<sup>a</sup>n=48.<br><sup>b</sup>Multiple responses possible.<br><sup>c</sup>Open-ended question.<br><sup>d</sup>n=41.
Table 3. Past experience of research participation and attitudes toward research (n=112).

<table>
<thead>
<tr>
<th>Experience with and attitude toward research</th>
<th>Value, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Past experience of research participation</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56 (50.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>55 (49.1)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td><strong>Trust in research</strong></td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>56 (50.0)</td>
</tr>
<tr>
<td>Somewhat high</td>
<td>51 (45.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>5 (4.5)</td>
</tr>
</tbody>
</table>
Table 4. Attitudes concerning trial procedures (n=112).

<table>
<thead>
<tr>
<th>Attitude</th>
<th>Value, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receipt of initial study information</strong>a</td>
<td></td>
</tr>
<tr>
<td>Postal letter</td>
<td>86 (76.8)</td>
</tr>
<tr>
<td>Meeting with a physician, psychologist, or nurse</td>
<td>34 (30.4)</td>
</tr>
<tr>
<td>Telephone</td>
<td>18 (16.1)</td>
</tr>
<tr>
<td>Short message service text message</td>
<td>13 (11.6)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (9.8)</td>
</tr>
<tr>
<td><strong>Presentation of study information on a study website</strong>a</td>
<td></td>
</tr>
<tr>
<td>Text</td>
<td>81 (72.3)</td>
</tr>
<tr>
<td>Video</td>
<td>66 (58.9)</td>
</tr>
<tr>
<td>Image(s)</td>
<td>43 (38.4)</td>
</tr>
<tr>
<td>Audio</td>
<td>23 (20.5)</td>
</tr>
<tr>
<td><strong>Who should send study invitations</strong>a</td>
<td></td>
</tr>
<tr>
<td>Researcher</td>
<td>84 (75.0)</td>
</tr>
<tr>
<td>Psychologist</td>
<td>44 (39.3)</td>
</tr>
<tr>
<td>Nurse previously met</td>
<td>43 (38.4)</td>
</tr>
<tr>
<td>Parent of a child treated for cancer</td>
<td>36 (32.1)</td>
</tr>
<tr>
<td>Psychologist previously met</td>
<td>32 (28.6)</td>
</tr>
<tr>
<td>Nurse</td>
<td>30 (26.8)</td>
</tr>
<tr>
<td>Another option, not specified</td>
<td>11 (9.8)</td>
</tr>
<tr>
<td><strong>Acceptability of controlled trial procedures</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Waiting list randomized controlled trial</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53 (47.3)</td>
</tr>
<tr>
<td>Maybe</td>
<td>41 (36.6)</td>
</tr>
<tr>
<td>No</td>
<td>18 (16.1)</td>
</tr>
<tr>
<td><strong>Length of waiting list</strong></td>
<td></td>
</tr>
<tr>
<td>1-2 months</td>
<td>20 (17.8)</td>
</tr>
<tr>
<td>3-4 months</td>
<td>15 (13.4)</td>
</tr>
<tr>
<td>5-6 months</td>
<td>17 (15.2)</td>
</tr>
<tr>
<td>&gt;6 months</td>
<td>18 (16.1)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (9.8)</td>
</tr>
<tr>
<td>Would decline participation</td>
<td>17 (15.2)</td>
</tr>
<tr>
<td>Missing</td>
<td>14 (12.5)</td>
</tr>
<tr>
<td><strong>Active treatment randomized controlled trial</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>49 (43.7)</td>
</tr>
<tr>
<td>Maybe</td>
<td>42 (37.5)</td>
</tr>
<tr>
<td>No</td>
<td>18 (16.1)</td>
</tr>
<tr>
<td>Missing</td>
<td>3 (2.7)</td>
</tr>
<tr>
<td><strong>Patient-preference controlled trial</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>59 (52.7)</td>
</tr>
<tr>
<td>Maybe</td>
<td>34 (30.3)</td>
</tr>
<tr>
<td>No</td>
<td>17 (15.2)</td>
</tr>
</tbody>
</table>
Discussion

Principal Findings

This cross-sectional, Web-based survey examined attitudes and preferences toward and willingness to participate in a hypothetical trial of an internet-administered psychological intervention for parents of children treated for cancer. Furthermore, differences in the response rate between two modes of study invitation (standard letter vs professionally illustrated postcard) were examined. To the best of our knowledge, this is the first survey to examine attitudes and preferences toward the design of and participation in internet-administered psychological intervention trials within the population. Summarizing the main findings, an overall 32.0% (112/350) response rate was yielded, yet no difference was found in the response rate between modes of study invitation. Self-reported current and past emotional distress was common. Internet-administered psychological support, under guidance of a psychologist, was deemed acceptable by the majority of those parents currently reporting emotional distress and of the surveyed population as a whole. Examination of acceptable recruitment methods indicated the most acceptable method of study invitation would be via postal letter, with full study information presented on a study website via text or video and delivered by a researcher. On the whole, parents responded that they would either accept, or maybe accept, participation in each presented hypothetical trial design (waiting list control, alternative active treatment, patient-preference), with no overall indication of a preferred trial design.

It is interesting to note that no association between the mode of invitation and the response rate was detected. As such, this suggests professional illustration may not increase study response rates. This finding is in contrast to research indicating that professionally designed invitation packs can improve recruitment rates [36]. Still, other studies on the optimization of patient information sheets via professional design and user-testing have failed to yield larger response rates compared with providing standard study information [37,38]. Given these findings, the time and financial resources required to engage a professional design service may not be warranted. A note of caution is, however, due here as the main design modification was the use of professional illustration and presentation via a postcard versus standard study invitation letter. Future research may be required to examine whether additional design modifications (eg, language, structure, and length) may impact response rates.

Another noteworthy finding was that parents showed an overall preference for receiving initial study invitations via the telephone as acceptable. However, this survey specifically examined the acceptability of telephone contact regarding the receipt of initial study invitation, rather than preferred ways of receiving study invitation reminders. Further work may aim to examine what methods of sending study reminders would be considered acceptable. Moreover, it is interesting to note that the majority of parents responded receiving full study information on Web in text and video format would be perceived as acceptable. Indeed, research suggests the provision of trial information via video, supplementing the provision of written information, may improve participation rates [40].

Interestingly, similar percentages of parents responded they would agree, or maybe agree, to participate in trials using waiting list control, alternative active treatment, and patient-preference designs. Furthermore, little difference was found concerning acceptable waiting times for a hypothetical waiting list RCT. As such, the majority responded they would be willing to participate in hypothetical trial designs utilizing randomization procedures. This finding is in contrast to research reporting that a fear of randomization is a common reason for declining trial participation [41]. One potential explanation for this finding may be the presentation of an informational video to participants explaining randomization and different designs presented in the survey. Indeed, previous research has demonstrated that clinical trial educational videos can reduce barriers to trial participation and increase preparedness to consider clinical trial enrollment [42]. Furthermore, almost half of the parents responded that they had previously participated in research, and almost all reported high to moderately high levels of trust in research. Again, this finding contrasts with previous research, whereby fear and mistrust of clinical trial research has been reported [43]. Given many parents had participated in past research, the surveyed population may already have increased levels of knowledge regarding trial design, resulting in more positive attitudes toward trial participation.

In line with previous research [9,11], a substantial proportion of parents responded that they had experience of past and current emotional distress. This finding further supports research demonstrating parents experience a need for psychological support from the end of cancer treatment, persisting into the long term [12]. Although in contrast to previous research [12-14], the majority who had sought support for their distress had received support from a health care professional. Despite this, it is important to bear in mind that the survey did not examine the type, quality, or acceptability of psychological support received by parents. In addition, survey results indicate that internet-administered psychological interventions, supported by a psychologist, potentially represent an acceptable type of support for parents of children previously treated for cancer. These findings are in line with wider research indicating generally high levels of acceptability for the delivery of internet-administered psychological interventions [21].
However, future research is required to examine the acceptability of the internet-administered psychological intervention from the perspective of actual intervention users.

Limitations

This study has several limitations. First, willingness to participate in a hypothetical trial of an internet-administered psychological intervention may not predict actual trial enrollment [44]. Even though the majority of respondents demonstrated a willingness to participate in a hypothetical trial, findings may not represent the decision made if parents were offered participation in a “real-life” trial. A related limitation pertains to the examination of response rates. The study was a brief Web-based survey; however, trial participation requires time and commitment [39]. Therefore, response rates obtained in this Web-based survey may not reflect actual trial response rates. In addition, there was no formal measurement of emotional distress utilizing a standardized and validated self-report or clinician-administered measurement of distress. As a consequence, it is difficult to determine whether parents were experiencing levels of emotional distress suitable for psychological support. Thus, findings may not be generalizable to parents experiencing clinical levels of emotional distress appropriate for formal psychological support. Still, percentages of parents responding that they had experienced either past or current emotional distress are in line with earlier studies examining clinically relevant levels of psychological distress in the population [11]. An additional limitation is the small survey sample size, resulting from a 32% response rate. This is especially important considering parents who did not respond may have different attitudes and preferences toward trial design and conduct. Indeed, previous work suggests a category of nonresponders to research labeled “prior decliners” who have an established and unmodifiable position of declining participation in research [45]. Importantly, the majority of parents who did respond had previously participated in research, and therefore, surveyed sample may represent parents with higher levels of acceptability concerning research.

Another limitation pertains to only examining the acceptability of more traditional clinical trial recruitment strategies, for example, postal recruitment and clinician referral. However, evidence suggests Web-based recruitment strategies are effective for internet-administered intervention trials [28,46] and future studies may wish to examine attitudes and preferences toward Web-based recruitment strategies. The adoption of postal, rather than Web-based, recruitment strategies may also have reduced the survey participation rate. A further limitation concerns the cross-sectional survey design adopted. Adopting a mixed-methods approach may have facilitated a more thorough exploration of research questions and aided interpretation of survey findings. Finally, the order of response alternatives may have resulted in primacy effects.

Notwithstanding these limitations, this is to our knowledge the first study to examine attitudes toward clinical trials, preferences regarding study design, and willingness to receive internet-administered psychological support among parents of children previously treated for cancer. The results from this study will have considerable implications for the design of a planned feasibility study [47], such as initial study invitations being sent via postal letters by the research team, full study information being presented on Web via both text and video, and the provision of support from a psychologist.

Conclusions

Clinical trial conduct is time and resource intensive. While research has been performed to examine attitudes and preferences toward clinical trial design and participation [33,48,49], little is known about attitudes and preferences toward trial design and participation in this study population. What also remains unclear is the acceptability of internet-administered psychological interventions from the perspective of parents of children previously treated for cancer. This study builds upon prior research to develop an ICBT intervention for the population and preliminary investigation of the acceptability of planned study procedures [10,23]. Survey findings have further enhanced our understanding of the acceptability of internet-administered approaches for the population, alongside an appreciation of potentially acceptable study procedures and design. Results will inform the design of a feasibility study of an ICBT intervention for parents of children previously treated for cancer [47], to further examine methodological, procedural, and clinical uncertainties [25,50].

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Postcard and letter invitation text (English translation).

[PDF File (Adobe PDF File), 25KB - mental_v5i4e10085_app1.pdf]
Multimedia Appendix 2
Full study information (English translation).

[PDF File (Adobe PDF File), 24KB - mental_v5i4e10085_app2.pdf]

Multimedia Appendix 3
Informed consent (English translation).

[PDF File (Adobe PDF File), 26KB - mental_v5i4e10085_app3.pdf]

Multimedia Appendix 4
Informational video (Swedish).

[MP4 File (MP4 Video), 89MB - mental_v5i4e10085_app4.mp4]

Multimedia Appendix 5
Informational video (English transcript).

[PDF File (Adobe PDF File), 27KB - mental_v5i4e10085_app5.pdf]

Multimedia Appendix 6
Informational video PowerPoint slide (English translation).

[PPTX File, 2MB - mental_v5i4e10085_app6.pptx]

Multimedia Appendix 7
Web-based survey (English translation).

[PDF File (Adobe PDF File), 40KB - mental_v5i4e10085_app7.pdf]

References


Abbreviations

ICBT: internet-administered cognitive behavioral therapy
MRC: Medical Research Council
RCT: randomized controlled trial

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Original Paper

Advice for Health Care Professionals and Users: An Evaluation of Websites for Perinatal Anxiety

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School of Psychology, Open University, Milton Keynes, United Kingdom

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Abstract

Background: Many websites are available with information and resources for perinatal anxiety; however, there is limited research on the quality and content of these sites.

Objective: This study aims to identify what sites are available on perinatal anxiety, identify any information and therapeutic advice given, and review its accuracy and website design.

Methods: We conducted an evaluation of websites for perinatal anxiety. Eligible websites (N=50) were evaluated for accuracy of information, resources for mothers, website quality, and readability.

Results: Information was often incomplete and focused on symptoms rather than risk factors or impact of untreated perinatal anxiety. Websites often had information on treatment (46/50, 92%), but much less on screening (19/50, 38%). Most sites provided at least some resources to support mothers (49/50, 98%), but active, guided support was infrequent (25/50, 50%). Website quality was extremely variable and mostly difficult to read (42/50, 84%).

Conclusions: This study recommends the top 4 websites on perinatal anxiety for health care professionals and users. There is a need for websites to be developed that provide accurate, evidence-based information that women can relate to with quality support resources. Furthermore, these sites should be easy to use and readable.

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KEYWORDS
anxiety; female; internet; perinatal; postpartum

Introduction

The perinatal period (ie, including pregnancy and the 12 months following childbirth) marks a profound change and transition for women, which can often be experienced as stressful and overwhelming. Indeed, research in this area suggests that approximately 15%-25% of women experience marked levels of anxiety in this period [1]. Despite being treatable once recognized, most women experiencing perinatal anxiety (PNA) do not seek help for their symptoms [2].

There are a number of reasons why women with PNA may not seek help. While there is mass public awareness about postnatal depression (PND), knowledge about other aspects of perinatal mental health is lacking at both public and health care professional (HCP) levels [3,4]. Thus, symptoms may go unrecognized. For those who do recognize their symptoms, concerns about being regarded as a bad mother [5] and the perceived stigma attached to mental health issues in this period may mean women are less likely to seek treatment [6,7]. This is problematic, as untreated PNA may be associated with a variety of negative outcomes in both the mother and infant, including preterm delivery, low birth weight, PND, excessive infant crying, bonding issues, problematic feeding behaviors, and adverse developmental and mental health problems in children [1,8-10].

One of the challenges in raising awareness of PNA is that the concept is relatively new. Furthermore, PNA has been conceptualized and operationalized in a range of different ways...
in the literature, varying from self-reported pregnancy-related anxiety symptoms to the exploration of incidence rates of clinically diagnosable anxiety disorders in the antenatal and postnatal periods. Thus, some caution needs to be taken when exploring this construct. For example, it is important not to overpathologize anxiety experienced in this period, as perinatal worry is common and often “normal.” Thus, a distinction needs to be drawn between common transient anxieties often experienced around childbirth and more persistent symptoms that may be more indicative of an anxiety disorder. However, as evidence suggests, even subthreshold anxiety symptoms may have a negative impact on maternal and infant outcomes [11,12]; thus, support for women who experience subthreshold symptoms remains important.

In addition, there may be a need to further consider how clinically significant PNA is diagnosed and recognized. While higher rates of anxiety disorders, similar to those seen in the general population (including generalized anxiety disorder and obsessive-compulsive disorder), are evident around childbirth [13], a significant proportion of women who experience anxiety in the perinatal period do not meet the criteria for Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) diagnosis, instead presenting with distressing levels of “maternally focused worry” [14,15]. Therefore, PNA may constitute a clinically distinct phenomenon that is not fully captured by traditional diagnostic methods and scales, resulting in the poorer recognition of these context-specific symptoms. Furthermore, the most common perinatal screening tool currently used in perinatal primary care (the Edinburgh Postnatal Depression Scale; EPDS [16]) was primarily designed to detect PND, which may contribute to the poorer recognition of PNA by both the public and HCPs.

One way to potentially increase public (and professional) awareness of PNA is to use Web-based technology to deliver clinically helpful information, diagnostic and self-help strategies, and evidence-based treatments over the Web. Web-based methods of delivery may be particularly helpful to women in the perinatal period, who may not have the flexibility or time to attend face-to-face appointments with HCPs; and the anonymity the internet affords may circumvent issues associated with stigma [17]. In addition, there is evidence that users who frequently search for health information online tend to be women [18]. Thus, the internet has the potential to break down barriers to help-seeking behaviors in the perinatal period and empower women to self-diagnose and gain support [19,20]. Moreover, the internet can offer HCPs an opportunity to learn more about PNA, delivering up-to-date information about symptoms, risks and outcomes, as well as evidence-based screening and treatment options. Despite this, little is known about the current state of Web-based support and information available for PNA. Thus, women and HCPs need the means to identify which websites are most reliable and provide quality information and resources for PNA.

The literature on perinatal mental health websites is limited. There have been 2 extensive reviews of websites for PND. The first study rated the content and technology of 34 PND-related websites using a general measure of depression, a measure of the website quality and readability [21]. Websites rarely presented current and accurate information on depression, had technological shortcomings, and were difficult to read. A significant number presented misleading information, and some advocated alternative treatment over treatment from an HCP. The second review rated 114 websites using more detailed scales that specifically evaluated information on PND and identified online support resources for women with PND [22]. Findings revealed that the information provided was inadequate and the website quality was variable. While resources for women were often provided, they had limited availability and scope. To date, there is no known review of PNA websites.

Using a similar review method to that of Moore and Ayers [22], this study aims to identify and evaluate current websites for PNA and evaluate their accuracy and quality on a variety of dimensions. This study had 4 key aims: (1) to identify what sites women searching for information about PNA might find; (2) to identify any information and therapeutic advice given and its accuracy; (3) to evaluate website design in terms of navigation, readability, presentation, and accessibility; and (4) to suggest sites that might be most helpful for HCPs and their clients or patients.

Methods

Search Strategy

We used lay search terms (Textbox 1) to identify websites an individual looking for information on PNA might find. Thirty combinations of these terms were entered into UK versions of the 4 most popular search engines (Google, Bing, Yahoo, and Ask) in February 2018 [23]. Browser history and cookies were deleted before conducting each search.

As Web users rarely access sites after the first 20 results [24], the first 20 results and featured sites (those paid to appear at the top of the search list) were assessed for inclusion. To be included in the study, websites had to contain at least 500 words about PNA.

Websites that did not contain any information on PNA and that solely focused on any of the following were excluded: other perinatal mental illnesses (eg, PND and puerperal psychosis), stillbirth, bipolar disorder, infant death, abortion, miscarriage, general and childhood anxiety, and general mental health. News items, magazines, blogs, forums, Facebook groups, and other social media were excluded; as were PDFs, videos, scholarly papers, training courses, paid for online therapy, sales promotions, other search engine results and broken links.
Website Evaluation
There is currently no validated measure that can be used to evaluate websites specific to PNA. While some validated measures exist to assess the quality of generic health and treatment information (such as DISCERN), they are not designed to assess the accuracy of information presented or evaluate whether it is evidence-based [25]. Therefore, the authors sought to develop a measure that could assess these dimensions, specifically in terms of PNA. As such, the authors developed a rating scale using a modified version of the measure devised by Moore and Ayers [22] to assess PND sites. This included the following 6 sections:

Accuracy of Information About Perinatal Anxiety
To assess the accuracy of the information presented on the sites, a review of previously validated scales investigating anxiety in the pre- and postnatal period (including pregnancy-related anxiety) was conducted. Distinct symptoms identified from these scales were compiled to form part of this scale, alongside the DSM-V [26] criteria for anxiety disorders. Similarly, a pragmatic review of the PNA literature was carried out to identify previously published, peer-reviewed papers that identified the risk factors associated with PNA, and its impact on mother and child. Each risk factor and impact outcome were also collated. This resulted in the production of 3 subscales as follows:

Symptoms
This subscale examined whether accurate and appropriate symptom information was given about common anxiety symptoms experienced by women in the perinatal period. A checklist of possible PNA symptoms was created by combing those outlined in the DSM-V [26] criteria for anxiety disorders (n=11), and distinct symptoms that were extracted from 3 validated PNA-specific measures (n=8)—The Perinatal Anxiety Screening Scale (PASS) [27], The Postpartum Specific Anxiety Scale (PSAS) [28], and the revised Pregnancy-Related Anxiety Questionnaire-Revised (PRAQ-R) [14]. Websites scored 1 point per symptom listed, with a range of 0-19.

Risk Factors
The second subscale included items related to factors that research has found to be linked to PNA, including poor social support, previous mental illness, and previous traumatic life event [10,29]. Again, websites scored 1 point for each risk factor given, with a range of 0-11.

Impact
The third subscale was divided into 2 sections (impact on the mother and impact on the infant) and included items research has identified as potential consequences of PNA, including diminished responsiveness to infant cues, low birthweight, and adverse developmental issues [30-32]. Using a similar method to those above, the range of scores was 0-13 (0-8 for maternal impact and 0-5 for infant impact factors). Impact on the father and partner of the mother were excluded, as there was insufficient evidence-based literature. A total score for information accuracy was created by summing symptoms, risk factors, and impact scores, with a possible range of 0-43.

Inclusion of Appropriate Treatment and Screening Information
This section noted whether websites included accurate information about appropriate screening tools for PNA and its treatment. In terms of treatment, a meta-review of systematic reviews assessing the treatment efficacy for PNA was carried out and efficacious treatment options were identified. These included face-to-face, group, and online CBT-based treatments, mindfulness and pharmacological interventions such as selective serotonin reuptake inhibitors[33,34]. Each website was categorized as either providing information about evidence-based treatment options, containing no treatment information, or including inaccurate or unsafe information that advocated alternative treatments over formal medical or psychological help. If a site contained information about treatment options, the nature of these treatments was noted.

Websites were also categorized according to whether they (1) provided PNA screening information to users using established, validated screening tools or (2) provided no information at all. They were then further coded according to the nature of the tool along 3 dimensions—generic anxiety scales, PNA-specific scale, PND scale, and the tools themselves were noted.

Available Help
Websites also received a score for the number of resources they offered; these were grouped into 3 categories as follows:

Tools for Mothers
These encompassed self-directed information and tools, including help-seeking advice, self-help, and coping strategies and relaxation techniques. Websites were assigned 1 point for each tool (range 0-14).

Support for Mothers
Support for mothers quantified the support websites offered that were guided (or monitored) by an HCP. This included online and offline support, including message-based counseling, helplines, and group meetings. Again, 1 point was assigned for each resource available (range 0-12).

Additional Resources
Additional resources scored any other resources that might be useful to mothers, including links to external sites, audio-visual resources, book reviews, and leaflets (range 0-11). The scoring criteria for each category were based on Moore and Ayers [22].
However, any additional resources that were identified as part of the review were added to the scoring criteria *pro re nata*.

**Website Quality**

The quality of each website was examined using 9 subscales, each scored on a scale of 0-2 (equating to poor, mediocre, and good).

**Contactability**

Websites scored points if (1) the author was identified and (2) the contact information was provided.

**Up-to-Date**

Points were assigned if (1) there was evidence of regular website maintenance and (2) all of their links were functioning correctly.

**Navigation**

Websites with a clear menu or index that linked to all pages on the site were assigned 2 points. Websites that were relatively easy to navigate but needed several clicks to access all pages scored 1. If sites were difficult to navigate, they scored 0. Common reasons for scoring 0 were the lack of menu or index, the presence of many confusing or hidden links, a structure that causes users to get stuck in a navigation loop, or sites that necessitated the use of a search option to find relevant information.

**Presentation**

Websites that looked “clean,” with clear, uncluttered pages, with a good balance between text and pictures were assigned 2 points. Conversely, websites scored 0 if they were confusing and overcrowded, with too much information on a page and no pictures. A score of 1 was given to sites that fell between the 2.

**Advertisements**

Advertisements can cause users to have a negative experience of a website, distracting them from the main purpose of the site, and disrupting its presentation and usability. The maximum points were assigned to sites without any advertisements, 1 point was given to sites that had some advertising, but which was relatively inconspicuous, and 0 was assigned to sites that contained adverts that impaired user experience.

**Accessibility**

Websites that required fees or special software to access information were assigned 0 points; those that required users to create an account (for free) before they could access information were rated 1; and sites where the majority of information was freely available and easy to access scored 2.

**Credibility**

Websites scored points if they (1) included evidence-based content and (2) showed that information was legitimate by containing relevant references and citations. Information was deemed “evidence-based” if it included more than just anecdotal or personal opinion and had been previously identified in the literature as being associated with a PNA cohort. This information was often provided without including citations. As this type of information was often reported without the inclusion of references, an additional scoring criterion was added to capture information about the frequency of appropriate citations.

**Engagement**

Points were assigned for sites that (1) included information that was well-targeted or personalized for the audience (eg, that was presented in an easily relatable manner, eg, by couching symptoms and information in terms of real-life stories and experiences, and how they might manifest in this cohort) and (2) used methods designed to hold user interest (eg, presenting information in different formats or containing a degree of interactivity).

**Audience Relationship**

This section considered qualitative information about the websites’ relevance to a perinatal audience along 4 dimensions.

**Website Specificity**

This section classified whether the PNA information identified belonged to websites dedicated to PNA or whether the PNA information was just a subsection of a site dedicated to other topics.

**Perinatal Anxiety Specificity**

This involved specifying whether the information provided about PNA was done so in its own right, or whether it conflated PNA with perinatal depression.

**Location**

As the location of the Web-owner may directly influence the relevance of content and resources offered, each website was given a country code.

**Author**

Finally, as the nature and content (and even credibility) of a website is likely to be influenced by its authors, each website was coded as being authored by one of the following: health institute, charity, a woman who had recovered from PNA, researcher, therapist, and other.

**Readability**

Finally, the initial paragraph of each site was copied into Microsoft Word to establish its Flesch-Kincaid Grade Level [35]. This measure uses a formula including total words, sentences, and syllables to calculate the level of education someone is likely to need (in years) to easily read the text. It is a reliable measure that is frequently used to assess how difficult it is to understand health information, and previous research considered the first paragraph a good representation of the content of websites [22]. Health education experts advise information to have a reading level of ≥8.

**Results**

**Website Identification**

We screened 4000 hyperlinks for eligibility. Search engine results yielded 47 websites that met the inclusion criteria. 3025 were duplicates and 575 were excluded with the following reasons: they included <500 words on PNA (n=188), focused solely on other perinatal mental illnesses (n=9), general anxiety
and childhood anxiety (n=37), or general mental health (n=21); they were news items (n=48), magazines (n=26), blogs (n=33), forums (n=7), Facebook groups and other social media (n=3), PDFs (n=11), videos (n=6), scholarly papers (n=87), training courses (n=17), paid online therapy (n=38), sales promotions (n=37), other search engine results (n=3), and broken links (n=4). Eligible websites were examined for hyperlinks to other websites (n=400). Resultant links were assessed for eligibility and yielded a further 3 websites for inclusion.

**Measure Reliability**

In total, 50 websites were reviewed by the primary author. To ensure the reliability of ratings, 10% (5/50) of the websites were selected using an online random number generator [36] and reviewed independently by the second author. This method was chosen to mirror a similar review of PND-focused websites [22]; furthermore, calculating the interrater reliability on a small subsample of cases and generalizing results to the full sample is a common, acceptable method when time and resources do not allow double ratings for all cases [37]. Intraclass correlations (ICC) revealed an excellent degree of reliability for the subscales perinatal anxiety information (ICC=.95), website quality (ICC=.94), and additional resources (ICC=.96), while treatment and screening displayed good reliability (ICC=.75). Discrepancies predominantly arose from missed information resulting from poor site navigation.

**Accuracy of Information**

Figure 1 shows the distribution of scores for information on symptoms, risk factors, and impact given by websites. All but 2 websites referred to at least one symptom of PNA, although the number of symptoms reported by the sites was variable (range 0-15; mean 8.02 [SD 3.97]). None of the sites reported all 19 symptoms, and 20% (10/50) reported <5. Where symptoms were described, the vast majority tended to be related to anxiety symptoms observed in the general population (mean 5.60 [SD 2.86]), rather than PNA-specific symptoms (mean 1.68 [SD 1.25]). The most frequently mentioned symptoms can be seen in Table 1, alongside frequently reported risks and impact information. Confusingly, 20% (10/50) of the websites included some of the symptoms on the rating checklist but did so in relation to PND, and not PNA (these were not scored).

The information presented for risk factors was also variable (range 0-10; mean 3.16 [SD 2.53]). None of the sites reported all 11 risk factors, 98% (49/50) reported <7, and 20% (10/50) reported none.

Impact information occurred the least with 42% (21/50) of sites failing to report anything on this scale (range 0-6; mean 1.46 [SD 1.74]). While 60% (30/50) of sites listed one or more impacts on the mother (range 0-4; mean 1.18 [SD 1.24]), only 22% (11/50) mentioned infant outcomes (range 0-4; mean 0.48 [SD 1.01]).

The total score for information accuracy was created by summing symptoms, risk factors, and impact scores, with a possible range of 0-43. However, the actual range observed was 1-25 (mean 12.64 [SD 6.06]).

**Treatment and Screening**

Most sites included information on treatment (46/50, 92%); 37 treatments were suggested with the most common being medication (38/50, 76%), cognitive behavioral therapy (28/50, 56%), and cognitive therapy (16/50, 32%).

In contrast, only 38% (19/50) of the sites contained mental health screening information. Ten scales were mentioned overall, with the EPDS cited most frequently (14/50, 28%). All other scales were generic mental health scales and not specific to the perinatal period. None appeared more than twice.

No sites contained inaccurate information or recommended alternative treatments over treatment from an HCP.
Table 1. The most commonly provided information across the websites.

<table>
<thead>
<tr>
<th>Information provided</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptoms</strong></td>
<td></td>
</tr>
<tr>
<td>Worry about infant safety and welfare</td>
<td>41 (82)</td>
</tr>
<tr>
<td>Persistent unjustified worry</td>
<td>40 (80)</td>
</tr>
<tr>
<td>Somatic symptoms of panic</td>
<td>36 (72)</td>
</tr>
<tr>
<td>Obsessive and intrusive thoughts</td>
<td>70 (35)</td>
</tr>
<tr>
<td><strong>Risk factors</strong></td>
<td></td>
</tr>
<tr>
<td>Previous traumatic life event</td>
<td>30 (60)</td>
</tr>
<tr>
<td>Negative birth experience</td>
<td>20 (40)</td>
</tr>
<tr>
<td>Stress during pregnancy</td>
<td>20 (40)</td>
</tr>
<tr>
<td>Poor social (or partner) support</td>
<td>19 (38)</td>
</tr>
<tr>
<td><strong>Impact</strong></td>
<td></td>
</tr>
<tr>
<td>Relationship issues or sexual dysfunction</td>
<td>13 (26)</td>
</tr>
<tr>
<td>Difficulty fulfilling family roles</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Low birth weight</td>
<td>9 (18)</td>
</tr>
<tr>
<td>Adverse effects on infant development</td>
<td>6 (12)</td>
</tr>
</tbody>
</table>

Table 2. The most commonly used tools, support, and resources across the websites.

<table>
<thead>
<tr>
<th>Available help</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tools</strong></td>
<td></td>
</tr>
<tr>
<td>Information on how to seek help</td>
<td>41 (82)</td>
</tr>
<tr>
<td>Standard self-help information</td>
<td>29 (58)</td>
</tr>
<tr>
<td>Stigma reduction tools</td>
<td>22 (44)</td>
</tr>
<tr>
<td>Stories from other mothers</td>
<td>22 (44)</td>
</tr>
<tr>
<td><strong>Support</strong></td>
<td></td>
</tr>
<tr>
<td>Telephone helplines</td>
<td>16 (32)</td>
</tr>
<tr>
<td>Forums</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Referrals to health care professionals</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Therapy appointments</td>
<td>4 (8)</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td></td>
</tr>
<tr>
<td>External links</td>
<td>27 (54)</td>
</tr>
<tr>
<td>Associated social media</td>
<td>23 (46)</td>
</tr>
<tr>
<td>Downloads</td>
<td>20 (40)</td>
</tr>
<tr>
<td>Contacts</td>
<td>20 (40)</td>
</tr>
</tbody>
</table>

Available Help

A range of help was provided across the sites including 14 different tools for mothers with PNA (see Multimedia Appendix 1 for full details). Of the sites evaluated, 98% (49/50) contained information about at least one tool (range 0-14; mean 5.36 [SD 3.39]). In addition, one site presented all 14 support tools on the measure (maternalmentalhealthnow.org).

In contrast, websites were relatively conservative in terms of the active support they offered, with only 50% (25/50) of sites offering some form of guided support (range 0-4; mean 0.94 [SD 1.20]). However, most provided links to additional resources (86% [43/50] contained at least one complementary resource; range 0-9; mean 3.20 [SD 2.41]). The most commonly supplied tools, support, and resources can be seen in Table 2. The total score for available help was calculated by adding together the 3 subscales (range 2-23; mean 9.50 [SD 5.75]).
Website Quality

The website quality varied substantially between the reviewed sites (range 6-17; mean 13.42 [SD 2.55]), although 60% (30/50) of sites scored over 13 (out of 18). Overall, the websites performed well on contactability (98%, 49/50), accessibility (92%, 46/50), and advertisements (84%, 42/50). Sites tended to do a bit worse on up-to-dateness and credibility, with the majority of sites scoring in the midrange on these dimensions (Figure 2). Sites were more likely to receive a “poor” rating on measures of navigation, clarity, advertisements, and engagement.

Audience Relationship

An analysis of the website specificity revealed that 34% (17/50) of PNA information belonged to sites that were dedicated to perinatal mental health, especially the remaining 66% (33/50) were more general sites containing subsections (or pages) with information on PNA.

In addition, the PNA specificity was relatively low, with only 32% (16/50) of websites clearly separating PNA and PND. This proportion was similar for both sites dedicated to perinatal illness (5/17, 29%) and those covering a broader area (11/33, 33%).

Half of the websites were located in the United Kingdom, 10 in Australia, 9 in the United States, 5 in Canada, and 1 in New Zealand. Of sites whose ownership was transparent, 21 were created by a charity, 14 by a health institute, 4 by therapists, 3 by researchers, and 2 by women who had experienced PNA themselves.

Furthermore, it was noticed that websites tended to be aimed exclusively at mothers (24/50, 48%) or both mothers and HCPs (13/50, 26%). Only 3 sites were intended to be used solely by HCPs (3/50, 6%), and the remaining websites addressed different combinations of mothers, HCPs, and others (10/50, 20%).

Reading Level

The reading level ranged from 7.1 to 37.4 and had a mean of 11.67 (SD 4.75). Only 16% (8/50) of sites had a reading level of ≥8 as recommended by health education experts [38,39].

Top Websites

To be rated as a top website for HCPs and users, sites had to rank in the 75th percentile (or above) for information, website quality, and available help, and include accurate information about both screening and treatment. Only 4 sites met these criteria: (1) perinatal.anxietybc.com; (2) pada.nz; (3) halton.ca; and (4) mind.org.uk. However, websites (2) to (4) conflated perinatal anxiety and postnatal depression.

Discussion

Principal Findings

This study aimed to identify and review websites that contain information about PNA, evaluate the accuracy of information given, and the quantity and suitability of therapeutic advice and resources offered. This was done using an adapted version of Moore and Ayers’ [22] original measure, tailored to PNA. The quality of websites’ navigation, readability, presentation, and accessibility was also reviewed. An additional aim of this study was to identify the current most useful websites available for HCPs and their clients. Information was often inadequate and focused on symptoms rather than risk factors or impact on the mother and infant. In addition, websites often had information on treatment, but few contained perinatal mental health screening information. While most sites provided at least some resources to support mothers, this was predominantly in the form of self-help or additional resources; active, guided support was infrequent. The website quality was extremely variable, with most presenting content that was difficult to read. The review suggests the top 4 websites for HCPs and their clients, and further advice is given to HCPs throughout this discussion.
This review identified 50 websites related to PNA, considerably fewer than 114 sites identified by Moore and Ayers in their review of PND websites [22]. This suggests PNA may still be comparatively underrecognized, undersourced, and underresearched [28,40]. No “gold standard” website was identified, as no single site contained complete information and resources, alongside a high score for the website quality. Mirroring the findings of Moore and Ayers [22], websites that scored well for information did not always score well for support and vice versa. However, 4 websites have been recommended for HCPs own use, and it is suggested they can recommend these sites to their clients considering the points raised in this discussion.

The information provided by websites was frequently incomplete, predominantly focusing on symptoms related to general anxiety rather than those that may be specifically related to PNA. This could prevent women relating to the information presented and prevent HCPs recognizing symptoms, thus potentially presenting a barrier to both help-seeking and treatment [15,41]. Conversely, while the most frequently mentioned symptom was “worry about infant safety and welfare,” sites rarely distinguished between common transient worries of this kind and those that are clinical, which may result in readers unnecessarily pathologizing normal behavior or experience. This is a factor HCPs may need to keep in mind when working with women in the perinatal period and when recommending these sites.

Websites often failed to deliver information on risk factors and impact. This could have negative repercussions for HCP users who need accurate information to help identify women at risk. Similarly, HCPs could point their clients to sites that have complete information on risk factors. Women might be assisted with preparing for prevention if they are informed of the risk factors and may be more likely to seek help if they are aware of the potential impact of untreated PNA on the mother and infant [22].

A key finding was that websites often conflated information on PNA with PND. This is concerning as women who access these sites may be looking to self-diagnose and may not identify with lists that contain both anxiety and depression symptoms (especially as depressive features tended to outweigh those related to anxiety). Although it is recognized that depression and anxiety can present together, this is not always the case [40]. Therefore, women who experience PNA in the absence of PND may conclude they do not have a mental health problem (and therefore not seek help) because their anxiety symptoms are not accurately represented by these websites. It is, therefore, noteworthy that only 1 of the 4 leading websites successfully separated PNA and PND. HCPs should, therefore, be cautious in recommending these sites and may need to provide their clients with supplementary evidence-based information that can help to separate these symptom profiles and relevant anxiety-related information.

Most websites mentioned treatment options, with pharmacological interventions being cited most often. While an effective treatment option for PNA, current research advocates nonpharmacological avenues as the first line of action [42]. Furthermore, pregnant and breastfeeding women may be reluctant to take medication in the perinatal period, so sites that fail to mention nonpharmacological options may put women off seeking help [43]. Positively, most websites did present alternatives to medication, with cognitive behavioral therapy and cognitive therapy most frequently suggested. As a recent review has shown these types of therapies to be effective for PNA [33], the inclusion of information about these treatment options is likely to be beneficial to both HCPs and women with PNA. HCPs should be aware that there is currently a dearth of research into efficacious PNA treatment and, thus, should ensure any treatment recommended by websites is supported by evidence.

In contrast to treatment information, screening tools were infrequently mentioned by the websites; when they were, the EPDS was most dominant. This raises some concerns, as the authors of the tool uphold that it does not measure anxiety [44], and other research suggests it does not reliably distinguish between anxiety and depression symptoms [45,46]. Thus, women self-screening might fail to recognize they have a problem, and HCPs might be ill-advised on the best measures for screening their clients. HCPs should consider providing clients with an alternative, validated PNA-specific measure such as the PASS [22], PSAS [23], and PRAQ-R [11].

All but one site provided mothers with access to at least one self-help tool, the most common being information on how to seek help, standard self-help advice, and stigma reduction. In addition, most sites presented additional resources that users could access. However, only half of the sites offered some form of active or guided support. This disparity is likely attributed to the challenges and cost implications involved in staffing and managing helplines, forums, support groups, etc. Whereas, additional resources (such as links, downloads, and generic social media pages) can be easily added to websites in a cost-effective and timely manner. However, it is worth noting that only half of the websites were based in the country where the review took place, which is likely to have serious implications for the accessibility and applicability of the tools, support, and resources offered. HCPs are, therefore, advised to check the availability of these resources in their clients’ locations before recommending the sites.

Overall, the website quality was found to be extremely variable. Sites were most likely to score poorly on navigation, clarity, advertisement, and engagement. In addition, and in line with previous research that has found online health information as difficult to read, most websites had a higher-than-recommended readability score [38,47]. These aspects are important to note, as they may prevent women from engaging with the sites, and getting the information they need. HCPs can use their discernment when recommending sites to tailor to individual needs.

In addition to the above recommendations made to HCPs, we also have some suggestions for future website development in this domain. Websites should include accurate and comprehensive evidence-based information that women can relate to, accompanied by high-quality supportive resources. In addition, these sites should be easy to use and read. Professionals
developing PNA websites should be careful not to pathologize new parents’ concerns and instead recognize that some worries are common and dissipate over time. Equally, they should give some thought to the separation and identification of different anxiety disorders (eg, generalized anxiety disorder, childbirth-related worry, and other forms of anxiety such as obsessive-compulsive disorder), as their symptom profiles and treatment trajectories are likely to differ.

The website content would benefit from distinguishing between the symptoms of PNA and PND, but also note they can occur together. Other recommendations are that websites should present comprehensive risk factors and impact on the mother and infant to assist in the prevention and detection. Information on both pharmacological and nonpharmacological treatment options that are supported by evidence could avoid barriers to care. Future websites should consider including validated PNA-specific measures such as the PASS [27], PSAS [28], and PRAQ-R [14] to maximize their utility. Future research could investigate and develop self-help tools, thus enabling websites to provide resources that are cost-effective. The usability and readability could be improved by piloting sites with HCPs and women in the perinatal period.

**Limitations**

One limitation of this study is that the measure used to assess websites is in its early stages of development and is yet to be validated. Currently, there is no validated measure that explicitly assesses the accuracy and appropriateness of information and resources provided, specifically related to PNA. This study builds on previous research that developed a rating scale specific to PND and aimed to develop a similar measure that focused on PNA. The measures were developed by both authors using DSM-V criteria, valid PNA scales, and evidence-based research. It is recommended that future works seek to validate the measure and compare it with other tools, such as DISCERN, which assess the quality of written health information [25].

Other limitations are that recommended websites are likely to date quickly with the evolving nature of the internet and growth in research and public awareness about PNA. Therefore, the top sites are likely to change over time. It is recommended that another review be done in the next few years to provide accurate top websites and include websites in all languages. A further limitation that needs to be addressed in future reviews is that the quality of the resources and efficacy of support tools provided were not established. Further research is also needed to explore how women use PNA websites and what they find most relatable and useful. It is likely that the number of PNA websites will expand and reviews might benefit from including a measure of the intended audience, for example, women in the community and those with more severe mental health needs. Appropriate resources might differ between groups and ratings should account for this. Overall, future reviews should recommend the top websites for information, resources, and website quality. The best websites should be clear in their focus on PNA information and resources and avoid confusing PNA and PND content.

**Conclusions**

This review is the first to rate a substantial number of websites for information that was specific to PNA and available help for those experiencing it. The top 4 sites for HCPs and their clients are suggested. A key finding is that no website scored top for information, resources, and website quality. It is concerning that websites often conflated information about PNA with PND, as this could be misleading at best and at worst prevent women from seeking the help they need. To conclude, there is a need for websites to be developed that provide excellent evidence-based information that women can relate to and quality resources for women with PNA. These websites should clearly separate information on PNA and PND, be of sound quality for usability, easy to read, and built around research that identifies what women with PNA want from websites. This study provides guidance for HCPs recommending websites to their clients and professionals developing websites for PNA.

**Authors’ Contributions**

DM initiated the design, carried out all website ratings, assisted in data analysis, interpretation, and drafted the manuscript. VH secured funding for the project, participated in the design, reviewed a selection of websites, initiated data analysis, interpretation and drafted the manuscript.

**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**

Rating scales for information and online resources.

[PDF File (Adobe PDF File), 48KB - mental_v5i4e11464_app1.pdf ]

**References**


Abbreviations

- DSM-V: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
- HCP: health care professional
- ICC: intraclass correlations
- PASS: Perinatal Anxiety Screening Scale
- PNA: perinatal anxiety
- PND: postnatal depression
- PRAQ-R: Pregnancy-Related Anxiety Questionnaire-Revised
- PSAS: Postpartum Specific Anxiety Scale
Gamified Cognitive Bias Modification Interventions for Psychiatric Disorders: Review

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Abstract

Background: Automatic biases, such as attentional biases and avoidance and interpretative biases, have been purported to be responsible for several psychiatric disorders. Gamification has been considered for cognitive bias modification, mainly to address the core issues of diminishing motivation to train over time, as bias modification intervention tasks tend to be highly repetitive. While a prior review has suggested how gamification strategies could be applied to such tasks, there remains a lack of systematic evaluation of gamified cognitive bias modification interventions in the literature.

Objective: The objective of this review is to understand the overall effectiveness of a gamified approach for cognitive bias modification and inform future research that seeks to integrate gamification technologies into existing conventional bias modification interventions.

Methods: To identify the relevant articles for our review, the following search terminologies were used: (“cognitive bias” OR “attention bias” OR “interpret bias” OR “approach bias” OR “avoidance bias”) AND (“training” OR “modification” OR “practice” OR “therapy”) AND (“gamification” OR “game elements” OR “game” OR “gaming” OR “game mechanics”). PubMed, MEDLINE, PsycINFO, and Scopus databases were searched systematically for articles published after 2000. Articles were included if they described a gamified cognitive bias modification task and included participants with underlying psychopathological symptoms. Data were systematically extracted from the identified articles, and a qualitative synthesis was performed.

Results: Four studies evaluated gamified cognitive bias modification interventions. Two studies included participants with anxiety symptoms, one with affective symptoms, and one with alcohol problems. The conventional visual probe task paradigm was used in 3 studies, and the attentional visual search task paradigm was used in the last study. We found gaming elements incorporated to include that of animations, sounds, feedback, and a point-scoring system for response time and difficulty. Of the 4 identified studies, only 2 reported their gamified interventions to be effective.

Conclusions: Our review is the first to systematically synthesize the evidence for gamified cognitive bias modification interventions. The results arising from our review should be considered in the future design and conceptualization of gamified cognitive bias modification interventions.

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KEYWORDS
attention bias; cognitive bias; gamification; psychiatry
Introduction

Automatic biases are involved in the psychopathologies of several psychiatric disorders, including anxiety and alcohol and tobacco disorders [1-5]. Cognitive biases include attention, approach/avoidance, and interpretative biases, and these biases can be retrained. Modification of these automatic biases could be achieved with tasks such as the visual probe task (which involves the repeated pairing of probes with neutral stimulus) [6], approach/avoidance task (which involves presenting the salient stimulus in a push-away format) [7], or cognitive bias modification for interpretation (which involves training individuals to disambiguate ambiguous scenarios in a positive way) [8]. Prior reviews have synthesized the evidence for cognitive bias modification [9,10]. In a review by Cristea et al [9], 25 trials involving participants with alcohol and tobacco disorder were identified; bias modification was found to be effective for attentional and approach biases, with an effect size of 0.60. Jones et al [10] reviewed meta-analyses and reported that cognitive bias modification was effective for anxiety disorders with effect sizes ranging from 0.13 to 0.74, depressive disorders with effect sizes ranging from 0.35 to 0.85, and appetitive disorders (defined to include eating and addictive disorders) with effect sizes ranging from 0.003 to 0.36.

Most conventional cognitive bias modification interventions have been delivered in the laboratory, but in recent years, rapidly advancing Web technologies have been increasingly adopted. Wiers et al [11] administered a Web-based attention control training and approach bias retraining intervention for 136 participants with problem drinking and reported a reduction in drinking across all the intervention groups. Similarly, William et al [12] harnessed the potential of Web technologies for the delivery of an online cognitive bias modification training and reported it to be effective in reducing depressive and distress symptoms. In addition to Web technologies, mobile technologies are being used to transform the delivery of bias modification interventions. It has been reported that a mobile app could help in improving insomnia symptoms [13].

Just as technology has transformed the mechanism of delivery of cognitive bias modification intervention, advances in gamification have transformed the nature of conventional cognitive bias modification interventions. Gamification is defined as the use of game-design features in a nongaming context [14], and the term “serious games” refers to games that are designed and built specifically for education, training, or behavioral modification [15]. These technologies have been adopted in health care, and some have been evaluated. Currently, most of these gamified interventions are used in chronic disease rehabilitation and mental health [16], with the most common gamification technique being feedback. Lumsden et al [17] synthesized the evidence for gamification for cognitive assessment and training. The authors reported gamification helped improve engagement in the short and longer term and made the task more attractive. Other studies have found increased self-empowerment [16] and improved existing skills sets [16]. More recently, Lau et al [15] reported in a review that serious games could help improve psychiatric symptoms, with an effect size of 0.55.

Boendermaker et al [18] reviewed how gamification might help address one of the core challenges of conventional interventions, that of motivation to train; these tasks tend to be highly repetitive with a need for multiple training sessions. The article highlighted several potential gamification strategies and explored how they have been used in some studies. The gamification approaches used included the addition of gaming elements to existing tasks, transformation of a conventional task into a serious game, identification of an underlying theory of the intervention and development of a game, addition of a full gaming approach to a conventional task (both intrinsic and extrinsic combinations), and use of over-the-shelf entertainment games. While this review provides timely insight into how gamification strategies have been adapted for bias modification interventions, it was not a systematic review with a database search. Other research on the evaluation of a gamified variant of an attention bias modification task determined that a gamified intervention was effective for anxiety [19]. However, to date, there is no systematic evaluation of gamified cognitive bias modification interventions in the literature. This is needed to understand the overall effectiveness of a gamified approach for cognitive bias modification and inform future research that seeks to integrate gamification technologies into existing conventional bias modification interventions.

The primary aim of our research was to review gamification in cognitive bias modification for psychiatric disorders. Our secondary aim was to identify gamification elements used in cognitive bias modification interventions and evaluate the evidence for their effectiveness by assessing whether the gamified intervention resulted in changes in biases or improvement in secondary outcomes (eg, improvements in anxiety or depressive scores, reduction in the absolute amount of alcohol consumed) and if any motivational improvement was seen.

Methods

The methods for our systematic review are based on our protocol, published elsewhere [20].

Search Strategy

To identify relevant articles for the review, the following search terminologies were used: (“cognitive bias” OR “attention bias” OR “interpret* bias” OR “approach bias” OR “avoidance bias”) AND (“training” OR “modification” OR “practice” OR “therapy”) AND (“gamification” OR “game elements” OR “game” OR “gaming” OR “game mechanics”). PubMed, MEDLINE, PsycINFO, and Scopus databases were systematically searched for articles published after 2000; before 2000, there were limited computer-based interventions. When full-text access was not available, the original authors were contacted for their articles.

Inclusion and Exclusion Criteria

Articles were included if they described a cognitive bias modification intervention in the form of a gamified task and included participants assessed to have underlying psychopathological symptoms such as depressive, anxiety, or addictive symptoms. Articles were excluded if they were opinion...
Screening, Data Extraction, Sorting, and Selection
All articles identified using the search strategy were downloaded and imported into a reference manager (Endnote X8, Clarivate Analytics). The articles were screened based on their titles and abstracts by two independent authors, MZ and JY. Full copies of the shortlisted articles were evaluated against the inclusion and exclusion criteria with any disagreement resolved by a discussion with the third author (GS).

For relevant articles, the following data were extracted:

- Publication details: authors, study year, and country in which the study was conducted
- Study design (observational or experimental design)
- Sample size
- Type of sample (treatment seeking or community sample)
- Demographics of sample (mean age, gender proportion)
- Psychopathological symptoms of participants and methods of ascertaining psychiatric symptoms
- Details of gamified cognitive bias modification intervention (mechanics of game-play and the conventional cognitive bias modification intervention that the gamified task was based on)
- Primary outcomes and secondary outcomes: effectiveness of gamified cognitive bias modification intervention and any changes in psychiatric symptoms

Data Integration and Synthesis
A qualitative synthesis of the evidence extracted from the articles was performed. Due to the heterogeneity in the outcomes reported, it was not appropriate to conduct a meta-analytical synthesis.

Results
Identified Studies
The predefined search strategy identified 1008 citations from 4 bibliographic databases; after duplicate articles were excluded, 970 records were screened and, of these, 962 were excluded as not relevant to the topic of interest. Eight full-text articles were downloaded for further evaluation against the inclusion and exclusion criteria. Four citations were excluded as they did not fulfill the inclusion criteria, leaving 4 articles for the qualitative synthesis. Figure 1 provides an overview of the study selection process. For an overview of the characteristics of the selected studies, see Multimedia Appendix 1.

Characteristics of Identified Studies
Two of the 4 studies identified involved participants with anxiety symptoms [19,21]. One involved participants with alcohol-related problems [4] and one, participants with affective symptoms [22]. All studies were experimental, randomized controlled designs recruiting participants from universities with mean ages of participants 20 to 30 years. All studies were conducted in a western setting. Two studies came from the United States, one from the Netherlands, and another from Belgium. None of the studies used a structured clinical interview to ascertain symptomatology or diagnosis but relied on validated questionnaires (State-Trait Anxiety Inventory [19,21], Mood and Anxiety Symptoms Questionnaire [22], and Alcohol Use Questionnaire and Alcohol Use Disorders Identification Test questionnaire [4]). Three studies based their gamified intervention on the visual probe task and one on the attentional visual search task. Gaming elements integrated into these tasks included animations, sound effects, reward points, time pressure, and levels of complexity.

Characteristics of a Gamified Cognitive Bias Modification Intervention
Two studies [19,21] used the same app for their intervention, a gamified attention bias modification app based on the conventional dot-probe task. The gamification elements included that of animated characters, a system for points scoring, and sound effects. Two animated characters would appear on the screen simultaneously, both disappearing into a hole. One character would cause a path of grass to rustle behind and participants undertaking the intervention were asked to trace the path in the grass. Based on the author’s description of the gamified intervention, 4 different sounds were played, and different rewards were given depending on participant accuracy and speed. The lowest pitch sound would be played and red jewel awarded for slow response or responses that were least accurate, a medium pitch sound would be played and purple jewel awarded for moderate speed and accuracy, and a high pitch sound would be played and gold jewel awarded if fast and accurate. There was also a feedback sound for incorrect responses. There were 2 variants of the gamified intervention: 25 minutes of training along with 20 minutes of rest or 45 minutes of training with no rest. Points accumulated as the intervention progressed, and feedback was given immediately on completion.

Pieters et al [22] used a gamified app for cognitive bias modification for anxiety symptoms, based on the conventional visual attention task. The game required participants to tap on smiling faces, with smiling faces making up 60% of the faces and disgust faces the remaining 40%. Once the participant tapped on the smiling face, the face bounced up for a short distance and become untappable for 0.5 to 1 second. Participants were instructed to prevent the smiling faces from falling down the screen by tapping on them. Points were awarded to incentivize game play. A point was awarded for tapping the smiling face the first time and 5 points awarded if the same smiling face was tapped a second time. There was negative scoring with the loss of 3 points if a smiling face was not tapped and fell off the screen.
Boendermaker et al [4] used a shot game for attention bias modification, based on the conventional visual probe task. The gamified intervention included a reward system, graphics, animations, sound effects, time pressure, and levels. Their game resembled a slot machine with a coin-based reward system. Like the conventional task, participants were required to identify the probe that replaced the position of the alcohol or neutral image. Participants won bonuses for responding rapidly and were given access to new levels in the game.

Three studies delivered the gamified cognitive bias modification intervention using a mobile device, and Pieters et al [22] used a computer.

**Reasons for Gamification**

Two studies described the reasons for inclusion of gamification. The intervention by Boendermaker et al [4] included gaming elements to potentially increase participant motivation to train via the intervention. The authors also sought to determine if the inclusion of gaming elements increased the effectiveness of the conventional visual probe task. Dennis et al [10] were interested in whether the inclusion of gamification changed the effects of the attention bias modification.

**Primary and Secondary Outcomes**

Of the 4 studies, 2 [19,21] reported the gamified variant of the cognitive bias modification intervention to be effective. Dennis et al [19] reported that the long-training attention bias modification task resulted in a reduction of threat bias and difficulties individuals had with disengaging from threat-related stimulus. There were also corresponding reductions in the subjective and observed anxiety and stress. Similarly, the authors of the second paper [21] reported that the single session of gamified attention bias modification was effective in improving the performance of the attention bias modification task. However, the authors reported that significant results were observed among females only. Contrary to the findings of Dennis et al and Dennis-Tiwary et al [19,21], Pieters et al [22] reported that their gamified intervention did not result in any reduction in attention biases or associated mood-related measures.

In the study involving participants with alcohol-related problems [22], the gamified variant of the cognitive bias modification task did not reduce attention bias and failed to achieve a decline in overall alcohol consumption. Of importance, the study by Boendermaker et al [4] was the only study that investigated the effects of gamification and motivation of participants in using the training task. Boendermaker et al [2] reported that motivation to train did not increase with the addition of gaming elements. In fact, participants assigned to receiving the gamified variant reported having lower motivation to continue the training task as compared to participants assigned to other conditions.

**Discussion**

**Principal Findings**

Our review is the first to systematically synthesize the evidence for gamified cognitive bias modification interventions. Of the 4 studies that evaluated a gamified cognitive bias modification intervention, 2 studies included participants with anxiety symptoms, one with affective symptoms, and one with alcohol problems. Gamified interventions were based on the conventional visual probe task in 3 studies and the attentional visual search task in the last study. The gaming elements
incorporated into the task included animations, sounds, feedback, and a point-scoring system for response time and difficulty. Two publications discussed their rationales for gamification, one sought to determine if gamification enhances motivation, and one to determine if the gamified attention bias modification was as effective as a conventional modification. Out of the 4 identified studies, 2 studies reported their gamified intervention to be effective. Of significance, these 2 studies used the same app and were from the same research group. The 4 studies applied gamification across a variety of psychiatric disorders—anxiety and affective and addictive disorders. The conditions that gamified cognitive bias modification interventions target are like those targeted by conventional mobile-based cognitive bias modification interventions. The review by Zhang et al [23] evaluated the published literature and reported that out of 8 identified studies, at least 4 studies used a mobile intervention to target anxiety-related disorders (anxiety and social anxiety disorders). In their review of meta-analyses, Jones et al [10] included 5 meta-analyses that examined anxiety-related outcomes. Thus, anxiety conditions have been extensively investigated in the published literature. This could, therefore, explain why there have been more studies that have applied gamification techniques in increasing the inherent effectiveness of existing conventional training tasks.

All identified studies have based their gamified intervention on the conventional cognitive bias modification intervention, which is of importance, as the conventional cognitive bias modification intervention is the most commonly used task. Three studies were based on the conventional visual probe task and one on the attentional visual search task. In line with the recommended gamification techniques of Boendermaker et al [18], it appears that all 4 studies have used intrinsic integration with evidence-based training task as a basis, given that all 4 studies based their intervention on a conventional task and added gaming elements to that task. Adopting intrinsic integration makes tasks more engaging and might increase the inherent levels of motivation to continue training. Unfortunately, we found no evidence that the adoption of intrinsic integration led to increased motivation to train as only 1 study [4] included motivation to train as an outcome measure, and in that study, there were no improvements.

In keeping with the objectives of the review, we identified some of the common gaming elements that are incorporated in the published gamified interventions: animations, sound effects, point-scoring systems, time pressure, and levels. In their review, Hoffman et al [14] proposed a taxonomy of gamification strategies that could be applied for the evaluation of gamification strategies in apps. The authors used the taxonomy to evaluate stress management apps and found that feedback or performance-orientated strategies were frequently used in the 62 evaluated apps. Like the review of Hoffman et al [14], our findings demonstrated that performance-orientated gamification strategies are used for some of the gamified apps (time pressure and levels in the Boendermaker et al [4] study). Economic gamification strategies are more commonly used, with 4 studies reporting the usage of a point system. The differences in our findings, as compared to that for stress management apps, is not unexpected. Prior research highlighted the importance for designers to carefully consider the gamification techniques used, depending on the nature of the app and how gamification could affect user interaction [14]. Thus, for cognitive bias modification interventions, incorporating feedback might be less feasible, as feedback usually involves a comparison to a set standard or others’ performance. Digital rewards like points might be more tangible, both as an extrinsic motivator and as a surrogate indicator of how well one is performing on the task.

The existing evidence is inconclusive for gamified cognitive bias intervention effectiveness, as only 2 of the 4 studies reported positive findings, but several implications arise from our review. Why gamification is effective in some studies and not others must be determined to guide consideration of which gamification strategies to adopt in an intervention. User perspectives of what makes an app engaging and which strategies result in short and longer term engagement are important to consider in the design of gamified cognitive bias modification interventions. While only 4 studies were identified for this review, Zhang et al [23] found that there were 17 commercial cognitive bias modification apps in the app stores. It might be helpful to analyze the gamification features in commercial cognitive bias modification apps and see if certain gamification features are associated with higher rates of downloads, a surrogate measure of acceptability. Also, a qualitative analysis of the feedback that individuals provide for the gamified commercial apps might be helpful for developers or health care professionals who are creating a new gamified intervention.

**Strengths and Limitations**

A major strength of our review is that we systematically identified from the published literature gamified cognitive bias modification interventions and synthesized the evidence for their overall effectiveness. We also identified the gamification strategies that they have adopted. Our review will be of importance for future research seeking to design and evaluate gamified cognitive bias modification interventions, as it provides information about gaming elements that might affect whether interventions are effective. Despite the strengths, there are some limitations. In our review, we were limited to a qualitative synthesis because a meta-analytical synthesis was not appropriate given the heterogeneity in the studies and outcomes reported. Our synthesized results might have limited generalizability, as 2 studies used similar apps and tested the apps in a university sample.

**Conclusions**

By identifying gamified cognitive bias modification interventions in the published literature and synthesizing their evidence, our findings have helped bridge the gaps in previous reviews. The results arising from our review should be considered in the future design and conceptualization of gamified cognitive bias modification interventions.
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Original Paper

An App That Incorporates Gamification, Mini-Games, and Social Connection to Improve Men's Mental Health and Well-Being (MindMax): Participatory Design Process

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Abstract

Background: Men have different mental health needs as compared with women, and women make up the primary audience of most digital mental health interventions. An Australian football-themed (specifically Australian Football League, AFL) app named MindMax incorporating psychoeducation, gamification, mini-games, and social connection was developed in an effort to address this issue.

Objective: The aim of this study was to identify the best way to structure and present MindMax, an app that aims to deliver psychoeducational modules, and create a Web-based community centering on well-being, AFL, and video games for men aged 16 to 35 years who are interested in AFL or video games.

Methods: We conducted 6 participatory design (PD) workshops with people aged 16 to 35 years in 3 cities in Australia, to identify the best way to present MindMax, and contracted a digital development agency to develop MindMax. We then iteratively tested MindMax prototypes with 15 user experience testing interviews across 3 separate time points: 2 before app launch and 1 after app launch.

Results: A total of 40 individuals (25 male and 15 female) participated in the PD workshops, and a total of 15 individuals (10 male and 5 female) participated in user experience interviews. Broadly, participants expressed a preference for activities requiring active engagement that practiced useful skills. They were also sensitive to how content was presented and wanted the ability to customize their own app experience. Although participants agreed that social motivations were important for engagement with an app, they recommended not to mimic existing social networks.

Conclusions: In basing itself strongly within the AFL subculture and by incorporating gamification as well as mini-games, MindMax aimed to tackle mental health help-seeking barriers for people who enjoy AFL or video games, with a particular emphasis on men, and to provide psychoeducation on strategies to increase mental health and well-being. If MindMax is successful, this would indicate that generalizing this approach to other traditional sporting codes and even competitive video gaming leagues (esports) would be fruitful.

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KEYWORDS
football; mental health; well-being; video games; adolescent; young adult; cell phone; gamification; sport; men’s health; social connection
Introduction

Men’s Well-Being and Internet Interventions

As participants in mental health research are heavily biased toward being female [1,2], research outcomes may not be fully generalizable to men. A growing body of evidence suggests that men’s experiences of mental health problems and treatment differ to those of their female counterparts [3,4]. For example, young men have higher rates of suicide prevalence and lower rates of mental health literacy and health care service access than young women [1,3]. Furthermore, women are more receptive to structured internet health interventions than men [4]. This problem is especially urgent for young people as most mental health problems are developed during young adulthood [5]. Furthermore, mental health outcomes at a young age persist and potentially worsen in the long term, even among those receiving clinical care [6]. A targeted approach to improving mental health that aims to give younger people the tools to manage their own well-being would be helpful in addressing this issue.

Western norms of masculinity (in particular, the emphasis on self-reliance and on silently coping with psychological distress) act as barriers to help seeking [7] and contribute to the worse outcomes displayed by young men. This is exacerbated by the small but significantly higher tendency for young men to avoid addressing their friends’ mental health problems directly and to avoid recommending they seek help from external sources, relative to their female peers [8]. Furthermore, the high levels of mental health stigma that persist in young men and their negative perceptions of mental health professionals work in tandem with the previous to contribute to high reluctance to formally seek help from mental health professionals [7]. Instead, young men tend to seek informal help from the internet, with 1 study on 16- to 24-year-old men finding nearly 55% of their sample reported having done so [7]. The same study further reports that, within their sample, younger men were more likely to seek informal help from the internet than older men.

An approach to internet interventions that enables and informs such informal help seeking would be a natural fit to this pattern of behavior. An evidence-based approach toward men’s mental health and well-being that addresses the problems outlined above should therefore be (1) accessible on the internet, (2) action-based and informal (not clinical), (3) anonymous with the potential for social connection, (4) self-directed, and (5) based in subcultures men are already present in [7]. Importantly, women should not be excluded as in addition to benefiting from the intervention themselves, they can also act as supportive others, connecting these interventions and other mental health initiatives to the men in their lives.

Sports and video games are mainstream topics with significant male fan bases. The sporting code that is the focus of this study, Australian Football League (AFL), is a type of Australian football and enjoys the support of 6 million people across Australia [9]. Similarly, a recent nationwide survey reports that over three-quarters of Australians aged 15 to 34 years play video games and that 70% of all men surveyed were video game players [10]. Both cultures are further combined in esports (competitive video gaming) [11], esports is a growing industry popular among younger people, with nearly as many millennials preferring watching their favorite esport to watching their favorite traditional sport (40% vs 42%) [12]. Furthermore, many sporting leagues including AFL have partnered with esports teams [11] and video game companies to host esports events [13]. Although they remain distinct subcultures, sports and video games are highly compatible, mainstream in the general population, and well suited to utilization in a mobile health (mHealth) app intended to promote mental health and well-being.

Gamification and Applied Games

The general usage of games and game features for nonentertainment purposes is known as “applied games” [14]. This includes not just applying commercial video games outside of an entertainment context, for example, psychological therapy [15], but also serious games (video games developed for a primary purpose other than player enjoyment [16]) and gamification [17,18]. In the same way that traditional video game design works to engage both the extrinsic and intrinsic motivation of its players, applied games have inherent “effectiveness potential” [19], where users of interventions that incorporate applied games can be motivated to explore the intervention deeper for additional motivations besides self-improvement. Furthermore, the inherent design characteristics of video games have been shown to be complementary to subjective well-being concepts, for example, the Seligman positive emotions, engagement, relationships, meaning, and achievement (PERMA) model [20,21]. There is also evidence for a positive impact of moderate video game play on well-being [22-25].

Gamification, in particular, has been named a promising strategy with which to promote engagement in digital health interventions [19,26,27]. Although the most well-known gamification elements are points, badges, and leaderboards [28], prioritizing these elements can undermine the complex series of cognitive, emotional, and social affordances that make games intrinsically motivating and enjoyable to play [29]. The most successful mHealth initiatives that incorporate gamification have been carefully designed to include both extrinsic and intrinsic motivators [30,31].

The term gamification has been defined as the “use of game design elements in non-game contexts” [17] as well as “a process of enhancing a service with affordances for gameful experiences in order to support user’s overall value creation” [18]. The latter definition by Huotari and Hamari is particularly useful in an mHealth (both mental and physical health) context, with “value creation” potentially being the improvement of the user’s health; the adoption of health behaviors; the provision of a fun, engaging educational experience; or all of the above. This definition also emphasizes the goal of gamification rather than its methods and recognizes that what some individuals may term “game design elements” may not be considered as such by others, complementing the overlap between gamification and other health behavioral change frameworks such as persuasive systems design [32]. Finally, this definition is drawn from a service marketing approach. By viewing the digital health
intervention as a core service, it becomes easier to visualize how the components of this service can be enhanced with motivational affordances. Approaching applied games (including gamification) from this perspective could thus lead to a more compatible and natural integration of applied games (including gamification) into mental health care.

Although empirical study of the effects of gamification is still in its infancy, there is evidence, albeit outside of health, that it leads to higher and more involved user engagement with an app or service [33,34]. However, the impacts of gamification within electronic health and mHealth remain poorly understood [35-37]. Although application varies by health domain, many mHealth apps do not utilize gamification [36], and those that do tend to contain limited applications of it [38]. As evidence of individual differences in gamification element preferences is emerging [39], it is clear that to provide the enjoyable and engaging experiences initially hoped for, when gamification (and applied games in general) is applied to mHealth, it must be with due consideration.

Participatory Design and Knowledge Translation
Although researcher-led mHealth initiatives have a key strength in applying evidence-based best practice, it is often at the expense of user experience. It is difficult to compete with large corporations who invest millions of dollars into creating seamless, intuitive, and engaging user experiences to entertain their consumers. This level of investment is near impossible in academia, which may result in a jarring experience for users accustomed to a contemporary internet experience [40]. Another key tension within mHealth initiatives is that their aims and objectives often act as barriers to uptake, especially among populations that engage the most in behaviors the intervention hopes to reduce (eg, drinking alcohol [41]). It is important to identify how best to present the health and therapeutic content of mHealth initiatives to the target audience. One method of achieving this is through participatory design (PD) [42].

The key principle of PD is to involve all stakeholders of a project in an iterative cycle of design and development [43,44]. This allows them to influence its design to better suit their past, present, and future needs, ideally leading to higher effectiveness and engagement among the target population [1]. Furthermore, when executed well, PD methodologies increase the acceptability of interventions to stakeholders [44] and can be harnessed to make knowledge translation of research outcomes more efficient [43,45]. This is especially important in mHealth, as given the rapid pace of technological development, the field must reduce the lag between health research and translation as much as possible.

Study Context and Objectives
As part of its daily operations, the Australian Football League Players’ Association (AFLPA) offers mental health and well-being training to more than 800 players across the National League [46]. This training focuses primarily on resilience and well-being. Well-being is a separate construct of positive mental health that is distinct to mental illness [47]. A focus on well-being is more broadly applicable to the general population as both people with and without mental illness can directly benefit from learning how to maintain and improve their well-being. Notably, increasing subjective well-being leads to improvements in individuals’ lives, such as healthier relationships, more positive emotions, increased feelings of autonomy, and increased self-acceptance [21].

In collaboration with Queensland University of Technology and The University of Sydney’s Brain and Mind Centre, the AFLPA obtained funding to execute a multipronged initiative to improve mental health and well-being, focusing on men aged 16 to 35 years but not excluding other groups of people [48]. The app resulting from this collaboration was named MindMax and aimed to deliver a modified version of the AFLPA’s existing mental health programs in a portable, digital format. The target audience is hence men aged 16 to 35 years who are interested in AFL or video games.

MindMax was designed according to the 5 recommendations made by previous research [7] outlined in the first section of the Introduction. For example, educational content was split into multiple small modules lasting around 10 min each, to enable self-directed learning and to give users a choice in what aspects of their well-being they wish to focus on [40]. A secondary aim of MindMax was to create a Web-based community centering on well-being, sports (in this case AFL), and video games. To achieve this aim, the AFLPA engaged a select number of AFL players as ambassadors for the app. Their role would include being spokesperson within the app modules and community area as well as promoting the app to the AFL industry and general public.

Although the basic components of MindMax were drawn from the literature and decided on by researchers and the AFLPA, it was unclear how best to present them in a way that would be acceptable to the target audience. The aim of this study was, therefore, to use PD and user testing methodologies on multiple iterations of MindMax to obtain key insights from end users on how best to present its content, design, and features.

Methods

Participant Recruitment
Our recruitment strategies consisted of putting up posters, distributing postcards, and advertising in student mailing lists. We also asked affiliated organizations to assist in recruitment for locations not in Sydney. We reimbursed PD workshop participants with a gift voucher worth Aus $50 and user experience interview participants with a gift voucher worth Aus $30 to thank them for volunteering their time and expertise. The University of Sydney’s Human Research Ethics Committee (Protocol No. 2016/652) approved this project before the start of research activity.

Phase 1: Participatory Design Workshops

Design
The PD methodologies used in this study are based on recommendations by the Young and Well Cooperative Research Centre [44]. Specifically, we adapted the iterative PD and knowledge translation methodology used by Ospina-Pinillos et al [45] to fit the needs of our project.
In phase 1, we held 2 PD workshops in each of 3 Australian capital cities in early September 2016, making 6 workshops in total. The aim of these workshops was to identify how best to frame the well-being concepts discussed in MindMax and, more broadly, how to structure a mental health and well-being app to the intended audience. Moderators took notes during the workshops. Workshops lasted 3 hours and consisted of 3 stages: discovery, evaluation, and prototype.

**Discovery**

Workshop moderators facilitated participant discussion of their knowledge and usage of and preferences for, health and well-being apps/websites. Specifically, participants discussed their preferences for app design and content, their social usage of health and well-being apps, applying gaming concepts to mental health and well-being, and data tracking and privacy. Although moderators focused on mental health in particular, both mental and physical health were discussed.

**Evaluation**

Moderators then presented screenshots of existing health and well-being apps/websites to participants for their critical evaluation. These apps were a combination of popular commercial health and well-being apps (including physical health) as well as output of previous academic and government mental health and well-being mHealth projects. Screenshots portrayed a variety of features of interest, including social connection (dashboard and community pages), gameful elements (mini-games, challenges, and progress bars), and psychoeducation. Marker pens were provided for participants to annotate the screenshots.

**Prototype**

Finally, in the context of the previous 2 stages of discussion, moderators asked participants to design concepts, specifications, or potential user journeys for a mental health and well-being app. Sketchbooks and marker pens were provided for this activity.

**Phase 2: Knowledge Translation**

Following the PD workshops, all moderator notes and participant artifacts (produced during the evaluation and prototype stages) were collated and analyzed by an independent knowledge translation team consisting of a group of young people (aged under 25 years) who were short-term interns at The University of Sydney’s Brain and Mind Centre. The team adopted an approach similar to descriptive content analysis [49], manually coding the notes and artifacts by 3 overarching semantic themes: content (the information and activities within the app), design (the visual design of the app), and features/concept (the conceptual design and features of the app). The team then used these themes and codes as guidelines to produce a knowledge-translated design of MindMax (see Figure 1).

**Phase 3: User Experience Testing Interviews**

**Timeline and App Details**

We presented the outcomes of the PD workshops and the resulting knowledge translation to the AFLPA, who concurrently contracted a digital agency (Long Division Digital, Melbourne) to produce a prototype of MindMax, drawing principles from the outcomes as appropriate and feasible. This prototype and further iterations were tested in one-on-one user experience interviews at The University of Sydney’s Brain and Mind Centre across 3 time points: December 2016, March 2017, and November 2017. MindMax was launched to the public in June 2017. Hence, 2 time points were before launch and 1 time point was after launch. Drawing on previous recommendations in user experience research [50], we aimed for a total of 15 participants (5 participants per round) to allow for as many insights to be captured across multiple iterations of MindMax, as efficiently as possible.

During the first time point, we tested a hybrid Web-based prototype with limited functionality, and the moderator assisted participants in accessing the app build through a mobile phone internet browser. At this point, only the *Fit Minds* psychoeducational module was available. During the second time point, we tested an in-progress native build with greater functionality (see Figure 2). At this point, 3 psychoeducational modules were available: *Fit Minds, Values,* and *Thoughts.* During the third time point, which was 5 months after MindMax was launched on the App Store and Google Play Stores, we tested an updated version of MindMax (see Figure 3) and asked participants to download it onto their mobile phones. At this point, 5 psychoeducational modules were available: *Fit Minds, Values, Thoughts, Mindfulness,* and *Emotions,* as well as “Flick Footy,” a casual game involving kicking a football to score goals.

Along with the social component (community feed), the psychoeducational modules and Flick Footy formed the reward system within MindMax, where completing psychoeducational modules and posting in the community feed earned users points, called “footies,” which could then be spent to play Flick Footy. In addition to this, modules also contained mini-games (see Figure 4) that aimed to allow users to interact with the lessons in a more active way.

[49] Cheng et al JMIR MENTAL HEALTH
Figure 1. Selected sketches from the knowledge-translated design of MindMax.
Figure 2. The beta build tested in March 2017. Left: the avatar creation process; middle: a goal-setting activity in Fit Minds; right: an activity in Values.

Figure 3. The updated launch version tested in November 2017. Left: the psychoeducational module selection screen following a layout change; middle: the new goal-kicking casual game, “Flick Footy,” which cost “footies” to play. “Footies” are earned by interacting with the social or psychoeducational components; right: an anonymized example of a “shareable” generated by a user after completing Fit Minds.
Psychoeducation modules were accessible through a tab named “Train/Training” (depending on the version of MindMax) and were designed to last around 10 min. They consisted of information pages, interactive activities, and videos that contained information about the module topic and featured AFL players as spokespersons. The videos with AFL players were a montage of informal interviews relating to the module topic and were presented as a way to get to know another side of the player. During certain points of each module, shareable content (a “shareable”) was generated and posted to the community feed. These posts could be toggled to display to all MindMax users (public) or to the user only (private).

Fit Minds was an introductory module with the objective of creating a “MaxFive” plan to improve well-being, Values aimed to help users identify their values and ways to act upon them, Thoughts aimed to help users identify and deal with unhelpful thoughts (including a mini-game illustrating the concept of letting unhelpful thoughts pass by; see Figure 4), Mindfulness aimed to introduce users to mindfulness meditation, and Emotions aimed to help users gain a better understanding of their emotions and how to deal with negative emotions. The Mindfulness and Emotions modules contained 2 guided audio meditation tracks recorded with 2 different AFL player ambassadors, and users could choose which player to meditate with. Information was presented in a casual, masculine tone to reflect the target audience of the app (men aged 16 to 35 years interested in AFL or video games).

Finally, although this study details the iterative design and development process of MindMax, a more in-depth explanation of the theory behind MindMax, including its applied games components, has been previously published [48]. As per the recommendations of Tondello et al [51], MindMax was also designed to incorporate multiple types of applied games to appeal to a wide variety of users.

**Interview Protocol**

User experience testing interviews followed a semistructured format. We first collected demographic information, specifically gender, age, mobile phone model, and operating system, and how many hours per week participants spent playing video games and watching AFL matches. We then explained to participants that interviews would be conducted using a
think-aloud protocol, where participants verbalize their thoughts while completing a series of predetermined tasks. Although there are weaknesses with think-aloud protocols, such as their reliance on participant subjectivity and their inability to capture subconscious cognitive processes, concurrent think-aloud protocols nonetheless have the ability to capture crucial insights at a low cost \[52\]. The predetermined tasks included procedures such as registering an account, creating an avatar, playing a casual game, and completing psychoeducation modules. The predetermined task list spanned all contemporarily available app features and was hence updated for each subsequent time point.

Participants were allowed to complete the tasks in their preferred order. They were given flexibility as to which modules they chose but were on occasion directed to complete specific modules to ensure an even spread of feedback. All participants completed at least two modules. Although participants were given the opportunity to ask questions during the interview, they were encouraged to complete the tasks unprompted and to the best of their ability. A researcher typed notes of the process.

**Results**

**Participant Characteristics**

Due to the convenience sampling strategy employed while recruiting for PD workshops (phase 1), participants naturally tended toward video game design students in Brisbane, AFLPA-affiliated individuals in Melbourne, and mental health and technology academics and students in Sydney. In Brisbane and Melbourne, the workshops were divided into 2 groups: aged 16 to 25 years and aged 26 to 35 years. Workshop and participant characteristics are summarized in Table 1 and listed in the chronological order they were conducted.

Table 2 shows the characteristics of the user experience testing interviews and participants (phase 3). One participant (aged 39 years) at the second time point (March 2017) was discovered not to fall within the age range of the target audience, but we made the decision to proceed to gain any relevant insights the participant had to offer toward making the app more broadly accessible. Finally, to eliminate the possibility of bias arising from previously brainstorming this topic at length, user experience interviewees were different across all time points and none had previously attended any MindMax PD workshops.

**Participatory Design Workshop: Descriptive Content Analysis**

App likes and dislikes were collected directly during the evaluation phase of PD workshops, where we asked participants to annotate screenshots of multiple existing health and well-being apps/websites. These preferences were coded by an independent knowledge translation team consisting of young people (younger than 25 years) according to the semantic themes content, design, and features/concept. Codes that were observed 3 or more times are presented below.

**Content**

Compared with the other 2 semantic themes, content had the least observations. The most frequently observed preference was that participants disliked activities perceived to be “useless”, “ant климатич”, “simplistic”, “condescending”, “childish”, or “boring”. Although they were receptive to activities promoting self-reflection, participants disliked vague suggestions (eg, “do something kind for yourself”) and liked having examples of how to do so. Ultimately, participants preferred information that was clear, nonrepetitive, and instructive (not descriptive—“tell me how, not why”). Although participants appreciated explanations for how an activity would benefit them, they preferred this information to be contained within a collapsible content box they could open if desired.

**Design**

Participants overwhelmingly expressed dislikes of excessive blank space and also excessive amounts of text. “Gimmicky” user interfaces (UIs) and graphics received more criticism for looking “childish” and “cheap” than praise for looking “interesting” and having “cool colours”. Furthermore, dark colors such as dark green and brown were criticized for being “depressing” and “ugly”. Instead, participants preferred more conservative UIs with multiple pleasant colors (eg, pastel colors or light to medium blue) paired with simple graphics and names that clearly described the purpose and features of the app. Finally, participants liked how one app listed the number of people that had joined a particular psychoeducational course, as it showed the course appeared to be popular and, therefore, worth trying.

Table 1. Participatory design workshop and participant characteristics.

<table>
<thead>
<tr>
<th>Workshop (n=40), n</th>
<th>Location</th>
<th>Age group (years)</th>
<th>Gender split</th>
<th>Recruitment pool</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (6)</td>
<td>Melbourne</td>
<td>16-25</td>
<td>3 males, 3 females</td>
<td>AFLPA(^a)-affiliated individuals</td>
</tr>
<tr>
<td>2 (5)</td>
<td>Melbourne</td>
<td>26-35</td>
<td>3 males, 2 females</td>
<td>AFLPA(^a)-affiliated individuals</td>
</tr>
<tr>
<td>3 (10)</td>
<td>Sydney</td>
<td>Mixed</td>
<td>4 males, 6 females</td>
<td>Mental health and technology academics and research students</td>
</tr>
<tr>
<td>4 (4)</td>
<td>Sydney</td>
<td>Mixed</td>
<td>2 males, 2 females</td>
<td>Mental health and technology academics and research students</td>
</tr>
<tr>
<td>5 (8)</td>
<td>Brisbane</td>
<td>16-25</td>
<td>8 males</td>
<td>Video game design and research students and staff</td>
</tr>
<tr>
<td>6 (7)</td>
<td>Brisbane</td>
<td>26-35</td>
<td>5 males, 2 females</td>
<td>Video game design and research students and staff</td>
</tr>
</tbody>
</table>

\(^a\)AFLPA: Australian Football League Players’ Association.
Table 2. User experience testing interview and participant characteristics.

<table>
<thead>
<tr>
<th>Time point and participant</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Mobile phone (operating system, OS)</th>
<th>Video game play (hour/week)</th>
<th>AFL(^a) match watching (hour/week)</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2016: Web-based alpha prototype (n=4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td>29</td>
<td>Female</td>
<td>iPhone 6 (iOS 10.1)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>P2</td>
<td>33</td>
<td>Female</td>
<td>iPhone 5 (iOS 9)</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>P3</td>
<td>26</td>
<td>Male</td>
<td>iPhone 6 (iOS 10.1)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P4</td>
<td>29</td>
<td>Female</td>
<td>Samsung S7 Edge (Android; OS unsure)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>March 2017: native app beta (n=5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P5</td>
<td>19</td>
<td>Male</td>
<td>iPhone 6 (iOS 10.2.1)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>P6</td>
<td>24</td>
<td>Male</td>
<td>iPhone 6 (iOS 10.2.1)</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>P7</td>
<td>39</td>
<td>Female</td>
<td>iPhone 6 (iOS 10.2.1)</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>P8</td>
<td>21</td>
<td>Female</td>
<td>iPhone 6 (iOS 10.2.1)</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>P9</td>
<td>20</td>
<td>Male</td>
<td>iPhone 6 (iOS 10.2.1)</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>November 2017: native app 5 months after launch (n=6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P10</td>
<td>19</td>
<td>Male</td>
<td>Xiaomi RedMe Note 4 (Android 6.0)</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>P11</td>
<td>22</td>
<td>Male</td>
<td>Oneplus 3T (Android 6.0)</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>P12</td>
<td>22</td>
<td>Male</td>
<td>Samsung S5 (Android 6.0.1)</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>P13</td>
<td>22</td>
<td>Male</td>
<td>Samsung J7 Prime (Android 6.0.1)</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>P14</td>
<td>22</td>
<td>Male</td>
<td>Samsung Galaxy S5 (Android 6.0.1)</td>
<td>1 on average; 3 in holidays</td>
<td>0</td>
</tr>
<tr>
<td>P15</td>
<td>20</td>
<td>Male</td>
<td>iPhone 5 (iOS 11.0.3)</td>
<td>24</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^a\)AFL: Australian Football League.

**Features/Concept**

A large number of participants liked the idea of graphs and similar indicators such as goal progress bars, finding it motivational to track their progress. Similarly, a large number of participants also liked the concept of challenges/missions, encouraging them to go beyond their comfort zone. Quizzes attracted both positive and negative feedback, though the former was greater than the latter. Although participants liked having long-term goals and unlockable achievements, their reaction to rewards was ambivalent. Those who liked the concept felt they were “helpful and keep people coming back,” whereas those who did not found there to be “no reward for the player outside of a small number going up.” Participants also liked the skeuomorphic activities in several of the presented apps/websites, where participants could interact with the object on the screen similar to real life (such as scrunching up a piece of paper).

Finally, although competition was seen as “motivating” and “healthy” in the context of a physical health app, participants were ambivalent toward how it, and other types of social sharing options, could be implemented in mental health contexts. Participants felt that any social option that mimicked a major social network would be redundant and that they would not use it. Participants also felt that compared with physical health, mental health was a more private issue that complicated social sharing, both for the sharer and the people they would be sharing their mental health status with. In particular, participants raised the inappropriateness of such features for someone with poor mental health or who was in distress. Instead, participants suggested that social features be used to promote social connection and communication. That is, they should be “supportive rather than competitive.”

**Other Insights**

Furthermore, participants emphasized the importance of being able to customize their app experience, for example, through being able to customize their display image or avatar (if appropriate) or by having their responses to in-app questions influence their app notifications or recommendations. Participants also suggested the incorporation of design elements common to video games, including regular content updates, events, team competitions, and cosmetic digital rewards (eg, avatar hairstyles or clothing). Finally, the issue of mental health stigma was raised, and participants suggested the app have a function for facilitating conversations between men, for example, scheduling real-life activities between friends, where difficult topics could be broached in shoulder-to-shoulder conversations. Participants also specified that the app should adopt an approach of self-improvement, rather than fixing a deficiency.

**User Experience Testing Interviews**

**Summary Across Time Points**

Below, we present insights participants expressed during the user experience testing interviews and relevant quotes.
At alpha and beta build, participant feedback comprised identifying software bugs and glitches, criticizing unintuitive UIs and unclear wording, and raising privacy concerns. However, participants also expressed appreciation for the opportunity to see a more personal side of AFL athletes and for the underlying concept of the app:

- It's great! I like the idea and concept of it. Mindfulness, wellbeing. What it’s trying to achieve. [P5]
- [It was] entertaining, kinda helpful—showed me a lot of values I didn’t know about—so, informative, engaging. [P9]

At 5 months after launch, negative participant feedback included identifying software bugs and glitches as well as questioning whether the social component would be used and critiquing its similarity to existing social networks such as Instagram.

However, most participants at this time point found MindMax to meet their user experience standards and to be an overall positive experience that provided some value:

- I think overall this app is just for people to try out for curiosity. [...] Sometimes you want to say things to vent, but you can’t really say things to an app. This is like the fries, if the psychologist is a Big Mac. [P13]
- It’s nice to have prominent masculine role models showing it’s okay to express emotion. Actively saying it’s okay to do so seems like a good thing to do for males in general. [P14]

Privacy concerns were raised across all time points. Although participants felt the information they provided MindMax was not particularly sensitive (and some provided false information to MindMax as a further precaution), they were worried that this information would be mistreated (eg, sold to marketers).

**Content and Delivery**

A total of 2 participants were red-green color blind and expressed that the colors used within MindMax were easy to differentiate.

There was a wide range of reactions to the casual tone of the app. Some participants appreciated it:

- Good sense of humour. It like makes you feel relaxed. [P5]
- If it’s too formal, I feel a bit of pressure. [P6]

However, on the other hand, some disliked it:

- It’s cringey, like those Facebook memes. Makes me take it less seriously. [P14]

Participants also asked for more detail and specific, contextualizing examples:

- Having an example [...] guidance as to what kind of behaviours are definitive of these values. [...] [Something] more personalised to my chosen value. [P14]

Videos were commonly skipped or watched for only the first few seconds. Participants requested the ability to rewind and fast-forward through videos and an indication of what to expect (through subtitles or a transcript). Although all videos were a maximum of 90 seconds long, they were still considered too long:

- Once I see a video, I think “this is going to take a while.” Maybe if there was the length of the video on the bottom left or bottom right. If it was like 10 seconds I might watch it. [P11]

On 1 occasion, a participant skipped a video that contained key context explaining a later activity in the module, leading to brief confusion.

**Interactive Activities**

MindMax’s psychoeducational modules contained a variety of short interactive activities illustrative of the information in the modules. These activities ranged from uploading selfies and creating “shareables” (eg, a “MaxFive” plan for improving well-being) to share on the community feed, to more in-depth, reflective activities such as guided meditation.

Participant reactions to the social activities were mixed. Although some participants thought they were different and new, others felt they were inappropriate:

- There’s places for selfies and this is not one of them. [P9]

(In response to negative feedback to the tone of the activity and privacy concerns, the selfie activity was removed in the launch version of the module.)

Participants who completed the Mindfulness and Emotions modules tended to skip the guided meditation activity halfway through but were also overall more positive about the activity:

- That was pretty cool. [...] I don’t meditate usually so this was a nice experience. [P11]

Overall, participants were more positive about activities that required more focus and active participation, particularly in the context of MindMax’s psychoeducational modules being presented as Training:

- If I didn’t have to physically write the postcard it wouldn’t have resonated so much. [P15]

The Mindfulness module fits the concept of “Train” the most. Thinking of a motivational quote and putting it on a picture isn’t training. [P11]

**Avatar**

All female participants perceived avatar customization choices to lack feminine options and expressed feelings of alienation:

- None of the options look like me, so I’ll make something that’s representative of something else. [P4]

This was exacerbated by the default avatar (presented as a base for users to customize) having a mustache. Female participants preferred starting with a blank avatar to this. Male participants did not report feeling alienated by the avatar customization choices.

Although participants preferred the freedom of being able to upload their own profile picture, the majority recognized that
The same participant also questioned whether it was appropriate to tie such a simple game so strongly to MindMax’s reward system:

_I like video games, and these are very rudimentary, not very interactive, not very engaging [...] if these are the rewards for the activity you’re doing it’s a low reward for something so personal that you have to engage in. Games kind of cheapen the experience._

**Discussion**

**Principal Findings**

This series of studies aimed to use PD and user testing methods to determine the best way to present MindMax, an AFL-themed app aiming to deliver psychoeducation on mental health and well-being and to create a Web-based community centering on well-being, AFL, and video games. Our results suggest that the concept of combining mental health and well-being with sports and video games was well received by users. Participants gave further insights throughout MindMax’s development period that future mental health and well-being mHealth initiatives can learn from, whether or not they intend to incorporate applied games.

A consistent finding across PD workshops and user experience interviews was that participants did not have strong feelings about what content was presented, but rather how it was presented. Although participants found being presented with too much information at once off-putting, they did not want to be deprived of additional, contextualizing content as a result. Instead, they wanted to be able to control the flow of information, for example, through collapsible content boxes, and to have alternate modes of information, for example, through video subtitles and transcripts. Videos, in particular, were skipped on multiple occasions. This, along with previous research [4], suggests that key information should be presented in a variety of mediums in a way that minimizes repetitiveness.

Participants were sensitive to the formality (and lack thereof) of the various tones adopted by the health and well-being apps presented in PD workshops and in MindMax. Although a formal tone was perceived as intimidating, participants considered an informal tone less pressuring, but some also took the content less seriously as a result. Participants also did not want the tone to be patronizing or paternalistic and yet appreciated specific, direct instructions. Careful writing is needed to achieve this balance. Appropriate levels of formality and prescriptiveness likely vary based on the target audience and must be tested thoroughly with target users. Participants also expected a personalized experience [40], anticipating that MindMax would remember information they entered about themselves (eg, gender or the value they wanted to affirm) and that it would use that information in ways to help the user improve their well-being.

We also observed that participants preferred activities that required active engagement and practiced useful skills, paralleling earlier research on the topic [7]. Activities such as guided meditation and writing a postcard to a loved one, which required comparatively more effort to complete, were better
received than activities such as posting a selfie or choosing a quote from a preselected set of quotes. This suggests that our initial intention of reducing cognitive effort and making modules as easy to complete as possible was ineffective and may have undermined the purpose of MindMax. Instead, these findings suggest that user effort should be funneled toward completing activities.

Participants appreciated fun touches to app design (eg, skeuomorphic interactions), but ultimately the majority of participants seemed to prioritize the functional aspects of health apps, such as the ability to track their own health and well-being and information on how to improve their health and well-being. This does not mean there is no room for fun and enjoyment in mental health and well-being apps (multiple successful implementations of gamification in mental health and well-being [30,31] support this). Rather, any implementation of playfulness or supplementary conceptual flavor should be considered and tested carefully.

**Social and Applied Game Elements**

Participants overall agreed that social motivations were important to attract and keep them engaged with a mental health and well-being app and that they would prefer the social component to be in relation to their existing social networks. Although they found social comparison and competition (both common gamification features [28]) motivating for improving physical health, they felt that incorporating comparison and competition in a mental health and well-being app could be inappropriate, particularly in cases where the user or someone in their network was in distress. During user experience testing, we observed image management behaviors where participants moderated how they expressed themselves as they were conscious of their potential audience. This was not a desired user behavior and could potentially undermine the improvement of mental health and well-being.

In PD workshops, participants suggested that MindMax and similar apps should complement and enable, rather than emulate, online and offline social connection. Crucially, this social component should be a different experience compared with a mainstream social networking service. This was difficult to implement in practice, and MindMax ended up failing to follow this recommendation, instead implementing a community feed that user experience interviewees found extremely similar to Instagram. However, future conceptualizations of a social component could draw inspiration from cooperative games and incorporate more gamification elements that appeal to multiple types of users (players), such as social discovery, gifting, and unlockable content [51].

Our user experience interviewees, mostly experienced video game players, also expressed concerns that MindMax’s implementations of applied games lacked depth, which undermined their user experience. Their familiarity with video games may have contributed to their reduced interest in Flick Footy, which was a simple casual game with only 1 aim (score as many goals as possible). In addition to offering a unique, engaging experience, a more sophisticated implementation of cooperative game mechanics could potentially address these concerns and increase MindMax’s appeal to more hardcore video game fans.

**Limitations**

The largest limitation of our findings is that during the user experience interview stages, we recruited locally (in Sydney) and therefore found it difficult to recruit AFL fans. However, much of our feedback was not AFL-related and would be useful to anyone designing an app incorporating applied games for mental health and well-being. MindMax’s usage analytics will give an indication of how people interested in AFL perceive and use MindMax and will be the focus of future investigation.

Another limitation is that although the iterative nature of our user testing allowed us to evaluate and improve on subsequent versions of MindMax, in practice, we were limited by financial, technological, and organizational constraints. The time frame of the grant required that development work occur in tandem with the user testing reported in this study. As a result, many features recommended by participants were determined to be unfeasible and descoped. For example, the social component that heavily resembled Instagram was implemented as ultimately there were not enough resources or time to create and implement an alternate concept for the social component. Similarly, although our female participants’ dissatisfaction with the masculine tone of the app was noted, it was not directly actioned given the focus of the project on reaching men in the target age demographic. Finally, given the need to prioritize basic functionality and content inclusion initially, the amount of time available for applied game design and development was reduced, which is reflected in the negative feedback on the games from interviewees with significant video games experience. Although it is also possible that the casual games in MindMax may never have appealed to more experienced video game players, more PD involving more stakeholders than just the research team and potential end users may have led to a smoother development process.

However, participant feedback, especially late-stage feedback, was able to be incorporated later in the project. MindMax underwent continual improvements beyond the time frame covered in this study, introducing new features and events until February 2018. This included new psychoeducational modules, redesigns of UI and existing modules, trophies, team functionality, and a “Flick Footy Max” campaign in December 2017 to promote engagement with the app. In “Flick Footy Max,” MindMax users competed to score the highest in “Flick Footy” to win a PlayStation 4 Pro and a MindMax-themed AFL football. Participant feedback hence continued to influence the development of MindMax beyond what is described in this study.

**Future Applications**

MindMax is based in both the AFL and video games subcultures, with the aim of appealing to men who enjoy these subcultures [7]. Although we encountered some difficulties during development, many of which are inevitable on projects with defined time frames and funding windows, we ultimately produced an app containing psychoeducation, applied game elements, and a social component that was considered by user
experience interviewees to be satisfactory. We plan to analyze the impact of MindMax via usage analytics and multiple time point survey data assessing users’ levels of well-being and judgments of MindMax’s usability.

Lessons learned from MindMax can be broadly applied to any app intending to help users improve their mental health and well-being, especially those planning to incorporate applied games. They can also be extended to other traditional sporting codes such as cricket, rugby, and soccer, and furthermore, to esports. The increasing collaboration between traditional sports and esports [13] and the growing popularity of esports among younger people [12] may make a broad sports approach including esports suitable to apply to youth mental health. Finally, in the same way that traditional sporting codes such as AFL, rugby union, rugby league, and cricket are now promoting awareness of mental health problems, esports leagues can consider doing the same.

Conclusions
This study details the PD workshops and user experience testing that was conducted to obtain insights on how best to present MindMax. As an AFLPA initiative funded by Movember, MindMax presents a novel approach to evidence-based mental health and well-being education focusing on Australian men aged 16 to 35 years who enjoy AFL or video games. MindMax incorporates applied games and is couched in the Australian rules football (specifically AFL) subculture. If the implementation of MindMax is successful, there is the potential to generalize its model to other sporting codes such as rugby and cricket and even to partner with esports initiatives.

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Conflicts of Interest
IBH was an inaugural Commissioner on Australia’s National Mental Health Commission (2012-18). He is the Co-Director, Health and Policy at the Brain and Mind Centre (BMC), University of Sydney. The BMC operates an early-intervention youth service at Camperdown under contract to headspace. IBH has previously led community-based and pharmaceutical industry-supported (Wyeth, Eli Lily, Servier, Pfizer, and AstraZeneca) projects focused on the identification and better management of anxiety and depression. He was a member of the medical advisory panel for Medibank Private until October 2017, a board member of Psychosis Australia Trust, and a member of Veterans Mental Health Clinical Reference group. He is the Chief Scientific Advisor to, and an equity shareholder in, Innowell. Innowell has been formed by the University of Sydney and PwC to deliver the Aus $30 million Australian Government-funded “Project Synergy.” Project Synergy is a 3-year program for the transformation of mental health services through the use of innovative technologies. None of the other authors declare any conflicts of interest.

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Abbreviations

AFL: Australian Football League
AFLPA: Australian Football League Players’ Association
mHealth: mobile health
PD: participatory design
UI: user interface
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Patient's Perspective on Using Mobile Technology as an Aid to Psychotherapy

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Abstract
This piece draws from a patient’s perspective on his treatment using mobile health technology in conjunction with weekly group and individual psychotherapy. Research has demonstrated that using telepsychology as part of mental health treatment shows great promise to help advance the field of psychotherapy. Using mobile health technology such as mobile phone apps allows for collaboration with patients and their providers. This was written after several consultations with an individual diagnosed with borderline personality disorder who prefers to remain anonymous but was forthcoming with information regarding his use of mobile health technology in order to benefit the field of mental telepsychology.

(Keywords: mobile phone app; technology; patient perspective)

Introduction
This piece draws from a patient’s perspective on his treatment using mobile health technology in conjunction with weekly group and individual psychotherapy. Research has demonstrated that using telepsychology as part of mental health treatment shows great promise to help advance the field of psychotherapy. However, limited research has been done on mobile health apps. Despite the minimal research in this area, there are currently more than 10,000 mental health apps [1]. Using mobile health technology such as mobile phone apps allows for collaboration with patients and their providers. Furthermore, research has found no difference in the effectiveness between traditional face-to-face psychotherapy and therapeutic interventions that use the internet in some form [2].

Brief Case
Alex Jones is a 30-year-old man who was diagnosed with both borderline personality disorder and major depressive disorder approximately 6 years ago in 2012. Prior to 2012, Alex graduated from college with a degree in art. After graduating from college, Alex worked for a few years as an art teacher at a local elementary school in Massachusetts; however, in the winter of 2012 he noticed his overall well-being started to decline. At this point, Alex began seeing a psychologist weekly for individual psychotherapy appointments and a psychiatrist monthly in order to sustain a beneficial medication regime.

In 2015, Alex had his first inpatient hospitalization following a suicide attempt. For the next 2 years, Alex had several inpatient hospitalizations and subsequently attended several day treatment programs. By 2017, Alex was “fed up” with his constant mood changes, suicidal ideation, and lack of relationships. During Alex’s intake appointment at a day treatment program, he made the following statement:

“It’s annoying that I never feel the same way. I wake up and have no idea what I will feel that day. I know this is impacting my life, particularly, my relationships, but I don't know what to do about it.”

Alex’s main goal at the time of this intake was to understand how to better track his mood symptoms with the ultimate goal of reviewing patterns in and consequences of his mood.

In the fall of 2017, Alex was attending at partial hospitalization program that used dialectical behavior therapy (DBT) [3], an evidenced-based therapy created for individuals diagnosed with borderline personality disorder. DBT targets patterns of behavior
that are not helpful, such as self-harm, suicidal ideation, substance abuse, and poor relationships. As part of the DBT treatment, clients are asked to use a diary card in order to track their daily symptoms and urges. However, Alex did not like using the diary card because he felt it was inconvenient to carry around and would draw attention if he used it in a public place.

It’s embarrassing. I’m a 30-year-old man and yet I have to carry around a notebook like a child. People look at me weird when I randomly take out a notebook and I don’t want to deal with that.

Alex and his therapist began to explore how mobile health technology might better suit his needs. As a result of these conversations, Alex began testing different mental health apps on his mobile phone. He felt that this was more subtle than taking out a notebook, primarily because other people did not know what he was using his mobile phone for. In order to determine which app Alex felt best fit his needs, he began by searching on “depression” in the App Store on his iPhone. The first app Alex tried was Happify, which provides individuals with tools and strategies that help with dysregulation. Alex did not find this app helpful because he was not looking for treatment strategies but rather a way to simply track his mood. Upon consulting with one of his friends, who also regularly sees a psychologist, Alex tried Moodtrack Social Diary Card. This app allows individuals to graph their moods. In addition, the app has a group chat feature that allows users to talk to one another about what they are experiencing. However, the app requires users to pay in order to keep their journal private. Given that Alex wanted to keep his identity on the app anonymous and was unwilling to pay for the app, the Moodtrack Social Diary Card was not a good fit.

Given that Alex did not like these first 2 apps, he searched again in the App Store on his iPhone and discovered the Daylio app [4]. This mobile health app is free and allows users to keep a private diary. On Daylio, users are asked to enter a quick, 2-step entry picking their mood and adding activities they have done throughout the day. The app also has a statistics and calendar section that allows users to better understand their patterns and habits. Finally, Daylio provides a section where users can write notes; in this section, Alex recorded what DBT skills he used that day. Alex chose to use this mobile health app because it was free, intuitive, and allowed for easy analysis of data. Alex and his therapist determined that Daylio best fit Alex’s current needs (ie, tracking mood, daily activities, and skills used each day). In the spring of 2017, Alex chose to use Daylio and found that as he used it more consistently, it allowed for more collaboration with his providers.

Alex found using Daylio to be informative, which resulted in him becoming more engaged during therapy sessions. Alex eagerly shared the information from the Daylio app at each appointment with his therapist and together they used the data in order to inform treatment decisions. Because Alex used the app daily, it allowed him to discover his triggers and how he typically responded to those triggers. In addition, Alex was surprised by how frequently he was using DBT skills and how they actually helped his mood throughout the day. Based on this information, Alex felt he had more ownership over the DBT skills, which resulted in him becoming more engaged in therapy and more connected with other patients in the partial hospitalization program and helped Alex feel he would be ready for discharge from the program at an earlier date than scheduled.

**Brief Discussion**

Alex’s case is important because it demonstrates how using mobile health apps can be beneficial in psychotherapy, both for clients and their providers. After the use of a mental health app, Alex, a client typically unengaged in therapy, became an active participant in his treatment. Having a free, easy-to-use, consistent tracking device allowed Alex to take ownership of his triggers, reactions, and symptoms. Furthermore, Alex was able to concretely see how frequently he was putting DBT skills to use in everyday life. While Alex is just one individual case and therefore cannot be generalized to all individuals with the same diagnoses, the main themes of Alex’s case are of significance to clients and providers alike.

Alex’s case shows how technology can aid in minimizing mental health stigma. Originally, Alex did not want to use a diary card (or other tracking device) because he was ashamed that individuals would see him using it and judge him for needing mental health treatment. According to Corrigan [5], mental illness stigma often leads to individuals opting out of or not fully participating in psychotherapy. Once Alex discovered that using Daylio was subtle, as people just “thought I was on my phone doing whatever,” he felt more comfortable implementing it as part of his everyday routine.

Furthermore, Alex’s case underscores how the use of mental health apps allows for more collaboration between clients and their providers. Prior to using the Daylio app, Alex and his provider were frequently not on the same page in terms of treatment goals. However, once Alex began consistently using the Daylio app to track his mood, daily activities, and skill use, he and his therapist were able to collaborate to create common goals based on concrete data the app generated. Alex stated he felt more “heard” and “validated” after using Daylio because he and his therapist could visually examine how his week went and use treatment techniques that would encourage a more positive response in the future.

Finally, this case demonstrates that technology can be used in conjunction with psychotherapy rather than the either/or approach frequently seen. For Alex, technology provided him the data that was necessary to both inform treatment and increase his self-awareness. The decision to use an app only occurred after a collaborative conversation between Alex and his therapist in which multiple options were reviewed in order to satisfy Alex’s current need. In this case, technology was successfully used to augment a pre-existing treatment plan. As mental health apps continue to be developed, it is important to use the therapeutic alliance to help patients match app functions with their needs and treatment plans.
Conflicts of Interest
None declared.

References

Abbreviations
DBT: dialectical behavior therapy

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Efficacy and Moderation of Mobile App–Based Programs for Mindfulness-Based Training, Self-Compassion Training, and Cognitive Behavioral Psychoeducation on Mental Health: Randomized Controlled Noninferiority Trial

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Abstract

Background: Mindfulness-based interventions, self-compassion training, and cognitive behavioral therapy have garnered much evidence in their salutary effects on mental health. With increasing application of smartphone and mobile technology on health promotion, this study investigated the efficacy and possible moderators of mindfulness, self-compassion, and cognitive behavioral psychoeducation training mobile apps in the improvement of mental health.

Objective: The aim of this study was to examine the efficacy of 3 mobile app–based programs: mindfulness-based program, self-compassion program, and cognitive behavioral psychoeducation program in improving mental well-being and reducing psychological distress. Changes in mindful awareness and self-compassion were also assessed. To further delineate the suitability of each program for different types of individuals, individual difference variables (ie, discomfort with emotions and tolerance for ambiguity) were explored for potential moderation.

Methods: This study was a 3-arm, randomized, controlled, noninferiority trial examining the efficacy of mindfulness-based program, self-compassion program, and cognitive behavioral psychoeducation program. Participants were randomized into either 1 of the 3 conditions. Throughout the 4-week, 28-session program, participants spent 10-15 min daily reviewing the course content and practicing various related exercises. At preprogram, postprogram, and 3-month follow-up, participants also completed Web-based measures of mental well-being, psychological distress, mindful awareness, and self-compassion as well as the proposed moderators.

Results: Among the 2161 study participants, 508 and 349 completed the post- and 3-month follow-up assessment, respectively. All 3 conditions (mindfulness-based program: N=703; cognitive behavioral psychoeducation: N=753; self-compassion program: N=705) were found to be efficacious in improving mental well-being and reducing psychological distress. All conditions enhanced mindful awareness at postprogram. Significant interaction effect was found on self-compassion; cognitive behavioral psychoeducation and self-compassion program, but not mindfulness-based program, significantly enhanced self-compassion at postprogram. No significant differences regarding usage and users’ satisfaction were found among the 3 conditions. None of the proposed moderators were found to be significant.
Conclusions: Mindfulness-based, self-compassion, and cognitive behavioral psychoeducation mobile apps were efficacious in improving mental well-being and reducing psychological distress among adults at postprogram and 3-month follow-up. Future app-based psychological training programs should consider gamification and personalization of content or feedback to enhance engagement and mitigate the high attrition rates that are common in app-based health promotion programs.


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KEYWORDS
mental health; mobile apps; mindfulness; compassion

Introduction

Mobile Mental Health

Mental health is an essential part of health that contributes to individuals’ overall well-being [1]. However, about 450 million people suffer from mental or behavioral disorders worldwide [2]. According to a recent territory-wide epidemiological study conducted in Hong Kong, the prevalence rate of common mental disorders in Hong Kong was estimated to be around 13.3%, with the highest prevalence among adults aged 26 to 35 years [3]. Furthermore, only 26% of these individuals sought mental health services in the past year. Given that mental ill health causes tremendous burden to individuals, families, and society, mental health promotion should be advocated and propagated in the community.

With the increasing utilization of mobile phones and tablet devices, mobile intervention becomes a viable option to educate individuals about mental health and to promote well-being. In Hong Kong, the number of mobile service subscribers was 16.72 million as of March 2016 [4], compared with 8 million in June 2012. The penetration rate of 228.3% in Hong Kong was one of the highest figures globally. The amount of mobile data usage has increased ten folds from 2006 to June 2016, demonstrating the rapid and continual increase of smartphone and internet usage [5].

Mobile apps have dominated the browsing time of mobile phone users. In a survey conducted by comScore, Inc. in 2012 [6], 82% of the time spent on mobile media happened via apps, and this percentage has risen to 90% in 2015 [7]. Given the ubiquitous nature of apps, such media can potentially provide a highly accessible, convenient, and anonymous way to promote mental health on a large scale to populations who would otherwise not seek help due to inconvenience, stigma, and other help-seeking barriers [8,9].

Cognitive Behavioral–Based Psychoeducation Training

The cognitive behavioral approach has been widely applied and suggested to be one of the most evidence-based approaches in reducing psychological distress and promoting mental well-being [10]. In recent years, internet-based and mobile apps that are based on the cognitive behavioral approach have been developed to help people cope with stress, increase emotional awareness, and promote wellness [11-14]. The cognitive behavioral approach can modify ones’ emotion regulation, reduce psychological distress, and promote mental health by changing the cognitive appraisal process and the mood-related behaviors of the individuals [15]. Recently, Rathbone et al [16] reviewed 8 studies concerning the efficacy of cognitive behavioral therapy (CBT)-related mobile apps and concluded that these apps appeared to repeatedly show improvements in symptom severity on a range of psychological issues including depression and stress. Although the long-term effectiveness was unclear, the short-term effect was evident.

Cognitive behavioral approach is also culturally appropriate in the Chinese culture. The Chinese socialization process emphasizes on structure and hierarchy, clearly defined roles, and responsibility. As such, Chinese clients generally display low tolerance for ambiguity. Given that cognitive behavioral approach is directive and structured, it is suitable for the Chinese population [17]. In addition, as the Chinese culture is strongly influenced by Confucianism that emphasizes on the importance of education and learning, the psychoeducational component in CBT is especially suitable for the Chinese population. Chinese culture has a common belief that any desired change could be brought about by diligent learning. In Hwang’s [18] recommendation, to meet the therapeutic needs of Chinese clients, 1 principle is to promote psychoeducation that engages clients in their familiar student role. Mobile apps are well positioned to deliver cognitive behavioral–based psychoeducation as they can engage users with multimedia tools and provide clear information to aid understanding of mental health concepts [19].

Mindfulness-Based Training

In addition to utilizing the cognitive behavioral approach to reduce stress and promote mental health, in the recent decade, ample research has demonstrated the power of mindfulness and self-compassion in promoting mental health [20-22]. These approaches have their theoretical roots in Asian philosophies, and they are culturally adaptive approaches among Chinese communities [23].

Mindfulness-based training is an approach that focuses on the cultivation of conscious awareness in the unfolding of events in the present moment [24]. It emphasizes the transience of all thoughts and feelings. It involves self-regulation of attention and orientation toward the present moment with openness [25]. Meta-analysis showed mindfulness-based training to have a medium effect size in improving anxiety (Hedges g=0.63) and depressive symptoms (Hedges g=0.59) across all samples. Mindfulness-based training has also been found to have a medium effect size (Hedges g=0.53) in comparison with waitlist
Mindfulness-based training is increasingly being delivered online because of technology advancement in recent years. Research on an 8-week internet-based mindfulness-based training showed that compared with waitlist control, internet-based mindfulness training improved university students’ and staffs’ mental well-being, and the effect was sustained at the 3-month follow-up [27]. Another study compared internet-based mindfulness training with internet-based cognitive behavioral training among college students and working adults and found that both were efficacious in improving mental health, psychological distress, life satisfaction, sleep disturbance, and energy level upon training and at 3-month follow-up [28]. In addition to our studies, Spijkerman et al [29] in their review and meta-analysis also reported that online mindfulness-based interventions have significant benefits on mental health outcomes, including depression (Hedges g=0.29), anxiety (Hedges g=0.22), well-being (Hedges g=0.23), and stress (Hedges g=0.51).

Self-Compassion Training

Self-compassion training is another acceptance-based approach that has garnered empirical evidence in improving one’s well-being [30-32]. Self-compassion is defined as a caring attitude toward oneself in the face of hardship or perceived inadequacy, a recognition of suffering and failure as shared human experience, and a balanced approach to thoughts and feelings without suppression or exaggeration [33]. Self-compassionate individuals were found to bring awareness to their emotions and approach their distressing feelings with kindness and understanding, instead of avoidance and self-judgment, and they are more capable of transforming negative emotions into more positive states. Self-compassion has been demonstrated to be positively related to life satisfaction and positive affect and negatively related to negative affect, depression, and anxiety [22,34-36]. Interventions such as the 12-week Compassionate Mind Training (CMT) program [37] and 8-week Mindful Self-Compassion (MSC) program [38] have found to lead to significant increase in happiness and reduction in self-criticism, shame, sense of inferiority, stress, depression, anxiety, and global psychological distress. In addition to face-to-face training programs, researchers have used brief writing and self-help exercises to improve mental well-being. Results showed that participants reported increase in physical health, self-compassion, happiness, self-reassurance and ability to self-soothe, and decrease in depression and psychological distress [39-42].

Exploration of Moderators

Despite evidence showing the efficacy of cognitive behavioral, mindfulness-based, and self-compassion approaches in improving mental health, little attention has been put into understanding which individual difference variables may affect the efficacy of these approaches and which can inform the choice of intervention for different individuals. Previous studies showed that people scoring high on neuroticism tend to show greater decrease in anxiety and depressive symptoms 3 months after mindfulness-based stress reduction program, whereas introverts were less likely to drop out from mindfulness-based training [43,44]. However, the underlying personality qualities and individual cognitive styles leading to differential treatment outcomes are still inconclusive. To examine who benefits from our mobile apps in this study, we hypothesized 2 moderators, specifically, discomfort with emotions and ambiguity tolerance, which might affect response to interventions.

Discomfort With Emotions

Mindfulness and self-compassion intervention involve bringing one’s awareness to present moment emotions, either positive, negative, or neutral. Individuals with strong discomfort when experiencing emotions may have difficulties remaining in contact with such emotions. This may result in difficulty in engaging mindfulness or self-compassion practices. The study conducted by Sass et al [45] showed that reductions in distress were significantly moderated by discomfort with emotions in a brief mindfulness-based intervention. Individuals with the most discomfort with emotions showed less reduction in distress after the mindfulness-based intervention. To our knowledge, no study has examined this moderation effect in self-compassion training, but we expect to see a similar effect as compared with mindfulness-based training given that they both originated in Buddhist philosophy. On the other hand, cognitive behavioral training aims at changing the cognitive appraisal process and mood-related behaviors of the individual. While focusing on the cognitive and behavioral aspects, less emphasis was placed on experiencing and remaining in contact with one’s emotions as compared with the other 2 approaches. In this sense, a resistance toward own emotion may not affect the change mechanism as much and hence would be less likely to moderate the effect of a cognitive behavioral training.

Ambiguity Tolerance

An important precursor to effective acceptance-based practices, including mindfulness and self-compassion, is the receptivity to new ways of being with emotional pain and suffering [46]. Van den Hurk et al [47] found that the practice of meditation is associated with higher levels of curiosity, openness, and receptivity to new experiences. This openness may be moderated by one’s level of ambiguity tolerance, which is defined as a range, from rejection to attraction, of reactions to ambiguous situations or stimuli when confronted by an array of complex, unfamiliar, or incongruent clues [48,49]. Mindfulness-based and self-compassion training rely very much on experiential learning. Thus, in these training programs, the experience may be unpredictable and variable across individuals. As mentioned earlier, it was suggested that people with low tolerance for ambiguity might benefit from a cognitive behavioral approach because of its structured context and concrete therapeutic goals, plans, and procedures [17]. Together, we hypothesized that individuals with lower levels of ambiguity tolerance may find mindfulness-based and self-compassion training more difficult to grasp than cognitive behavioral psychoeducation; thus, they are less likely to benefit from them.

Aims and Hypotheses

Despite the fact that mindfulness, self-compassion, and cognitive behavioral approaches have garnered much evidence in their
salutary effects on mental health, few studies have compared their efficacy on improving mental health in a single trial and examined how individual characteristics may affect the outcome of these intervention approaches. Moreover, most of these studies adopted the usual program format with a long program period (eg, 8 weeks to 12 weeks) and formal practices (eg, meditation that lasts for 45 min). This can be an obstacle for adults living with a packed schedule in a fast-paced city such as Hong Kong. To accommodate the local context of our target population, instead of the usual program format, our study attempted to develop and test an intervention protocol with the average engagement time being shortened to 10 to 15 min a day, for 28 days.

This study used a randomized, controlled, noninferiority trial to compare the efficacy of a 4-week mobile app–based mindfulness-based program (MBP), self-compassion program (SCP), with a cognitive behavioral psychoeducation program (CBP) in enhancing mental health among adults in Hong Kong. We hypothesized that participants in all programs will show significant and equivalent improvement in mental health at postprogram, and the changes will be maintained at 3-month follow-up. Then, we expected participants’ mindful awareness would be cultivated in both MBP and SCP but not in CBP given the shared origin in Buddhist philosophy and the emphasis on awareness. Self-compassion was expected to be cultivated in SCP but not in the other 2 conditions. We also hypothesized that the levels of discomfort with emotions and ambiguity tolerance will post differential impact on the efficacy of the 3 respective programs. Specifically, people with lower discomfort with emotions and ambiguity will benefit more in CBP compared with the other 2 programs, and people with high levels of ambiguity tolerance will benefit more in both MBP and SCP compared with CBP.

Methods

Trial Design

This study is a 3-arm, randomized, open-label, parallel, positive-controlled trial with 3 intervention groups (MBP, SCP, and CBP). Given that the cognitive behavioral approach is a well-established, evidence-based approach for an array of mental health conditions [10], it is treated as a comparison condition that provides a more stringent evaluation of SCP and MBP as an active comparison condition and can control for demand characteristics and participant expectancies that would otherwise not be possible with a waitlist control condition. Clinical ethics approval was obtained from the principal investigator’s institution and the Hospital Authority of Hong Kong for interventions involving humans as participants. Trial registration was done through institutional registry (Trial no: ChiCTR-TRC-13003468).

Mobile App Development

The Living With Heart (LWH) mobile app was developed, and it contained 3 training programs mentioned above. It runs on iOS and Android platform. A Web-browser version was also developed so that it can be accessed through various devices including mobile phones, tablets, and desktop computers. It was made available on Google Play and Apple Store, along with the website, since March 2015 after functional tests were conducted. The mobile app (and website) is fully automated and includes the following common features: (1) mood tracking function with which users can record their mood and its intensity as frequently as they wish based on either mindfulness, self-compassion, or cognitive behavioral approach that they have learned; (2) well-being tips feature with which users receive daily messages and quotes relevant to mindfulness, self-compassion, or cognitive behavioral psychoeducation, depending on to which condition the users were assigned; (3) sticker earning feature with which user can earn stickers as they progress through the sessions and they can share their accomplishments on a social networking platform such as Facebook; and (4) practice alarm feature with which users can time their practice and set timers reminding them to practice. Besides written materials, all contents have also been audio-recorded to facilitate users to listen to the content if they are unable to read the materials on the go. Screenshots of the LWH mobile app are shown in Multimedia Appendix 1.

Interventions

In addition to the above-mentioned common features, all 3 conditions consisted of 28 daily sessions, which were divided into 4 weekly modules. The course contents were released weekly, and all 7 sessions of that particular week are available to the user on the first day of that week. Users were encouraged to read the content at their own pace with suggested home practices every week. All contents were developed by the research team members who were clinical psychologists and practitioners of cognitive behavioral, mindfulness-based, or self-compassion interventions.

Mindfulness-Based Program

MBP consists of 4 weekly sessions adapted from the internet-based mindfulness-based training that have been developed in the previous study [28]. Mindfulness exercises, including body scan, mindful breathing, mindful eating, mindful walking, 3-min breathing space, and thought distancing exercise [50], are audio-recorded to facilitate participants to practice mindfulness. Readings and graphics are included to explain the concept of mindfulness and to share with participants the common difficulties they may come across during mindfulness practices.

Self-Compassion Program

The SCP was based on the teachings of self-compassion from Neff and Germer [38]. The self-compassion exercises were adapted from the resources provided by the Center for Mindful Self-Compassion founded by Neff and Germer in 2013. Exercises included compassionate body scan, affectionate breathing, loving-kindness meditation for beginners, compassionate walking, soften-allow-soothe, self-compassion break, and self-compassion journaling. In addition to various exercises, readings and graphics were presented in each session to explain the concept of self-compassion and its relevance to mental health. Audio guides are provided to the participants to perform the self-compassion exercises.
Cognitive Behavioral Psychoeducation Program

In the CBP, different coping strategies and exercises to manage stress, including problem-solving skills, emotional management skills, and cognitive strategies to tackle automatic negative thoughts associated with their stress, were introduced to the participants. Relaxation skills, including abdominal breathing, progressive muscle relaxation, and imagery relaxation, were also taught with audio guides. The sessions contained information and graphics about mental health, stress, and cognitive behavioral approach to educate participants on the basic strategies to promote one’s mental health.

Participants

This study targeted adults in the general population who fulfilled the following inclusion criteria: (1) age over 18 years, (2) read and understand Chinese, (3) own a mobile device such as a mobile phone or tablet, and (4) have consistent internet access for their mobile devices. Participants were recruited through (1) posting advertisements in free local newspapers, magazines, online advertising channels (Bing and Google Ad), and the social networking site (Facebook) and (2) sending mass emails and distributing announcements to large institutions in Hong Kong.

Participants were recruited between March 2015 and April 2016. Individuals who were interested in the study could download the mobile app through Apple Store or Google play or visit the website where informed consent was sought through the built-in consent form in the app or website. Apart from the inclusion criteria, details of the study aims, length of the program, involvement of the participants, and randomization of participants to interventions were also described. For safety, participants are reminded that the mobile app is not equivalent to a psychological treatment. They were reminded to seek professional support at any occurrence of suicidality or other medical issues. Information on help-seeking resources was provided. They were also informed that the study was conducted by the Department of Psychology at The Chinese University of Hong Kong. Individuals who agreed to participate proceeded to registration after giving informed consent by clicking the agree button. From there, an activation link was sent to the participants, and they were randomly assigned to 1 of the 3 conditions.

Randomization

Randomization took place when participants activated their user account in the email that was sent immediately to their email address after they provided informed consent on the study website. A simple randomization to 1 of the 3 conditions was performed by the computer system automatically. Participants were informed about their assigned condition after they had completed the pretraining questionnaire when they logged into the app or website.

Measures

Participants filled in the pre-, post-, and follow-up assessments online via the website or mobile app. Trained supporters contacted the participants via a phone call and short message service text messages once after the end of the program and at 3-month follow-up to encourage the completion of postprogram and follow-up evaluations.

Demographics

At baseline, participants were asked about their demographics and background information such as age, gender, education level, income, occupation, marital status, and religion.

Primary Outcomes

Mental Well-Being

The World Health Organization 5-item Well-Being Index (WBI) [51] was used to measure mental well-being. Participants were asked to indicate how they had been feeling over the past 2 weeks on a 6-point Likert scale from 0 (never) to 5 (all of the time). In this study, its Cronbach alpha was .90 at baseline, .92 at postprogram, and .93 at 3-month follow-up.

Psychological Distress

The 6-item Kessler Psychological Distress Scale (K6) was used to assess psychological distress. It is a well-established screening measure on psychological distress that involves questions about a person’s emotional state. Each question is scored from 0 (none of the time) to 4 (all of the time). Its reliability and validity have been widely established across different populations [52] and in Hong Kong [53]. In this study, its Cronbach alpha was .89 at baseline, .91 at postprogram, and .90 at 3-month follow-up.

Secondary Outcomes

Mindful Awareness

Five items with the highest factor loading from the Mindful Attention and Awareness Scale (MAAS) [54] were used to assess the participant’s level of mindful awareness in daily activities. Participants rate on a 6-point Likert scale ranging from 1 (never) to 6 (always). Higher scores mean having lower levels of mindful awareness. In this study, the Cronbach alpha of these items was .79 at baseline, .80 at postprogram, and .79 at 3-month follow-up.

Self-Compassion

To evaluate the effectiveness of the mobile app to enhance one’s self-compassion, 13 items from Self-Compassion Scale [55] were used. They were all positively framed items and were suggested to represent self-warmth in past studies [56,57]. Participants rate on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). In this study, the Cronbach alpha of these items was .93 at baseline, .92 at postprogram, and .93 at 3-month follow-up.

Moderators on Intervention Efficacy

Discomfort With Emotions

Six items with the highest factor loading from the Depressed Mood and Anxiety Subscales of the Affective Control Scale [58] that are based on the study by Melka et al [59] were used to measure discomfort with negative emotions. Cronbach alpha of these 6 items in this study at baseline, post, and follow-up were .87, .88, and .89, respectively.
Ambiguity Tolerance

Tolerance for ambiguity was measured by the 9-item Discomfort with Ambiguity subscale from the Need for Closure Scale [60]. Participants rated the items on a 6-point Likert scale from 1 (strongly disagree) to 6 (strongly agree). Higher scores mean having lower levels of tolerance for ambiguity. Cronbach alpha of these 9 items in this study at baseline, post, and follow-up were .75, .80, and .80, respectively.

Program Evaluation Outcome

Utilization and Satisfaction

At the end of the program, participants rated on the Chinese version of the 8-item Client Satisfaction Questionnaire (CSQ) [61] for their attitudes toward and satisfaction with their assigned condition on a 4-point Likert scale. Cronbach alpha of CSQ was .87 in this study, with items 4 (“would you recommend our program to a friend”) and 8 (“would you come back to our program if you were to seek help again”) deleted due to low item-to-total correlation (item 4: r = -.45 and item 8: r = -.50). To assess the level of utilization of each participant, participants’ percentage of unlocked sessions was recorded by the backend system of the mobile app, and their retention rate in completing the post and the 3-month follow-up assessments were also recorded. Participants were also instructed to call and/or email our research assistant for clarification in case of questions, problems, or feedback during the course of the intervention.

Analysis

All analyses were conducted using IBM SPSS 22.0. To examine and compare the efficacy between SCP, MBP, and CBP, both intention-to-treat (ITT) and per-protocol (PP) analysis were performed on the 2 primary outcome variables, that is, mental well-being and psychological distress, as well as the secondary outcome variables, that is, mindful awareness and self-compassion. For both analyses, a series of linear mixed model (LMM) analyses were conducted. Model for each outcome variable consisted of the main effect of time, condition, and the interaction effect of time by condition. First-order autoregressive covariance matrix was used. When the main effect of time or condition was significant, follow-up tests were conducted to compare the outcomes in postprogram and follow-up with the preprogram, and results were adjusted with Bonferroni correction.

In handling longitudinal missing data, Newman [62] has found in a series of simulation that maximum likelihood and multiple imputation approaches yielded better SE estimates than other approaches. In addition, it has been suggested that restricted maximum likelihood (and full information maximum likelihood) is superior to multiple imputation approach in estimating SE when handling missing data with second-level dependencies [63]. In this study, we handled missing data using the restricted maximum likelihood approach to better account for the missing data that involved second-level dependencies.

Effect sizes (ie, Cohen d) of each intervention were calculated by subtracting the postscore or follow-up score of each outcome measure from the respective prescore and then dividing the difference by the pooled SD [64]. Moderation was examined by the same LMM procedure described above, and the model consisted of the main effect of time, condition, and the moderator, the 2-way interaction effects (ie, time x condition, time x moderator, condition x moderator), and the 3-way interaction effect (ie, time x condition x moderator). A significant 3-way interaction effect (time x condition x moderator) indicates moderation effect.

Results

Recruitment and Participant Characteristics

A total of 3153 registrants had downloaded the mobile app and registered an account. A total of 27.62% (871/3153) chose not to activate their accounts, whereas 2282 registrants proceeded with account activation followed by randomization. Among those who proceeded to registration, 739 were randomized to the MBP, 748 to the SCP, and 795 to the CBP. Furthermore, 95.1% (703/739) randomized participants in the MBP, 94.3% (705/748) in the SCP, and 94.7% (753/795) in the CBP completed the prequestionnaire and began the program (see Figure 1 for study flowchart).

Demographics and baseline psychological attributes of the participants are shown in Tables 1 and 2. Overall, they had a mean age of 33.64 (SD 12.08), with the majority being female (72.88%, 1575/2161), and 79.59% (1720/2161) received or were receiving tertiary education (undergraduate or above).

Utilization Analysis

The mean completion rate of the 28 sessions (4 modules) of all participants (including completers and noncompleters) was 31.95% (SD 34.94), approximately 9 out of 28 days. The mean completion rate for MBP was 32.15% (SD 34.13), approximately 9 out of 28 days. The mean completion rate for SCP was 34.72% (SD 34.08), approximately 9 out of 28 days. The mean completion rate for CBP was 31.95% (SD 34.94), approximately 9 out of 28 days. The mean completion rate for MBP was 29.48% (SD 34.23), 32.15% (SD 34.72) for SCP, and 34.08% (SD 34.13) for CBP. The 3 conditions differ significantly on the overall progress, \( F_2 = 3.272, P = .04 \). Follow-up test showed that the progress was significantly greater in CBP than in MBP (\( P = .03 \)).
Figure 1. Consort flowchart of participants in our study. MBP: mindfulness-based program; SCP: self-compassion program; CBP: cognitive behavioral psychoeducation program.
Table 1. Baseline characteristics across conditions.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MBP&lt;sup&gt;a&lt;/sup&gt; (N=703)</th>
<th>SCP&lt;sup&gt;b&lt;/sup&gt; (N=705)</th>
<th>CBP&lt;sup&gt;c&lt;/sup&gt; (N=753)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>33.80 (12.40)</td>
<td>33.59 (11.91)</td>
<td>33.54 (11.95)</td>
</tr>
<tr>
<td>Range</td>
<td>18-83</td>
<td>18-69</td>
<td>18-68</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>203 (28.9)</td>
<td>199 (28.2)</td>
<td>184 (24.4)</td>
</tr>
<tr>
<td>Female</td>
<td>500 (71.1)</td>
<td>506 (71.8)</td>
<td>569 (75.6)</td>
</tr>
<tr>
<td><strong>Education, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary or below</td>
<td>10 (1.4)</td>
<td>8 (1.1)</td>
<td>7 (0.9)</td>
</tr>
<tr>
<td>Secondary</td>
<td>143 (20.4)</td>
<td>125 (17.7)</td>
<td>148 (19.7)</td>
</tr>
<tr>
<td>Bachelor/diploma</td>
<td>385 (54.7)</td>
<td>379 (53.8)</td>
<td>405 (53.8)</td>
</tr>
<tr>
<td>Master or above</td>
<td>165 (23.4)</td>
<td>193 (27.4)</td>
<td>193 (25.6)</td>
</tr>
<tr>
<td><strong>Employment, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>184 (26.6)</td>
<td>179 (25.9)</td>
<td>201 (27.3)</td>
</tr>
<tr>
<td>Full-time</td>
<td>377 (54.5)</td>
<td>394 (57.0)</td>
<td>394 (53.5)</td>
</tr>
<tr>
<td>Part-time</td>
<td>42 (6.1)</td>
<td>29 (4.2)</td>
<td>27 (3.7)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>24 (3.5)</td>
<td>33 (4.8)</td>
<td>55 (9.3)</td>
</tr>
<tr>
<td>Others</td>
<td>76 (9.3)</td>
<td>70 (8.1)</td>
<td>76 (6.2)</td>
</tr>
<tr>
<td><strong>Religion, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No religion</td>
<td>422 (60)</td>
<td>410 (58.5)</td>
<td>424 (56.8)</td>
</tr>
<tr>
<td>Christians</td>
<td>169 (24)</td>
<td>183 (26.1)</td>
<td>200 (26.8)</td>
</tr>
<tr>
<td>Catholics</td>
<td>40 (5.7)</td>
<td>43 (6.1)</td>
<td>51 (6.8)</td>
</tr>
<tr>
<td>Buddhists</td>
<td>64 (9.1)</td>
<td>57 (8.1)</td>
<td>63 (8.4)</td>
</tr>
<tr>
<td>Others</td>
<td>8 (1.1)</td>
<td>8 (1.1)</td>
<td>8 (1.1)</td>
</tr>
<tr>
<td><strong>Previous mindfulness experience, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>611 (86.9)</td>
<td>599 (85)</td>
<td>629 (83.5)</td>
</tr>
<tr>
<td>No</td>
<td>92 (13.1)</td>
<td>106 (15)</td>
<td>124 (16.5)</td>
</tr>
<tr>
<td><strong>Previous CBT&lt;sup&gt;d&lt;/sup&gt; experience, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>638 (90.8)</td>
<td>626 (88.8)</td>
<td>661 (87.8)</td>
</tr>
<tr>
<td>No</td>
<td>65 (0.1)</td>
<td>79 (11.2)</td>
<td>92 (12.2)</td>
</tr>
</tbody>
</table>

<sup>a</sup> MBP: mindfulness-based program.

<sup>b</sup> SCP: self-compassion program.

<sup>c</sup> CBP: cognitive behavioral psychoeducation program.

<sup>d</sup> CBT: cognitive behavioral therapy.
Table 2. Baseline characteristics across conditions.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>MBP(^a) (N=703), mean (SD)</th>
<th>SCP(^b) (N=705), mean (SD)</th>
<th>CBP(^c) (N=753), mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental well-being</td>
<td>3.00 (0.99)</td>
<td>2.99 (1.02)</td>
<td>2.99 (1.00)</td>
</tr>
<tr>
<td>Psychological distress</td>
<td>2.43 (0.88)</td>
<td>2.44 (0.83)</td>
<td>2.48 (0.86)</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mindful awareness</td>
<td>2.50 (0.91)</td>
<td>2.51 (0.88)</td>
<td>2.59 (0.93)</td>
</tr>
<tr>
<td>Self-compassion</td>
<td>2.82 (0.78)</td>
<td>2.79 (0.80)</td>
<td>2.80 (0.80)</td>
</tr>
<tr>
<td>Potential moderators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discomfort with emotions</td>
<td>4.29 (1.14)</td>
<td>4.32 (1.14)</td>
<td>4.35 (1.14)</td>
</tr>
<tr>
<td>Ambiguity tolerance</td>
<td>4.36 (0.67)</td>
<td>4.38 (0.71)</td>
<td>4.36 (0.67)</td>
</tr>
</tbody>
</table>

\(^a\)MBP: mindfulness-based program.  
\(^b\)SCP: self-compassion program.  
\(^c\)CBP: cognitive behavioral psychoeducation program.

Figure 2. Number of participants using the programs each week. MBP: mindfulness-based program; SCP: self-compassion program; CBP: cognitive behavioral psychoeducation program.

Figure 2 shows the number of participants who stayed in the program after each module. Numbers indicated that the majority of attrition was noted in the first week. Specifically, 69.0% (485/703) of participants in the MBP, 65.7% (463/705) in the SCP, and 66.4% (500/753) in the CBP stopped using the app after 7 days.

**User Experience**

Participants of the 3 conditions (MBP, SCP, and CBP) reported similar overall usage satisfaction as measured by the CSQ after removing item 4 and 8, \(F_{2,794.29}=2.319, P=.10\). Of the 508 users who responded to the CSQ, 79.9% (406/508) found the course contents good or excellent. In addition, 90.2% (458/508) stated that they generally or definitely got the service (learning experience) that they wanted. More than half of the participants, 56.1% (285/508), thought the program met most or almost all of their needs. Moreover, 88.0% (447/508) of users were mostly or very satisfied with the amount of help received in the program and 77.8% (395/508) found it somewhat helpful in dealing with their problems more effectively. Furthermore, 87.4% (444/508) of our participants were mostly or very satisfied with the mobile app in general.

**Attrition Analysis**

To investigate the potential causes of attrition, we compared the baseline attributes between participants who dropped-out (N=1653) with those who remained (N=508) at postprogram. Participants who stayed in the program (mean 34.75 SD 12.76) were significantly older than those who left (mean 33.3 SD 11.84), \(t_{794.29}=2.27, P=.02\). They also differed in terms of education level, \(\chi^2_{6}=14.23, P=.03\), with more people obtaining postgraduate education in the dropout group. No significant difference was found in all outcome measures and potential moderators at baseline.
**Intent-to-Treat Analysis Findings**

**Mental Well-Being**

Results from LMM analyses found that the mobile apps significantly enhanced participants’ well-being over time, $F_{2}=51.36, P<.001$. Scores on WBI significantly increased from baseline to postprogram (mean difference=0.31, 95% CI 0.22-0.40, $P<.001$) and from baseline to 3-month follow-up (mean difference=0.35, 95% CI 0.24-0.46, $P<.001$). There is no significant main effect of condition ($P=.43$). The nonsignificant time x condition interaction effect ($P=.67$) indicated that the improvements over time were identical across the 3 conditions.

**Psychological Distress**

Psychological distress as measured by the K6 was found to be significantly reduced in all 3 conditions, $F_{2}=44.60, P<.001$. Mean score of K6 significantly decreased from baseline to postprogram (mean difference=−0.26, 95% CI −0.33 to −0.19, $P<.001$), and this decrease was maintained at 3-month follow-up (mean difference=−0.22, 95% CI −0.31 to −0.13, $P<.001$) in all 3 conditions. No significant main effect of condition ($P=.72$) and interaction term ($P=.52$) was noted.

**Mindful Awareness**

The mobile apps significantly enhanced participants’ mindful awareness over time, $F_{2}=4.94, P<.01$. Mean scores of MAAS significantly decreased from baseline to postprogram in all 3 conditions (mean difference=−0.11, 95% CI −0.19 to −0.03, $P<.01$). However, the change from baseline to follow-up was not significant (mean difference=−0.04, 95% CI −0.13 to 0.06, $P>.99$). The main effect of condition was not significant ($P=.09$). There is no significant time x condition interaction effect ($P=.59$) as well.

**Self-Compassion**

A significant time x condition interaction effect was found, $F_{2}=2.72, P<.05$. This indicated a different change pattern across the 3 conditions. This interaction was followed up by post-hoc comparisons. We found that both SCP (mean difference=0.25, 95% CI 0.14-0.36, $P<.001$) and CBP (mean difference=0.21, 95% CI 0.09-0.32, $P<.001$) were able to enhance self-compassion at postprogram. MBP did not significantly improve self-compassion at postprogram (mean difference=0.06, 95% CI −0.06 to 0.17, $P=.70$). None of the conditions significantly improved self-compassion from baseline to 3 months after adjustment. It is noteworthy that the change in self-compassion from baseline to 3 months in MBP was approaching significance ($P=.055$).

**Per-Protocol Analysis Findings**

The PP population was defined as all participants who have completed all 28 days (100%) of the program. There were a total of 342 participants in this population, 104 in the MBP, 112 in the SCP, and 126 in the CBP group. Results of the PP analysis on the 2 primary outcomes were similar to the full sample analysis. Slight differences were found in the results regarding the 2 secondary outcomes.

**Mental Well-Being**

The mobile apps significantly enhanced participants’ mental well-being over time, $F_{2}=31.47, P<.001$. Scores on WBI significantly increased from baseline to postprogram (mean difference=0.37, 95% CI 0.24-0.49, $P<.001$) and from baseline to 3-month follow-up (mean difference=0.43, 95% CI 0.27-0.59, $P<.001$). There is no significant main effect of condition ($P=.98$). The nonsignificant time x group interactions ($P=.68$) indicated that the improvements over time were identical across the 3 conditions.

**Psychological Distress**

Psychological distress as measured by the K6 was found to be significantly reduced over time, $F_{2}=27.57, P<.001$. Mean scores of K6 significantly decreased from baseline to postprogram (mean difference=−0.30, 95% CI −0.40 to −0.19, $P<.001$) and from baseline to 3-month follow-up (mean difference=−0.27, 95% CI −0.40 to −0.15, $P<.001$). The main effect of condition was not significant ($P=.12$). There is no significant time x condition interaction effect ($P=.63$).

**Mindful Awareness**

Results in this PP analysis showed a nonsignificant main effect of time, $F_{2}=1.92, P=.15$. However, the condition effect was significant, $F_{2}=3.53, P<.05$. Follow-up tests showed that the mean MAAS score in SCP was significantly different from that of CBP (mean difference=0.27, 95% CI 0.03-0.52, $P<.05$). Specifically, MAAS scores in CBP (mean 2.613, SE 0.07, 95% CI 2.47-2.75) were higher than those in SCP (mean 2.34, SE 0.07, 95% CI 2.20-2.49), but did not significantly differ from that of MBP (mean 2.48, SE 0.08, 95% CI 2.33-2.63). The time x condition interaction effect was not significant ($P=.95$).

**Self-Compassion**

A significant time x condition interaction effect was found, $F_{2}=2.52, P<.05$. In the follow-up test, we found that both SCP (mean difference=0.34, 95% CI 0.17-0.50, $P<.001$) and CBP (mean difference=0.20, 95% CI 0.04-0.36, $P<.05$) were able to enhance self-compassion at postprogram, but not MBP ($P>.99$). None of the conditions significantly improved self-compassion from baseline to 3 months after adjustment.

Details of the ITT and PP analyses are shown in Tables 3 and 4.

**Findings on Potential Moderation Effects**

Results revealed that the proposed moderators did not moderate the effect of intervention efficacy in terms of WBI. The moderation of discomfort with emotions ($F_{2}=0.60, P=.66$) and ambiguity tolerance ($F_{2}=1.40, P=.23$) were not significant. Similarly, for distress reduction (K6), no significant interaction was noted. The moderation of discomfort with emotions ($F_{2}=0.55, P=.70$) and ambiguity tolerance ($F_{2}=0.62, P=.65$) were not significant.
Table 3. Means, SD, and SE of primary outcomes across conditions.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>MBP&lt;sup&gt;a&lt;/sup&gt;, mean (SD&lt;sup&gt;d&lt;/sup&gt;; SE)</th>
<th>SCP&lt;sup&gt;b&lt;/sup&gt;, mean (SD&lt;sup&gt;d&lt;/sup&gt;; SE)</th>
<th>CBP&lt;sup&gt;c&lt;/sup&gt;, mean (SD&lt;sup&gt;d&lt;/sup&gt;; SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>FU&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>N (ITT&lt;sup&gt;f&lt;/sup&gt;)</td>
<td>703</td>
<td>168</td>
<td>125</td>
</tr>
<tr>
<td>N (PP&lt;sup&gt;g&lt;/sup&gt;)</td>
<td>104</td>
<td>88</td>
<td>61</td>
</tr>
<tr>
<td>Mental well-being</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WBI&lt;sup&gt;h&lt;/sup&gt; (ITT)</td>
<td>3.00 (1.06; 0.04)</td>
<td>3.32 (0.91; 0.07)</td>
<td>3.26 (0.88; 0.04)</td>
</tr>
<tr>
<td>WBI (PP)</td>
<td>3.02 (1.02; 0.10)</td>
<td>3.32 (1.03; 0.11)</td>
<td>3.26 (0.88; 0.04)</td>
</tr>
<tr>
<td>Psychological distress</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K6&lt;sup&gt;i&lt;/sup&gt; (ITT)</td>
<td>2.43 (0.80; 0.03)</td>
<td>2.20 (0.65; 0.05)</td>
<td>2.15 (0.67; 0.06)</td>
</tr>
<tr>
<td>K6 (PP)</td>
<td>2.51 (0.82; 0.08)</td>
<td>2.15 (0.84; 0.09)</td>
<td>2.15 (0.78; 0.10)</td>
</tr>
<tr>
<td>Mindful awareness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAAS&lt;sup&gt;j&lt;/sup&gt; (ITT)</td>
<td>2.50 (0.80; 0.03)</td>
<td>2.43 (0.78; 0.06)</td>
<td>2.24 (0.78; 0.07)</td>
</tr>
<tr>
<td>MAAS (PP)</td>
<td>2.56 (0.92; 0.09)</td>
<td>2.44 (0.84; 0.09)</td>
<td>2.45 (0.78; 0.10)</td>
</tr>
<tr>
<td>Self-compassion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCS (ITT)</td>
<td>2.82 (0.80; 0.03)</td>
<td>2.88 (0.65; 0.06)</td>
<td>2.96 (0.67; 0.06)</td>
</tr>
<tr>
<td>SCS (PP)</td>
<td>2.78 (0.82; 0.08)</td>
<td>2.82 (0.75; 0.09)</td>
<td>2.91 (0.70; 0.09)</td>
</tr>
</tbody>
</table>

<sup>a</sup>MBP: mindfulness-based program.

<sup>b</sup>SCP: self-compassion program.

<sup>c</sup>CBP: cognitive behavioral psychoeducation program.

<sup>d</sup>SD was computed from SE multiplied by the square root of sample size.

<sup>e</sup>FU: follow-up.

<sup>f</sup>ITT: intent-to-treat analysis.

<sup>g</sup>PP: per-protocol analysis.

<sup>h</sup>WBI: well-being index.

<sup>i</sup>K6: Kessler Psychological Distress Scale.

<sup>j</sup>MAAS: Mindful Attention and Awareness Scale.

In light of the Buddhist origin of our interventions, we also tested whether there is any differential effect of participants’ religion on mental well-being and psychological distress. It was found that the changes in mental well-being and psychological distress did not differ significantly by religion, as revealed by the nonsignificant 3-way interaction effects in the LMM analyses with religion as the covariate (WBI: \( P = .55 \); K6: \( P = .79 \)).

In addition, as there was a large difference in the sample size of males and females, we therefore examined if there are any potential moderating effect of participants’ gender. It was found that the changes in well-being and psychological distress did not differ significantly across the 2 genders, as revealed by the nonsignificant 3-way interaction effects in the LMM analyses with gender as the covariate (WBI: \( P = .57 \); K6: \( P = .54 \)).
Table 4. Summary of time effects and effect sizes across conditions.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>MBP, Cohen $d$</th>
<th>SCP $b$, Cohen $d$</th>
<th>CBP $a$, Cohen $d$</th>
<th>Overall time effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post $e$, FU $f$, $i$, $j$, $k$, $l$</td>
<td>Post $e$, FU $j$, $k$, $l$</td>
<td>Post $e$</td>
<td>Post vs pre, mean difference (95% CI)</td>
</tr>
<tr>
<td>Mental well-being</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WBI $i$ (ITT)$b$</td>
<td>0.32</td>
<td>0.42</td>
<td>0.27</td>
<td>0.28</td>
</tr>
<tr>
<td>WBI (PP)$i$</td>
<td>0.31</td>
<td>0.51</td>
<td>0.40</td>
<td>0.40</td>
</tr>
<tr>
<td>Psychological distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K6 $j$ (ITT)</td>
<td>−0.28</td>
<td>−0.30</td>
<td>−0.35</td>
<td>−0.19</td>
</tr>
<tr>
<td>K6 (PP)</td>
<td>−0.44</td>
<td>−0.44</td>
<td>−0.31</td>
<td>−0.22</td>
</tr>
<tr>
<td>Mindful awareness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAAS $k$ (ITT)</td>
<td>−0.08</td>
<td>−0.10</td>
<td>−0.19</td>
<td>−0.03</td>
</tr>
<tr>
<td>MAAS (PP)</td>
<td>−0.13</td>
<td>−0.11</td>
<td>−0.13</td>
<td>−0.08</td>
</tr>
<tr>
<td>Self-compassion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCS $l$ (ITT)</td>
<td>0.07</td>
<td>0.17</td>
<td>0.32</td>
<td>0.16</td>
</tr>
<tr>
<td>SCS (PP)</td>
<td>0.06</td>
<td>0.16</td>
<td>0.43</td>
<td>0.22</td>
</tr>
</tbody>
</table>

$^a$MBP: mindfulness-based program.  
$^b$SCP: self-compassion program.  
$^c$CBP: cognitive behavioral psychoeducation program.  
$^d$Cohen $d$ was computed from postprogram/3-month follow-up score minus preprogram score divided by the pooled SD.  
$^e$Versus pre.  
$^f$FU: follow-up.  
$^g$WBI: well-being index.  
$^h$ITT: intent-to-treat analysis.  
$^i$PP: per-protocol analysis.  
$^j$K6: Kessler Psychological Distress Scale.  
$^k$MAAS: Mindful Attention and Awareness Scale.  
$^l$SCS: Self-Compassion Scale.

**Discussion**

**Principal Findings—Efficacy and Application**

Despite the fact that numerous mental health–related mobile apps are in the market, many of them have not been empirically tested. Even when tested, these studies often employed case studies and prepost design. This study was one of the few studies that used a rigorous RCT design in comparing the efficacy of mobile mindfulness-based training and self-compassion training with an evidence-based cognitive behavioral psychoeducation app. We also examined potential moderators that may affect training outcomes of the 3 conditions. Results demonstrated that the use of the 4-week MBP, SCP, or CBP led to significant improvement in mental well-being and reduced psychological distress in our participants who completed the online assessments, and these improvements were sustained at 3-month follow-up. The effect sizes obtained in this study were small to moderate on the primary outcomes ($d=−0.19$ to 0.51). They were comparable with other online mindfulness-based interventions in improving mental health [29]. Nonetheless, the effect sizes in our online self-compassion and mindfulness-based programs (as well as in CBP) were comparable with other unguided internet-based CBT trials, for instance, Berger et al [65], supporting these approaches to be noninferior to other unguided internet-based CBTs.

With 1 in 7 adults having a common mental disorder and only 1 in 4 of them seeking formal mental health services in Hong Kong [3], a population-based approach is likely to have the greatest impact in reducing mental health burden in the community [66]. In comparison with face-to-face interventions, mobile app interventions are easily accessible and have the potential to meet the need for mental health promotion and universal prevention in the community settings. This study showed that app-based mental health training programs are viable strategies that can be easily incorporated into existing service provision portfolios in promoting mental health in the general population.
This study opted for a noninferiority design that employed a cognitive behavioral psychoeducation control program instead of a waitlist or placebo control. Previous studies have demonstrated the efficacy of internet-based mindfulness-based training on well-being compared with waitlist control [27] and with CBP training [28]. Self-compassion training is also found to promote well-being compared with waitlist control in face-to-face setting [39,67]. We posit this approach as a logical scientific extension of the existing literature by showing the efficacy of a mobile app–based MBP, SCP, and CBP in the promotion of mental health. Besides, it is practically difficult to put participants on a waitlist control and withhold program content from them. As the mobile app was published on the app market (Apple store and Google Play) during the study period, everyone in the public could access and download the app freely.

Results showed that mindfulness-based training and self-compassion training was as efficacious as the CBP active comparison condition. Such comparable findings were encouraging. Cognitive behavioral training has been widely studied in the literature and has demonstrated its efficacy and effectiveness in managing psychological distress [10] and enhancing well-being in the general population [14]. The fact that mindfulness-based training and self-compassion training showed comparable improvement in mental health outcomes provided the public alternative evidence-based options to promote their mental well-being.

Cultivation of Mindful Awareness and Self-Compassion

Our secondary hypotheses on mindful awareness and self-compassion were only partially supported. In the ITT analysis, both MBP and SCP enhanced participants’ mindful awareness at postprogram as expected. The benefit in terms of mindful awareness enhancement in MBP participants was intuitive. As for SCP, the improvement was also in line with the literature. Neff [21] asserts that mindfulness is 1 of the 3 facets in forming self-compassion. It involves holding one’s painful thoughts and feelings in balanced awareness rather than over-identifying with them. Although not explicitly stated, the SCP modules inevitably involved mindfulness concepts. The meditation exercises in the SCP, for instance, self-compassion breathing exercise and loving-kindness meditation, also required participants to focus on the moment-by-moment experiences and therefore enhanced participants’ awareness.

Specifically, we did not find that mindfulness condition showed significantly greater improvement in the levels of mindfulness over time as compared with the improvement in SCP and CBP conditions. Similarly, Turner et al [68] also found that mindfulness-based stress reduction program did not show significantly greater improvement in mindfulness compared with the CBT condition among people with chronic lower back pain. The authors postulated that although CBT reduced catastrophizing through cognitive restructuring techniques, mindfulness might improve indirectly as a result. Similarly, in this study, some specific mediators were not measured in the study, including acceptance to painful experience in the SCP condition or reduced catastrophizing of experience in the CBP condition, which may affect levels of mindfulness. More research is needed to examine the mechanisms behind the change.

Similarly, the enhanced self-compassion in CBP participants was also unexpected. However, self-compassion may be related to unhealthy perfectionism. According to CBT models, unhealthy perfectionism was maintained by negatively biased thinking patterns such as self-critical thinking and self-imposed “should” and “musts” statements. These, in turn, contributed to an elevated self-criticism in oneself [69]. There was evidence that unguided self-help using CBT approach can reduce perfectionism [70]. A recent study [71] also found that the use of a CBT self-help booklet significantly improved participants’ self-compassion, although to a lesser degree compared with mindfulness-based cognitive therapy. Our findings added to this area of literature.

In addition, the differential change profiles of self-compassion across the 3 groups also caught our attention. When taking a closer look into the trends, self-compassion greatly improved and then gradually went down in SCP and CBP, whereas in MBP, self-compassion increased to a lesser extent after the program but gradually went up at 3-month, and this change approached significance (P=.05). Although mindfulness is the prerequisite of forming self-compassion as suggested by Neff [21], MBP participants who are trained in mindfulness may catalyze the cultivation of self-compassion in the long term. Future studies are warranted to test this speculation.

Another observation was that both the changes in mindful awareness and self-compassion did not sustain through the 3-month period. This is possibly due to an absence of practice reminder after the 28-day program. It is well accepted that mindfulness and self-compassion meditation requires persistent and long-term practice for it to be effective. We acknowledged that, however, the improvements in mental health were maintained, indicating that there may be other factors mediating the changes in mental health in our participants. These underlying factors need to be further explored in future studies.

Exploration of Moderators

Contrary to our hypotheses, the proposed moderators (discomfort with emotions and tolerance for ambiguity) did not appear to moderate the training effects. Reasons may be that all the measures used to tap onto the constructs are abridged versions to keep the brevity of the online questionnaire. Although all the measures had satisfactory internal consistency, their validity in measuring the intended constructs needs to be further investigated and confirmed. Given the findings of this study, we have no empirical evidence pointing to the suitability of different training programs for different types of populations. The general population seems to be equally responsive to mindfulness-based, self-compassion, and cognitive behavioral psychoeducation training. However, Teper et al [72] proposed that mindfulness-based training facilitated adaptive emotion regulation by fostering interoceptive awareness. Therefore, it seems reasonable to postulate that contemplative training involving mindfulness and self-compassion may deem more intrinsically rewarding for individuals who are interoceptive and introspective to begin with. Future studies should continue examining other possible moderating effects (eg, interoception...
and introspection) to better match users to programs that are compatible with their individual differences and preferences.

**Limitations and Future Directions**

Several limitations need to be considered when interpreting the results. First, the attrition rate of this study was high (76.5% at postprogram and 83.9% at 3-month follow-up). It must be recognized that high attrition has been a common concern shared by many internet-based intervention studies. For example, Mitchell et al [73] reported an attrition rate of 83% in their well-being promotion trial. In a systematic review of internet-based interventions for anxiety and depression, the completion rates ranged from 43% to 99% [74]. The use of an unguided self-help approach may have contributed to the low retention rate as well. Previous studies comparing guided versus unguided self-help approaches have reported higher adherence rate in guided interventions [75,76]. Although unguided self-help can reduce the cost and labor in providing coaching or guidance, it may compromise adherence and overall efficacy of the training program [77]. The unguided nature of the interventions may also explain these small effect sizes as other studies on unguided self-help also reported small to medium effect sizes [78].

Furthermore, the younger participants were more prone to withdraw from the study. This might affect the generalizability of our findings. The characteristics of dropouts are, however, closely consistent with Mispel et al [79] in their recent investigation of user characteristics in relation to attrition. They also found that male users and younger adults were more likely to quit an online intervention.

We noted the importance of users’ experience in the initiation phase as it was observed that most participants who dropped out ceased using the apps within the first 7 days. This provides indications for future mHealth interventions, especially when the apps will be freely accessible in the app market where people can download and try using them without monetary cost. Researchers should pay attention to users’ experience alongside the course contents when designing the apps. Future studies can consider gamification [80,81] or personalization of feedback [82] to enhance its appeal to the participants and increase the personal relevance of the training to each participant as well as the inclusion of online coaches or guidance to support the users during the course of the training.

Another limitation was that the inferior design of this study precluded us from ruling out the possibility of a placebo effect in explaining the improvement in mental health among our participants. To rule out the placebo effect, future studies should consider building a placebo control condition in the app such as reading an electronic book not related to psychology, but this may increase the cost of developing an additional placebo condition for the study.

Participants in this study by nature skewed toward people who are proficient in using computer or mobile devices. There is a possibility that these people might be more educated. The latest government statistics [83] revealed that nearly half of the Hong Kong citizens (49.7%) received up to secondary education, whereas in our sample, more than half of our participants were receiving tertiary education. These participants may have higher mental health literacy and be more open to participate in mental health programs. This limits the generalizability of our findings to all segments of the population (eg, less educated individuals, low income), even though Hong Kong has the highest penetration rate of mobile devices in the world [4]. Future studies should focus on how mobile app–based interventions can cater to different segments of the populations through various adaptations.

**Conclusions**

In total, the LWH mobile app was tested in this study and mindfulness-based, self-compassion, and cognitive behavioral training programs were found to be efficacious in promoting mental health and reducing psychological distress among adults in Hong Kong who used the app. Given the mental health burden in our communities, this study showed that mobile-based interventions can be an option for mass dissemination in improving public mental health.

**Acknowledgments**

The authors would like to acknowledge the Health and Medical Research Fund (Ref No. 11121081) for funding this project.

**Conflicts of Interest**

The first author of the study, WWSM, is one of the developers of the content of the trials. The developer of the mobile app and website was Red Soldier Limited.

**Multimedia Appendix 1**

Screenshots of the LWH application.

[PDF File (Adobe PDF File), 1MB - mental_v5i4e60_app1.pdf]

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Abbreviations

CBP: cognitive behavioral psychoeducation program
CBT: cognitive behavioral therapy
CSQ: Client Satisfaction Questionnaire
ITT: intention-to-treat
K6: Kessler Psychological Distress Scale
LMM: linear mixed model
LWH: “Living With Heart” mobile app
MAAS: Mindful Attention and Awareness Scale
MBP: mindfulness-based program
PP: per-protocol
SCP: self-compassion program
WBI: well-being index

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Using Facebook for Improving the Psychological Well-Being of Individuals Experiencing Homelessness: Experimental and Longitudinal Study

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Abstract

Background: Web-based social networks are a powerful communicative element and their use is increasingly widespread. Persons living in extreme social exclusion such as individuals experiencing homelessness can benefit from the positive elements of communication and relationship associated with social networking sites.

Objective: This study aimed to suggest the comparison of a Facebook training course and an office software course and their effect on psychological well-being in a group of individuals experiencing homelessness.

Methods: An experimental and longitudinal study was designed. Individuals experiencing homelessness were randomly assigned to either the Facebook group or the office software group, and their social skills, self-esteem, self-efficacy, and satisfaction with life were measured on 4 occasions: pretest, at the end of the training course, 1 month later, and 3 months later. A mixed analysis of variance of repeated measures (2 × 4) was performed.

Results: A total of 92 individuals experiencing homelessness participated in the study. The number of cases in which the 4 measurements were completed was 71 (35 in the intervention group and 36 in the control group). The mixed analysis of variance of repeated measures and the multiple regression analysis indicated a significant increase of the 4 analyzed parameters, with greater significance in the areas of social skills and self-esteem. The critical levels associated to the interaction Time × Program were significant in all variables and levels. Therefore, the scores in the 4 analyzed constructs were not equal according to the program carried out throughout the work. The effect size associated to the interaction Time × Program in the social skills scores was large (η² = 0.32); in the self-esteem and self-efficacy scores, it was medium, (η² = 0.13); and in the satisfaction with life scores, it was small (η² = 0.09). The results of the adjustment of the different models of multiple linear regression indicate that the number of hours devoted weekly to the use of Facebook was a predictor of the increase in the scores of social skills (B = 3.43, r² = 0.405) and self-esteem (B = 3.82). Age (B = 0.175) and self-efficacy (B = 0.09) were also variables, which with independence and in equal conditions, predicted self-esteem (r² = 0.29). Finally, self-esteem (B = 0.69) was also a predictor variable of the increase of satisfaction with life (r² = 0.195).

Conclusions: These findings suggest that Facebook could be a key element in homeless psychological well-being and socialization.

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KEYWORDS

homelessness; individuals experiencing homelessness; health; satisfaction with life; self-esteem; self-efficacy; social networking sites; social skills
**Introduction**

Homelessness is a situation of extreme social exclusion with very serious organic, psychological, and social consequences. Individuals experiencing homelessness display, when compared against the general population, higher levels and more acute episodes of mental health disorders [1] and associated mortality, and their symptomatology is more severe [2]. The prevalence of substance use disorders is also higher, including the consumption of drugs parenterally, which is associated with a higher contagion of infectious diseases such as HIV, hepatitis C, or tuberculosis [3]. Individuals experiencing homelessness receive health services less frequently and display an insufficient retention in treatment, which not only worsens their evolution and prognosis [4] but also indicates that they have an especially high demand for emergency room attention, which has an effect on public health expenses [5]. Childhood traumas and family conflicts are among the main causes of homelessness [6,7]. Apart from the mentioned issues, there is an increase in the possibilities of facing marginalization, unsatisfactory personal relationships, and few possibilities for personal development.

Works on loneliness in individuals experiencing homelessness have reported high levels of interpersonal isolation and self-alienation as a consequence of a situation of constant struggle for daily survival, violence, victimization, abuse, drug consumption, and social stigma [8,9]. All this has contributed to the generalized perception that individuals experiencing homelessness are lonely people isolated from the rest of society [10]. However, in the last 10 years, there have been substantial changes in humans’ communicative and relational dimensions. Internet use has reached practically all areas of society, and access to social networking sites (SNS) has multiplied in the last 15 years. The best example of this is the dramatic rise of Facebook, the SNS with the highest number of users, which went from having 500 million users in 2010 to having 2 billion users with a registered profile in May 2017 [11].

With the incorporation of SNS in daily life, scientific investigation of their influence on human behavior has proliferated, and behaviors related to homelessness are no exception. Until mid-2012, between 44% and 62% of individuals experiencing homelessness owned a mobile phone, between 24% and 40% owned a personal computer, and between 47% and 55% used the computer and accessed the internet [12], and these numbers seem to be increasing. The prevalence of use of SNS among individuals experiencing homelessness is not too distant from that of the general population; the main motivations for their use are the access to useful information and communication with friends and family [13].

The use of SNS presents great opportunities to improve the health of individuals experiencing homelessness. Work carried out with homeless youths to prevent sexually transmitted diseases showed that there exists a high association between Web-based communication and a significant decrease in risk behavior related to HIV and hepatitis C exposure, as well as a higher perception of the risk of people exposed to the possibility of contagion of HIV and hepatitis C [14,15]. SNS are effective tools to promote the increase of individuals experiencing homelessness’ participation in the processes of community intervention [16] and are proving to be a fundamental tool in the social inclusion and prevention of homelessness among refugees [17]. Regarding mental health, promoting communication with families and friends through SNS reduces the appearance of symptoms of severe mental disorders [18], and it is an opportunity to improve psychological well-being and reduce the probabilities of suffering certain symptoms of mental illness in adults as well [19,20].

Until now, studies carried out on the use of information and communication technologies (ICT) by homeless people recommended the development of formative proposals on learning how to use them. ICT use has been linked to an increase in levels of self-esteem and self-efficacy [21], which have an effect on all areas of the person. With regards to self-esteem, first, it must be considered that self-esteem is a psychological construct of great clinical importance due to its connection with psychopathology, stress, depression, anxiety, and general well-being [22]. Self-esteem is one of the key protective factors of other serious issues related to individuals experiencing homelessness such as loneliness, risk of suicide, or other incapacitating issues [23]. Investigation has proved that the longer a person spends experiencing homelessness, the more isolated they become from social support, which creates or worsens the problems associated with homelessness [24]. Self-esteem increases when individuals experiencing homelessness overcome new challenges and have healthy relationships. The deliberate use of SNS contributes to optimizing the resocialization process, increases subjective well-being, and softens the effect of the struggles faced on the street [25]. Recommendations suggest the capacitating of individuals experiencing homelessness to improve their competences in the use of SNS so that they can benefit proactively from the protective effects associated with internet-based communication [26].

The aim of this study was to confirm whether a group of training sessions to capacitate individuals experiencing homelessness to use Facebook indicates an increase of their communicational uses and whether this improves the levels of social skills in the internet-based surrounding, self-esteem, self-efficacy, and satisfaction with life. It is expected that participants will achieve better marks in these psychological constructs and that this improvement will linger on in time.

**Methods**

**Design**

The study used a longitudinal prospective and experimental design, and a randomized controlled trial pretest-posttest with an intervention group and control group.

**Participants**

A total of 92 individuals experiencing homelessness from a city in the northwest of Spain with approximately 100,000 inhabitants participated in the study. All participants were aged ≥18 years, and the recruitment took place from January to March 2017. The European Typology of Homelessness and Housing Exclusion (ETHOS) classification criterion was used to
determine the condition of individuals experiencing homelessness [27]. The ETHOS classification is described by the European Federation of National Organizations Working with the Homeless. It includes roofless and homeless people, as well as people in inadequate or unsafe housing, illegal housing, temporarily occupied housing, or substandard housing. The sample was formed using a probability sampling method on cases that met the inclusion criteria.

**Procedure**

The professionals in the harm reduction service in Girona who perform community tasks in outreach detected the cases of individuals experiencing homelessness. This team is part of the mental health and addictions public network that belongs to the Catalan government. Among others, one of its functions is to work with individuals experiencing homelessness on the street and to collaborate in shelters and at the city drop-in center, which is also public. The recruitment was carried out on the streets, in illegally occupied houses and the municipal shelter, bearing in mind the expertise that the team has in this kind of action.

The criteria of inclusion were (1) being an adult; (2) not having a Facebook account or in the event of having one, claiming to have low knowledge of its use; (3) wishing to be trained in order to improve one’s skills; (4) partaking voluntarily in the study; (5) having good Spanish language skills; and (6) being included in one of the categories of homelessness according to the ETHOS classification of homeless people.

The participants who met the criteria were assigned in a random, proportional, and stratified way, according to gender, origin (indigenous or foreign), and the weekly number of hours of use of SNS at intervention group or control group. The strata were defined bearing in mind that these are the principal variables that could bias the results of the study in the Spanish context [28]. Initially, 48 individuals experiencing homelessness were assigned to the intervention group and 44 to the control group.

For the intervention group, an educational training course aimed at learning or improving the use of Facebook was designed: creation of an email account or recovering forgotten passwords; signing up on Facebook; designing a user profile; visualizing it (how we are presented on the net); privacy options; searching for people; requesting and accepting friends; sending pictures, videos, or private messages; creating and following groups.

For the control group, a basic office software course similar to those offered by social services or nongovernmental organizations in the city to people with very serious risk of social exclusion was developed. For this purpose the contents of the 4 courses taught in different institutions in the area were gathered and homogenized: identifying the basic parts of a computer, switching it on and shutting it down, knowledge of the desktop and files, main uses of a text processor, saving documents, basic design of a curriculum vitae, access to the internet, exploring the main job search websites in Spain, creating email accounts, recovering passwords, and many more.

Job search is a relevant component in office software courses offered to people at risk of residential exclusion, as work reinsertion is normally one of the main aims in the social services’ working plans.

Both courses were carried out in sessions of 1.5 hours, once a week, for 8 weeks, in 2 rooms in 2 community sociocultural centers in the city. The training sessions were developed with prospective didactics, taking into account, as much as possible, the users’ previous experience, with individualized open attention. The training experience was based on the Zone of Proximal Development concept, that is, considering the distance between the actual developmental level as determined by independent problem solving and the level of potential development as determined through problem solving under adult guidance, or in collaboration with more capable peers [29]. In other words, despite the fact that the contents were predesigned, the trainers were especially sensitive and flexible to the demands and needs of the participants.

In order to facilitate this methodology, the participants were divided into small groups, and 12 university students collaborated in the project (6 for intervention group and 6 for control group), acting as trainers after they completed a 20-hour training session on office software, SNS, Facebook, and homelessness. In order not to condition trainers and to avoid bias in the study, they were not informed explicitly that it was an experimental intervention group or control group design. If necessary, the students introduced cross-study contents related to the social skills involved in the topics covered: for instance, the best way to address an employer (formal email format) or examples of how to be assertive when commenting on a Facebook post.

All participants were given an informative handout on the aims of the study and signed it. The students signed a confidentiality clause so as to preserve information regarding the participants.

The pretest was carried out on the first day of training in both groups, and the first posttest on the last day, at the end. The posttests were carried out 1 month and 3 months, respectively, after the training ended. They were distributed in the shelter where the individuals experiencing homelessness received assistance, food, or sleep accommodations, or at the drop-in center where leisure and reinsertion activities were available. To assist those who were not found in these places, and to ensure maximum participation in the posttest, different professional teams of the net of attention to individuals experiencing homelessness sought the participants and reminded them systematically about the importance of the tests. In certain cases, the open medium team attended the places in which the individuals experiencing homelessness lived to ensure that the tests were completed. The investigators who administered the posttests did not participate directly in any of the training sessions in order to reduce the social desirability effect in the assessment of the participants. The investigation protocol was approved by the Ethical Committee on Biomedical Research of Girona (Cod. XSO_2017_23/05/2017).

**Instruments**

The participants’ sociodemographic information and self-reports of internet use were gathered through an adaptation of a questionnaire on the use of SNS in adult populations [30]. At
the end of the intervention, the participants were asked about their general satisfaction and the utility of the activity in their daily life, in 2 Likert-type questions with answer choices ranging from 1-10 (1 “unsatisfied” to 10 “very satisfied”), and whether they would partake in a second treatment to refresh the knowledge they had learned or to learn more in depth. The dependent variables were analyzed with the following instruments:

1. The Multidimensional Scale of Social Expression-C [31] was used to assess social skills in the internet context. This is a Likert-type scale of 40 items with scores from 0-4 (lower and higher frequency of the occurrence of each item), in which a higher score indicates more adaptive social skills in the internet context, for example, “I’m afraid of speaking in public and doing it badly.”

2. Self-Esteem Scale [32] is valid and reliable for Spanish populations [33] as well as for both genders and different ethnic groups [34]. It is a scale of 10 items aiming to measure global self-esteem by assessing positive and negative feelings toward oneself. All items are answered using a Likert-type scale with 4 answer choices concerning how much the participant agrees or disagrees with statements such as “I have a positive attitude toward myself.”

3. The General Self-Efficacy Scale [35] was adapted to Spanish populations [36]. It is a Likert-type scale of 10 items with answer choices from 10-100 aiming to measure the degree of general self-efficacy, defined as the feeling of social competence in effectively dealing when facing different stressful situations, for example, “I can solve difficult problems if I try hard enough.”

4. The Life Satisfaction Scale [37] was adapted and validated for Spanish populations [38]. It is a Likert-type scale of 5 items with 5 answer choices (1-5) representing the participant’s level of agreement or disagreement. It aims to assess the cognitive perception of subjective well-being through a global assessment that the participant does concerning their own life using statements such as “The circumstances of my life are very good.”

Statistical Analysis

Central tendency and dispersion measures for the description of data were used. The sociodemographic variables for intervention group and control group were compared with the results of a chi-square test for the qualitative variables and the Student t test for independent and paired samples for quantitative variables. To determine the variability of measures in the scores of dependent variables social skills, self-esteem, self-efficacy, and satisfaction with life according to the type of program, a mixed analysis of variance of repeated measures (2×4) was applied for each. Observations were carried out pretest-posttest at the beginning of the training (T1), at the end of it (T2), 1 month later (T3), and 3 months later (T4). Subsequent post hoc contrasts (Bonferroni) were carried out, and the extent of the effect and potency were observed. On the other hand, the scores from each observation were correlated with the Pearson test, and a multiple linear regression model was adjusted for each of the variable dependents social skills, self-esteem, self-efficacy, and satisfaction with life including the quantitative variables age and number of hours using SNS in the model, with the aim of determining the predictor variables of increase in the analyzed psychological constructs.

Results

Participant Characteristics

A total of 21 participants were discarded on the grounds of not completing the posttest measures. The number of cases in which the 4 observations were completed was 71 (35 in the intervention group and 36 in the control group). Among the participants, 79% (56/71) were men, with an age average of 39 (SD 8.86) years and 55% (39/71) were foreign (not born in Spain). In the pretest, 69% (49/71) of participants claimed to have an email account and 68% (48/71) claimed to use Facebook at any time. The people with a registered profile accessed Facebook an average of 1.2 (SD 1.3) hours a week with the principal intention of contacting family (29/71, 41%) or friends (14/71, 20%) or having free time and leisure (5/71, 7%). As can be observed in Table 1, initially there were no differences regarding gender, origin, age, having an email account or not, number of hours of use of Facebook every week, and principal aim of the connection.

The repeated-measures mixed analysis of variance indicate that the critical level associated with the Time factor was <.05 in the evolution of the 4 levels of analysis of social skills, self-esteem, and satisfaction with life, but not self-efficacy. Regarding the Program factor and the interaction TimexProgram, the results were significant for all variables and levels. Therefore, the scores in the 4 analyzed constructs were not equal according to the program carried out throughout the work. In the social skills scores, the effect size associated with the interaction TimexProgram was large (η²=0.32), whereas in the self-esteem and self-efficacy scores, it was medium, (η²=0.13), and in the satisfaction with life scores, it was small (η²=0.09), following the Lacobucci interpretation [39]. The potency observed was very high in all cases (social skills=1, self-esteem=1, self-efficacy=1, satisfaction with life=.98). These results can be observed in Table 2.

Social Skills

The difference in averages in the Program factor (intervention group=control group) was 26.61 points (F1,69=33.04, P<.001). The post hoc analysis (Bonferroni) indicated that in the TimexProgram interaction, albeit there were no significant differences between the scores of both groups when the pretest was carried out (F1,69=.76, P=.39), differences did exist at the end of the intervention (F1,69=26.58, P<.001), 1 month later (F1,69=57.19, P<.001), and 3 months later (F1,69=41.04, P<.001). The difference in averages at each level may be observed in the graphic representation of the evolution of scores (Figure 1).
Table 1. Descriptive data of the sample and comparison of the intervention group and the control group by sociodemographic variables and pretest use of Facebook.

<table>
<thead>
<tr>
<th>Sociodemographic variables and pretest Facebook use</th>
<th>Intervention group (n=35)</th>
<th>Control group (n=36)</th>
<th>Total sample (n=71)</th>
<th>Intervention group and control group comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>χ² or t</strong></td>
<td><em>df</em></td>
<td><em>P value</em></td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>29 (41)</td>
<td>27 (38)</td>
<td>56 (79)</td>
<td>— a</td>
</tr>
<tr>
<td>Female</td>
<td>6 (8)</td>
<td>9 (13)</td>
<td>15 (21)</td>
<td>—</td>
</tr>
<tr>
<td>Origin, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td>17 (24)</td>
<td>15 (21)</td>
<td>32 (45)</td>
<td>—</td>
</tr>
<tr>
<td>Foreign</td>
<td>18 (25)</td>
<td>21 (30)</td>
<td>39 (55)</td>
<td>—</td>
</tr>
<tr>
<td>Registered email, n (%)</td>
<td>24 (34)</td>
<td>25 (35)</td>
<td>49 (69)</td>
<td>0.006 1 .57</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>38.94 (9.11)</td>
<td>39.14 (8.74)</td>
<td>39.04 (8.86)</td>
<td>-0.093 69 .93</td>
</tr>
<tr>
<td>Hours per week using Facebook, mean (SD)</td>
<td>1.20 (1.35)</td>
<td>1.19 (1.31)</td>
<td>1.20 (1.32)</td>
<td>0.018 69 .99</td>
</tr>
<tr>
<td>Use of Facebook, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To contact family</td>
<td>14 (20)</td>
<td>15 (21)</td>
<td>29 (41)</td>
<td>0.84 1 .42</td>
</tr>
<tr>
<td>To contact friends</td>
<td>9 (13)</td>
<td>5 (7)</td>
<td>14 (20)</td>
<td>0.73 1 .39</td>
</tr>
<tr>
<td>For leisure</td>
<td>3 (4)</td>
<td>2 (3)</td>
<td>5 (7)</td>
<td>1.23 1 .51</td>
</tr>
</tbody>
</table>

aNot applicable.
Table 2. Descriptive statistics and results of mixed repeated measurements analysis of variance.

<table>
<thead>
<tr>
<th>Analyzed constructs</th>
<th>Intervention, mean (SD)</th>
<th>Control, mean (SD)</th>
<th>Phase comparison, $F_{1,69}$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Time</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$F$ ($\eta^2$/Op$^a$)</td>
</tr>
<tr>
<td>Social skills</td>
<td></td>
<td></td>
<td>18.61 (0.21/1)</td>
</tr>
<tr>
<td>$T_1^b$</td>
<td>66.74 (4.05)</td>
<td>71.69 (3.99)</td>
<td>— $^c$</td>
</tr>
<tr>
<td>$T_2^d$</td>
<td>94.66 (3.64)</td>
<td>68.33 (3.58)</td>
<td>—</td>
</tr>
<tr>
<td>$T_3^e$</td>
<td>109.23 (4.37)</td>
<td>62.83 (4.31)</td>
<td>—</td>
</tr>
<tr>
<td>$T_4^f$</td>
<td>107.63 (4.30)</td>
<td>69.97 (4.24)</td>
<td>—</td>
</tr>
<tr>
<td>Self-esteem</td>
<td></td>
<td></td>
<td>4.22 (0.03/31)</td>
</tr>
<tr>
<td>$T_1$</td>
<td>20.37 (0.87)</td>
<td>21.86 (0.86)</td>
<td>—</td>
</tr>
<tr>
<td>$T_2$</td>
<td>24.49 (0.97)</td>
<td>19.91 (0.95)</td>
<td>—</td>
</tr>
<tr>
<td>$T_3$</td>
<td>23.11 (0.90)</td>
<td>17.83 (0.88)</td>
<td>—</td>
</tr>
<tr>
<td>$T_4$</td>
<td>20.94 (0.87)</td>
<td>18.86 (0.86)</td>
<td>—</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td></td>
<td></td>
<td>2.28 (0.03/57)</td>
</tr>
<tr>
<td>$T_1$</td>
<td>53.03 (1.96)</td>
<td>55.36 (1.93)</td>
<td>—</td>
</tr>
<tr>
<td>$T_2$</td>
<td>63.69 (2.00)</td>
<td>51.61 (1.98)</td>
<td>—</td>
</tr>
<tr>
<td>$T_3$</td>
<td>65.80 (1.80)</td>
<td>50.44 (1.78)</td>
<td>—</td>
</tr>
<tr>
<td>$T_4$</td>
<td>63.43 (2.10)</td>
<td>52.39 (2.07)</td>
<td>—</td>
</tr>
<tr>
<td>Satisfaction with life</td>
<td></td>
<td></td>
<td>5.96 (0.08/95)</td>
</tr>
<tr>
<td>$T_1$</td>
<td>10.63 (0.56)</td>
<td>11.14 (0.55)</td>
<td>—</td>
</tr>
<tr>
<td>$T_2$</td>
<td>13.86 (0.65)</td>
<td>11.28 (0.64)</td>
<td>—</td>
</tr>
<tr>
<td>$T_3$</td>
<td>14.31 (0.58)</td>
<td>10.67 (0.57)</td>
<td>—</td>
</tr>
<tr>
<td>$T_4$</td>
<td>13.99 (0.61)</td>
<td>12.83 (0.60)</td>
<td>—</td>
</tr>
</tbody>
</table>

$^a$Observed potency.

$^b$T$_1$: Observations performed pretest-posttest at the beginning of the training.

$^c$Not applicable.

$^d$T$_2$: Observations performed at the end of training.

$^e$T$_3$: Observations performed 1 month later.

$^f$T$_4$: Observations performed 3 months later.
The effect on the intragroup tests was significant in the measures $T_1-T_2(F_{1,69}=28.96, P<.001)$, $T_2-T_3(F_{1,69}=16.85, P<.001)$, $T_2-T_4(F_{1,69}=4.48, P=.038)$, $T_1-T_3(F_{1,69}=67.65, P<.001)$, and $T_1-T_4(F_{1,69}=47.01, P<.001)$. The measure between levels $T_2-T_4$ displayed a tendency toward significance ($F_{1,69}=3.78, P=.06$).

The analysis of averages for related tests for each group showed that in the intervention group, the average difference between $T_1-T_2$ was $-27.91$ points (SD $28.97$, $t_{34}=-5.70, P<.001$), between $T_2-T_3$ was $-14.57$ points (SD $20.91$, $t_{34}=-4.12, P<.001$), between $T_1-T_3$ was $-42.49$ points (SD $28.55$, $t_{34}=-8.80, P<.001$), and between $T_1-T_4$ was $-40.89$ points (SD $27.13$, $t_{34}=-8.92, P<.001$). Table 3 displays the Student $t$ test analysis for related samples carried out for each of the dependent variables. We can say that the program was effective at increasing social skills for the intervention group but not the control group, and this improvement lingered on in time until 3 months after the intervention.

**Self-Esteem**

In the case of self-esteem, the difference between the averages in the Program factor (intervention group–control group) was $2.61$ points ($F_{1,69}=7.47, P=.008$). In the pretest, there were no differences in the interaction Time$\times$Program in the scores of the 2 groups ($F_{1,69}=7.6, P=.39$). In the observation $T_2$ corresponding with the posttest, there were differences between the averages ($F_{1,69}=11.34, P=.001$) and likewise in $T_3(F_{1,69}=17.62, P<.001)$. In $T_4$, despite a slight tendency toward significance, there were no observed differences ($F_{1,69}=2.91, P=.092$).

In the intragroup tests, there were significant differences in the observations corresponding to $T_1-T_2(F_{1,69}=17.02, P<.001)$, $T_2-T_3(F_{1,69}=4.66, P=.02)$, and $T_1-T_3(F_{1,69}=25.47, P<.001)$ and also $T_1-T_4(F_{1,69}=16.26, P<.001)$ and $T_2-T_4(F_{1,69}=4.62, P=.02)$. There was no significance in the level $T_2-T_3(F_{1,69}=39, P=.54)$.

Although the Student $t$ test for paired samples analysis indicated an increase of average scores in the intervention group of $-2.74$ between $T_1-T_3$ (SD $5.85$, $t_{34}=-2.77, P=.01$), it did not happen with $T_1-T_4$: mean $-0.57$ (SD $3.90$), $t_{34}=-87, P=.39$. Therefore, the effect of the intervention expired between 1 and 3 months after the intervention. On the other hand, a decrease in the average scores of self-esteem in the control group between $T_2-T_3$ (mean $2.05$, SD $4.88$, $t_{34}=2.56, P=.02$), $T_1-T_3$ (mean $3.86$, SD $5.46$, $t_{36}=4.30, P<.001$), and $T_1-T_4$ (mean $2.89$, SD $3.57$, $t_{36}=4.92, P<.001$) was observed (Figure 2).

**Self-Efficacy**

Regarding self-efficacy, there was a difference in the averages in Program (intervention group–control group), of 9.03 points ($F_{1,69}=26.26, P<.001$). No differences were observed in time regarding the averages between groups $T_1(F_{1,69}=7.2, P=.40)$. There were differences between $T_2(F_{1,69}=18.41, P<.001)$, $T_3(F_{1,69}=36.73, P<.001)$, and $T_4(F_{1,69}=13.99, P<.001)$.

In the intragroup tests, there were significant differences between $T_1-T_2(F_{1,69}=29.61, P<.001)$, $T_1-T_3(F_{1,69}=24.99, P<.001)$, and $T_1-T_4(F_{1,69}=13.15, P<.001)$, but not in the rest of the levels ($T_2-T_3: F_{1,69}=1.32, P=.25$; $T_3-T_4: F_{1,69}=1.20, P=.28$; $T_2-T_4: F_{1,69}=0.07, P=.78$); see Figure 3.

---

**Figure 1.** Evolution of the scores in social skills in the intervention and control groups and the difference of averages at each level of analysis. IG: intervention group; CG: control group.
<table>
<thead>
<tr>
<th>Analyzed constructs</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>t</td>
<td>P value</td>
</tr>
<tr>
<td>Social skills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$T_1^a-T_2^b$</td>
<td>$-27.91 (28.97)$</td>
<td>$-5.70$</td>
</tr>
<tr>
<td>$T_2^a-T_3^c$</td>
<td>$-14.57 (20.91)$</td>
<td>$-4.12$</td>
</tr>
<tr>
<td>$T_3^a-T_4^d$</td>
<td>1.6 (14.94)</td>
<td>0.634</td>
</tr>
<tr>
<td>$T_1^a-T_3$</td>
<td>$-42.49 (28.55)$</td>
<td>$-8.80$</td>
</tr>
<tr>
<td>$T_1^a-T_4$</td>
<td>$-40.89 (27.13)$</td>
<td>$-8.92$</td>
</tr>
<tr>
<td>Self-esteem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$T_1^a-T_2$</td>
<td>$-4.11 (6.37)$</td>
<td>$-3.82$</td>
</tr>
<tr>
<td>$T_2^a-T_3$</td>
<td>1.37 (4.69)</td>
<td>1.73</td>
</tr>
<tr>
<td>$T_3^a-T_4$</td>
<td>2.17 (6.62)</td>
<td>1.94</td>
</tr>
<tr>
<td>$T_1^a-T_3$</td>
<td>$-2.74 (5.85)$</td>
<td>$-2.77$</td>
</tr>
<tr>
<td>$T_1^a-T_4$</td>
<td>$-5.71 (3.89)$</td>
<td>$-0.867$</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$T_1^a-T_2$</td>
<td>$-10.66 (14.27)$</td>
<td>$-4.42$</td>
</tr>
<tr>
<td>$T_2^a-T_3$</td>
<td>$-2.11 (12.48)$</td>
<td>$-1.00$</td>
</tr>
<tr>
<td>$T_3^a-T_4$</td>
<td>2.37 (16.03)</td>
<td>0.875</td>
</tr>
<tr>
<td>$T_1^a-T_3$</td>
<td>$-12.77 (15.56)$</td>
<td>$-4.86$</td>
</tr>
<tr>
<td>$T_1^a-T_4$</td>
<td>$-10.40 (14.41)$</td>
<td>$-4.27$</td>
</tr>
<tr>
<td>Satisfaction with life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$T_1^a-T_2$</td>
<td>$-3.23 (3.50)$</td>
<td>$-5.50$</td>
</tr>
<tr>
<td>$T_2^a-T_3$</td>
<td>$-4.57 (2.47)$</td>
<td>$-1.10$</td>
</tr>
<tr>
<td>$T_3^a-T_4$</td>
<td>1.31 (4.50)</td>
<td>1.73</td>
</tr>
<tr>
<td>$T_1^a-T_3$</td>
<td>$-3.69 (3.10)$</td>
<td>$-7.05$</td>
</tr>
<tr>
<td>$T_1^a-T_4$</td>
<td>$-2.37 (4.24)$</td>
<td>$-3.31$</td>
</tr>
</tbody>
</table>

* $T_1^a$: Observations performed pretest-posttest at the beginning of the training.
* $T_2^a$: Observations performed at the end of training.
* $T_3^a$: Observations performed 1 month later.
* $T_4^a$: Observations performed 3 months later.
Figure 2. Evolution of the scores in self-esteem in the intervention and control groups and the difference of averages at each level of analysis. IG: intervention group; CG: control group.

Figure 3. Evolution of the scores in self-efficacy in the intervention and control groups and the difference of averages at each level of analysis. IG: intervention group; CG: control group.
The independent measures made for each of the groups displayed significant average differences in both groups in the T\(_1\)-T\(_2\) comparison (intervention group: mean 10.66, SD 14.27, \(t_{34}=-4.42\), \(P<.001\); control group: mean 3.68, SD 6.81, \(t_{36}=3.28\), \(P=.002\)). In the intervention group, the self-efficacy scores increased from the pretest to the observations 1 month later (T\(_1\)-T\(_3\): mean 12.77, SD 15.56, \(t_{34}=-4.86\), \(P<.001\)) and 3 months later (T\(_1\)-T\(_4\): mean 14.41, \(t_{34}=-4.27\), \(P<.001\)). Contrarily, in the control group, they decreased in the measurement 1 month later (T\(_1\)-T\(_3\): mean 5.24, SD 14.18, \(t_{36}=2.25\), \(P=.03\)).

### Satisfaction With Life

Regarding satisfaction with life, the Program factor displayed a difference of averages (intervention group-control group) of 1.47 points (\(F_{1,69}=7.23\), \(P=.009\)). In the post hoc tests, as can be observed in Figure 4, no intergroup average differences were found in the first level of analysis (T\(_1\): \(F_{1,69}=4.22\), \(P=.052\)) or in the last level (T\(_4\): \(F_{1,69}=0.38\), \(P=.85\)). Contrarily, differences were found in T\(_2\)(\(F_{1,69}=8.04\), \(P=.006\)) and in T\(_3\)(\(F_{1,69}=19.88\), \(P<.001\)).

In the intragroup tests, there were significant differences between T\(_1\)-T\(_2\)(\(F_{1,69}=14.90\), \(P<.001\)), T\(_1\)-T\(_3\)(\(F_{1,69}=18.21\), \(P<.001\)), T\(_1\)-T\(_4\)(\(F_{1,69}=4.08\), \(P=.05\)), and T\(_1\)-T\(_4\)(\(F_{1,69}=8.13\), \(P=.004\)). Contrarily, no differences were found between T\(_1\)-T\(_4\)(\(F_{1,69}=0.57\)) and T\(_2\)-T\(_3\)(\(F_{1,69}=1.66\), \(P=.20\)).

The independent measurements carried out with the Student \(t\) test for paired samples in each group displayed differences in the averages in T\(_1\)-T\(_2\)(intervention group: mean 3.23, SD 3.50, \(t_{34}=-5.50\), \(P<.001\)), T\(_1\)-T\(_3\)(mean 3.69, SD 3.10, \(t_{34}=-7.05\), \(P<.001\)), and T\(_1\)-T\(_4\)(mean 4.24, \(t_{34}=-3.31\), \(P=.002\)). No differences were found in the control group.

## Descriptive Posttest and Multiple Linear Regression Analysis

The comparison of averages for paired samples carried out in the intervention group and control group to verify the variability in the weekly use of Facebook indicated that in both groups there was an increase in the number of hours. Between the pretest and the posttest at the end of the training course, participants in the intervention group increased their use of Facebook an average of 8 hours a week (SD 3, \(t_{34}=-13.11\), \(P<.001\)), and this number continued increasing at the end of the course, until 3 months later it reached ≥2 hours (SD 3, \(t_{34}=-3.44\), \(P=.002\)), with a total increase for T\(_1\)-T\(_4\) of 10 hours a week (SD 4, \(t_{34}=-13.67\), \(P<.001\)). The control group, on the other hand, did not display an increase in hours of use from the pretest to the end of the training course (\(t_{36}=0.15\), \(P=.88\)), but it did 3 months later, with an average of 1 hour a week (SD 2, \(t_{36}=-4.81\), \(P<.001\)). The average number of hours of use 3 months after the end of the training course was significantly higher in the intervention group than in the control group (intervention group=11 hours vs control group=2 hours; \(t_{69}=9.35\), \(P<.001\)). The variables corresponding to the weekly number of hours and age were also included in the linear regression model. The correlations corresponding to each of the quantitative variables in each level of observation (pretest and 3 posttests) were carried out with the \(r\) for the Pearson test. These data can be seen in Multimedia Appendix 1.
Table 4. Multiple linear regression for the dependent variables of social skills, self-esteem, self-efficacy, and satisfaction with life.

<table>
<thead>
<tr>
<th>Dependent variables of the model</th>
<th>Values</th>
<th>Collinearity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Estimated error</td>
</tr>
<tr>
<td>Social skills (r²=.405)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.154</td>
<td>.369</td>
</tr>
<tr>
<td>Use of Facebook (hrs/wk)</td>
<td>3.43</td>
<td>.599</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>−.132</td>
<td>.675</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>.319</td>
<td>.248</td>
</tr>
<tr>
<td>Satisfaction with life</td>
<td>−.882</td>
<td>.856</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-esteem (r²=.290)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.175</td>
<td>.062</td>
</tr>
<tr>
<td>Use of Facebook (hrs/wk)</td>
<td>.382</td>
<td>.122</td>
</tr>
<tr>
<td>Social skills</td>
<td>−.042</td>
<td>.022</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>.090</td>
<td>.043</td>
</tr>
<tr>
<td>Satisfaction with life</td>
<td>−.041</td>
<td>.154</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-efficacy (r²=.195)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>−.247</td>
<td>.180</td>
</tr>
<tr>
<td>Use of Facebook (hrs/wk)</td>
<td>.371</td>
<td>.360</td>
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<tr>
<td>Social skills</td>
<td>.078</td>
<td>.061</td>
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<tr>
<td>Self-efficacy</td>
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<td>.333</td>
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<tr>
<td>Satisfaction with life</td>
<td>.096</td>
<td>.426</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction with life (r²=.038)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.053</td>
<td>.053</td>
</tr>
<tr>
<td>Use of Facebook (hrs/wk)</td>
<td>.008</td>
<td>.106</td>
</tr>
<tr>
<td>Social skills</td>
<td>−.018</td>
<td>.018</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>−.027</td>
<td>.100</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>.008</td>
<td>.036</td>
</tr>
</tbody>
</table>

The results of the adjustment of the different models of multiple linear regression indicate that the number of hours devoted weekly to the use of Facebook was a predictor of the increase in the scores of social skills (B=3.43, r²=.405) and self-esteem (B=.382). Age (B=.175) and self-efficacy (B=.09) were also variables that, with independence and in equal conditions, predicted self-efficacy (r²=.29). Finally, self-esteem (B=.69) was a predictor variable of the increase of self-efficacy (r²=.195; Table 4).

The number of participants in the intervention group that used Facebook 3 months after the training course increased when compared with the pretest by 27%, rising from 26 to 33 people. Of the 33 people, 88% (29/33) claimed that their principal motivation for using SNS was to communicate with another person: 57% (19/33) with family and 30% (10/33) with friends. The rest used SNS for leisure or regular access to information (4/33; 12%).

Finally, the general satisfaction with the course results did not show score differences between the groups (intervention group=7, SD 1, control group=7, SD 1, t_{69}=-.33, P=.74), although there did exist differences in the usefulness perceived by participants (intervention group=8, SD 1, control group=5, SD 2, t_{69}=7.31, P<.001). A total of 7 participants of the intervention group expressed their refusal to repeat the training course to learn concepts more in depth, compared with 15 participants of the control group (χ²=3.98, P=.05).

Discussion

There are no known precedents of experimental longitudinal studies with homeless people in which researchers have analyzed the effects of a training program on social skills in the internet context, self-esteem, self-efficacy, and satisfaction with life. The contents of the program in this study were based on the learning or improvement of the use of Facebook, compared with a series of sessions of basic office automation and Web-based job search. For this purpose, the scores of the analyzed psychological constructs obtained in the pretest were compared
with those from 3 posttest observations (end of treatment and one-month and three-month follow-ups).

The results obtained indicate that improving the use of Facebook contributes to the improvement of the psychological constructs in individuals experiencing homelessness and that this improvement does not disappear until at least 1 month after the intervention (up to 3 months in the case of social skills and self-efficacy). Therefore, the expected results are verified: participants in the program improved their scores in social skills, self-esteem, self-efficacy, and satisfaction with life, and this improvement continued over time. The improvement of the social skills in the internet context was accentuated in comparison to the rest of the analyzed variables. An analysis of the general population for any differences in social skills in the internet context and in “real” context revealed the existence of significant discrepancies in the results of both in inversely proportional relations [29]. This fact contributes to increase the mistrust that SNS generate as a risk factor with a potential to increase loneliness [40]. Nevertheless, the results obtained for individuals experiencing homelessness indicated that the people who devoted more time to Web-based social contact improved their social skills in this context, namely, the internet context, proving the effect on social skills in the real context. It must be said that even though behavior concerning the use of Facebook could be inversely related to the 2 types of social skills in the general population, we would not consider this conduct initially as maladaptive in individuals experiencing homelessness. In extremely hostile surroundings such as the ones faced on the street, communication through SNS contributes to the reduction of the tensions generated as a consequence of the discrepancies of the “real me” and the “virtual me,” as a result of the space of freedom of expression created in an environment with minimal face-to-face relationships [41].

This fact is very interesting in the analysis of the social relationships of individuals experiencing homelessness who preserve their secure and private space with mistrust. More prosocial and healthy relationships are generated in the SNS, as opposed to relationships in their closest surroundings, the street, or special centers devoted to offer social assistance [42]. Thus, the training of social skills in the internet context must be considered interrelated to relationships with real people, and not so much as limiting relationships. This is a starting point to homogenize the social abilities to develop, both in the internet context and in the “real” context, especially for individuals experiencing homelessness, who may have close relationships that are not very healthy and live in a historic period in which human development fields are taking place increasingly through the internet and SNS.

Learning to use Facebook fulfills two objectives: to improve the process of resocialization, soothing the effect of the hard situations faced, and to increase self-esteem. The reasons for this are access to information that the individual can filter and on the other hand and more importantly to provide individuals experiencing homelessness a way to contact friends and relatives through SNS [22]. Self-esteem is highly related to self-efficacy. In fact, the high tolerance indicates a high correlation of both variables but without the presence of problems associated with collinearity, which are established with values <0.1 [43]. People’s feelings and actions are affected by self-efficacy expectations. People with low levels of self-efficacy have negative feelings on their own capacities and consequently their self-esteem. The perception of self-efficacy facilitates positive thoughts of one’s capacities, motivating more challenging and persistent actions [35]. As we have seen, self-esteem and self-efficacy improve with the learning of SNS, but not with the basic office software training course, as has been suggested.

Other known proposals in basic office software training courses among individuals experiencing homelessness that explored the experience of using computers with a group of individuals experiencing homelessness without experience in the use of ICT, produced great acceptance and good attitude toward ICT [21]. After the training period, the participants claimed to have higher self-esteem and self-efficacy, although it was considered that self-efficacy was perceived in relation to a given situation (the use of technology). However, in our case, the construct has been considered in the wide sense, understanding self-efficacy as a global construct that refers to the stable belief that an individual has their own capacity to deal adequately with a series of stressors in daily life [35]. It is important to point out that the contents of the training assessed by Miller et al [21], despite displaying a component of priority search of employment, were based on occupational therapy strategies, unlike our case, in which the therapeutic factor was not considered (as is the case in the close context, in which trainings on job searching for vulnerable groups is based on the transmission of contents).

Thus, in basic office software training courses for people at risk of social exclusion, it is usually first assumed that unemployment is one of the main causes of homelessness, both in individuals experiencing homelessness and in the general population and second that the aim of the professionals who design the course is to reduce homelessness [28].

Nevertheless, despite the fact that unemployment is one of the structural causes of homelessness and access to employment increases the possibilities of inclusion in the general population, there should be an assessment of the most adequate strategies for job searching through ICT, especially with individuals experiencing homelessness and their different typologies.

Other studies support the finding that interventions based on specific occupational therapy for individuals experiencing homelessness are effective, given the distinctive therapeutic features of this type of intervention, which is not merely a training course [44]. In fact, as we have observed in the results of this study, interventions that consist exclusively of training could be counterproductive. The specific tools for Web-based job searching alone do not improve access to the work market in the general population substantially—not to mention in people with difficulties. However, in recent years, they have improved in this regard. Contrarily, contact with friends and relatives through SNS, and even job searching directly through SNS, alongside the use of specific websites and searching for work outside the internet context, results in a remarkable increase in the possibilities of employability [45], which is a factor to be taken into consideration when designing training action plans for individuals experiencing homelessness.

Regarding satisfaction with life, it is noteworthy to point out that the perception that individuals experiencing homelessness have of satisfaction with life is significantly lower than that of the general population [46]. These reduced levels of satisfaction with life are related to the housing situation, sociodemographic characteristics such as age, gender, mental and physical health, and the type of social attention received.

This complex situation is coherent with the results of this study. The levels of satisfaction with life can rise at the beginning of the program and are connected with improvement in the rest of the constructs. Satisfaction with life is the variable that is weaker longitudinally, and probably, the recovery of basic levels is related to other fields that are not directly related to communication through SNS.

In brief, SNS are presented as a channel of communication, relation, and access to information with a great potency to reinforce individuals emotionally and socially [47]. Everybody wishes to have quality relationships, and SNS help individuals experiencing homelessness to generate and maintain this type of relationship. Moreover, they have great importance in their recovery and stabilization, even in the case of people with severe mental disorders or drug addiction, whose prognosis is very often less encouraging [48].

Teaching how to use or offering a training course to improve the use of SNS, in this case, Facebook, increases exposure to this type of communication, which has the effect of increasing important indicators of psychological well-being. Contact with people who are important to individuals experiencing homelessness, such as friends and family, is of great value to them, and the contact has significant impact levels when carried out totally or partially through SNS [14]. Prososce contact with relatives and friends through Facebook increases protective factors of certain damage associated with homelessness and its risk behaviors. On the other hand, the lack of this type of important contact increases depressive symptoms, which prompt a decrease in levels of self-esteem, self-efficacy, and even satisfaction with life [18,49].

Consequently, there is coincidence with other studies as regards the recommendation of providing more public spaces and free and quality Wi-Fi spots to facilitate access to ICT and SNS for individuals experiencing homelessness and other groups facing extreme social exclusion, on the grounds of the multiple benefits associated with internet access [25,50].

This work has some limitations. First, despite the fact that we have proved that the use of Facebook improves scores in the psychological constructs, we do not know what type of connections and what contents in communication through SNS are the most adequate to improve the well-being of participants, which could be considered a limitation to our work. The second limitation is that our sample was limited and the intervention context is specific, which makes it difficult to extrapolate the results to the group of individuals experiencing homelessness, especially owing to multiple situations, of a highly different nature, which adhere to the concept of homelessness according to the ETHOS classification. Finally, it would be helpful to extend the follow-up period to 6 months.

Future lines of research have arisen from this work. First, we consider it interesting trying to replicate this work in different contexts. Second, it would be interesting to assess the effect of job search in individuals experiencing homelessness through SNS, in comparison with specific websites, such as the ones on which our control group proposal is based. Third, the use of mixed designs in which qualitative information can be accessed in parallel with adequate quantitative models is supported, in order to complement the information obtained with the contents of the type of connections that individuals experiencing homelessness maintain.

In conclusion, training courses for the use of SNS improve social skills in the internet context, self-esteem, self-efficacy, and satisfaction with life; this improvement continues 4-12 weeks after the intervention. Furthermore, the increase in SNS use that derives from the training course becomes a predictor element of improvement of social skills and self-esteem, the latter having a positive effect on self-efficacy. The increase of these constructs is related to a decrease in individuals experiencing homelessness’ levels of loneliness, isolation, and failure, and therefore, conducting training courses for individuals experiencing homelessness to improve their experience in the use of SNS improves their quality of life and psychological state and is an interesting educational offer for institutions that provide specific services.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Correlation matrix (r) of dependent variables in the four steps of observation.

References


44. McCallum R. Sample size in social science research. SAGE Publications; 1994.


Abbreviations

- ETHOS: European Typology of Homelessness and Housing Exclusion
- ICT: information and communication technologies
SNS: social networking sites
Website Analytics of a Google Ads Campaign for a Men’s Mental Health Website: Comparative Analysis

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Abstract

Background: Men with mental health and addictions problems seek information and help from health service providers and community support less often than women with such problems. Online health resources offer men rapid access to self-care recommendations and resources and anonymity; however, only a few websites are specifically developed for men. Headstrong - Taking Things Head-On was a community pharmacy and online health promotion initiative for men living with mental health and addictions problems. The Headstrong website was developed to offer a curated collection of print and online recommended resources (primarily self-help oriented) for depression, anxiety, insomnia, tobacco and alcohol use problems, and suicide. To increase awareness of the initiative and use of the website’s content and resource recommendations, a Google Ads campaign was developed.

Objective: This study aimed to compare user acquisition and behavior on the Headstrong website during and after a Google Ads campaign.

Methods: The Google Ads campaign was launched on December 21, 2017, and run until February 28, 2018. Website analytics (acquisition of new users, behavior in terms of at-website actions and duration, devices used, and conversions [link-outs to recommended resources]) in a 30-day period during the campaign (January 26, 2018 to February 24, 2018) were compared to a similar 30-day period after the campaign (March 23, 2018 to April 21, 2018). A cost analysis of the ad campaign was also performed.

Results: The ad campaign generated 3011 clicks and 4.5 million impressions in total. In addition, the campaign received 1311 website users during the 30-day period of the ad campaign as compared to 241 users during the 30-day period after the ad campaign (P<.001). Return visitor (17.7% vs 27.8%) and nonbounce (19.5% vs 39.8%) user rates as well as session duration (42 vs 102 seconds) and page views per session (1.4 vs 2.1) were lower during the ad campaign than after the campaign (P<.01 for all). The 30-day period of the ad campaign included 9 sessions with conversions initiated by an ad click. Paid and display ads accounted for 63% of the site traffic during the ad campaign, most of which came from mobile phone users. Desktops were the most-common device used after the ad campaign acquired the website via direct and organic searches primarily (92%). The estimated cost per session with one or more conversions was Can $54.69 and cost per conversion was Can $32.81.

Conclusions: A Google Ads campaign designed to direct men to the Headstrong website increased the number of user visits by more than five-fold. However, engagement by users responding to the ad campaign was substantially lower than that by users who visited the website via other acquisition methods, possibly reflecting the nonspecific online targeting of men by the ad campaign. General targeting of men online to promote men’s mental health appears to have limited value.
Original Paper

Introduction

“Headstrong - Taking Things Head On,” hereafter referred to as the Headstrong initiative and website [1], targeted men living with mental health and addictions problems in Nova Scotia, Canada. The use of male-specific interventions is a part of current recommendations to engage men in their mental health [2]. The internet has become a major source for users to acquire health information [3]. Recently, internet-based interventions in a mental health context were found to show beneficial effects [4]. Additionally, some reports suggest that men may be more likely to independently seek electronic health information than consult a health care professional [5-8].

Similar to other mental health promotion websites for men, the Headstrong website aimed to provide a male-friendly medium to start the self-help-seeking process [9]. The Headstrong website was accessible to men searching the internet on their own or when used in conjunction with other resources and was based on referral from a community pharmacist participating in the Headstrong initiative [1]. The main components of the Headstrong initiative included providing pharmacists with education, training, and resources including the Headstrong website to help promote men’s mental health. The objectives of the initiative were to promote access to resources available to the public through community pharmacies and the Headstrong website and to provide pharmacists with a process, knowledge, and resources to help men. The Headstrong website was developed and designed, with feedback from the project’s “male mentors,” specifically to engage men in order to help them identify opportunities to address selected mental health and substance use issues. It provided a curated library of recommended print and electronic resources for self-help on depression; anxiety; insomnia; problems with alcohol and tobacco use; and thoughts, intentions, and behaviors related to suicide.

The initiative and website were promoted around the project launch in October 2017 through in-pharmacy advertising and existing relationships with pharmacists and clients. In addition, the initiative and website were promoted through social media (Twitter and Facebook) and word of mouth. To increase awareness of the initiative and website, a Google Ads campaign (formerly, Google Adwords [10]) was developed to attract men living in Nova Scotia who searched for Headstrong website topics and performed general internet searches. Google Ads have been used in health-related contexts such as for patient recruitment in studies [11-14], web-based interventions [15-18], and increasing awareness of health promotion campaigns [19-23], as was the case with Headstrong website. There have been mixed results regarding the success of Google Ads campaigns compared to other digital advertising mediums such as Facebook advertisements [12,15,17].

The primary objective of this study was to compare user behavior during and after a Google Ads campaign on the Headstrong website (Figure 1) and analyze the associated cost.

Figure 1. Headstrong.life homepage.
Methods

Design

This study examined website analytic measures for the Headstrong website during and after the Google Ads campaign. The Headstrong website and initiative were launched on October 16, 2017. The Google Ads campaign was launched on December 21, 2017, and run until February 28, 2018. A 30-day period during the campaign (January 26, 2018 to February 24, 2018) was compared to a similar 30-day period after the campaign (March 23, 2018 to April 21, 2018). For the ad campaign period, we chose a 30-day range that did not include religious holidays, work or school vacations, or a broadcast call-in radio show that featured the website and profoundly influenced user traffic. Additionally, we changed the daily budget for our ad campaign from $30 to $15 per day. After observing an increase in traffic as a result of the ad campaign, we reduced the daily budget to extend the ad campaign for a longer period of time. The selected 30-day ad campaign range was during the $15 per day period. The 30-day period selected after the ad campaign coincided with the end of the Headstrong initiative in pharmacies (Figure 2).

Headstrong website visits were observed over the course of the Headstrong initiative, and website analytics were compared during and after the campaign for website acquisition. In addition, the devices used to access the Headstrong website and geographical targeting of Nova Scotia users were analyzed. Further, a cost analysis of the Google Ads campaign and specific ad groups were assessed. Google analytics terms used throughout this study are defined in Table 1.

Using a cost-per-click model, the Headstrong Google Ads campaign was geographically limited to users living in the province of Nova Scotia. The campaign featured numerous keywords to ensure that a broad range of people living in Nova Scotia could find the website in their search efforts. Specific keywords, supported by direct consultation with Google, were selected to help people already searching for mental health information, resources, or support in Nova Scotia to learn of the Headstrong website and its recommended resources. Nonspecific key words were also included to raise awareness of the website among men who were online for other reasons. A sample of keywords used in the campaign are provided in Table 2.

The campaign type used was “Search Network with Display,” which allows the advertisement to appear in Google search results for key terms outlined by the Headstrong team and on various websites, selected by Google, that were expected to be of interest to potential users based on their online activity [24]. Use of the display ads in addition to the Search Network option increased the opportunity to reach a wide audience. A sample of an advertisement that appeared for mobile devices is shown in Figure 3.

Statistical Analysis

Descriptive statistics were used to characterize user behavior. The Poisson mean test was performed to compare the rate of daily use of the website during and after the ad campaign. We used the Fisher exact test and Chi-square analysis for dichotomous data, and the unpaired t-test for analysis of continuous variables. Variances are expressed as standard deviations. Cost data are reported in Canadian dollars unless stated otherwise.

Figure 2. Timeline of the Headstrong – Taking Things Head-On initiative and the Google Ads campaign.
### Table 1. Definitions of Google analytics terminology.

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analytics</strong></td>
<td></td>
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<tr>
<td>Average pages per session</td>
<td>The average number of pages viewed during a session on the website</td>
</tr>
<tr>
<td>Average session duration</td>
<td>Total duration of all sessions (in seconds) divided by the number of sessions</td>
</tr>
<tr>
<td>Bounce rate</td>
<td>The percentage of sessions that a person leaves the website from the landing page without browsing any further</td>
</tr>
<tr>
<td>Click-through rate</td>
<td>The percentage of users who view the ad and then click the ad</td>
</tr>
<tr>
<td>Conversions</td>
<td>A desired action once a user interacts with the ad. For the Headstrong website, clicking on recommended resources counted as a conversion</td>
</tr>
<tr>
<td>Conversion rate</td>
<td>The percentage of sessions on the website that lead to clicking of an outbound resource link</td>
</tr>
<tr>
<td>Cost per click</td>
<td>The amount paid to the advertiser each time an ad is clicked</td>
</tr>
<tr>
<td>Impressions</td>
<td>How many times the ad is viewed in any form on the internet</td>
</tr>
<tr>
<td>Nonbounce user</td>
<td>A user who proceeds to interact with the website after arriving on the landing page</td>
</tr>
<tr>
<td>Returning user</td>
<td>When the same user has more than one session</td>
</tr>
<tr>
<td>Session</td>
<td>A set of user interactions with the website that take place within a given time frame; a single session can contain multiple page views</td>
</tr>
<tr>
<td><strong>Acquisition</strong></td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>Users who visited Headstrong by typing the website directly into their internet browser</td>
</tr>
<tr>
<td>Display ad</td>
<td>Paid advertisements that appeared on the side of the user’s internet browser while browsing the internet on various websites determined by Google Ads for their relevance and suitability</td>
</tr>
<tr>
<td>Organic</td>
<td>Users who searched for the Headstrong website directly through a search engine</td>
</tr>
<tr>
<td>Paid search</td>
<td>Users who were specifically searching key terms of the Headstrong website Google Ads campaign</td>
</tr>
<tr>
<td>Referral</td>
<td>Users who found the website through some other website (not paid advertising)</td>
</tr>
<tr>
<td>Social</td>
<td>Users who found the website through a social media channel</td>
</tr>
</tbody>
</table>

### Table 2. Samples of keyword search terms used in the Headstrong Google Ads campaign.

<table>
<thead>
<tr>
<th>Ad group</th>
<th>Keywords&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental health</td>
<td>“Mental health”, “Mental Issues”, Mental health info, Mental wellness, “Mental Health Helpline”, Mental information, “Mental health is”</td>
</tr>
<tr>
<td>Smoking</td>
<td>“Quit smoking”, “Smoking cessation”, “Smoking”</td>
</tr>
</tbody>
</table>

<sup>a</sup>Keywords in quotation marks are referred to as “phrases”; these search terms were used exactly as seen in the quotation marks to present an advertisement to the potential user. Keywords without quotation marks can signal an advertisement for a potential user whose search includes the word, regardless of other words included in their search.
Results

Overall Campaign

The 69-day Google Ads campaign was initiated 66 days after the launch of the Headstrong initiative and resulted in 3011 visits to the Headstrong website and 4.5 million impressions. Daily counts of site visits from the launch of the website (October 16, 2017) to the end of the analysis period (April 25, 2018) are shown in Figure 4. The rate of visits was higher during the ad campaign (December 21, 2017 to February 28, 2018) than before or after the campaign.

Comparative Analyses: During and After the Ad Campaign

Analytics

The website attracted 1311 users during the 30-day ad campaign and 241 users in the 30-day period selected after the ad campaign. The average daily user count was higher (43.7 vs 8.0; \( P < .001 \)) and the return visitor rate was lower (17.7%, 232/1311, vs 27.8%, 67/241; \( P < .001 \)) during the ad campaign (Figure 5). The rate of nonbounce visits was lower during the ad campaign (19.5%, 256/1311, vs 39.8%, 96/241; \( P < .001 \)). Similarly, the session duration was shorter (42, SD 27, vs 102, SD 118 seconds; \( P = .009 \)) and the average number of pages viewed per session was lower (1.4, SD 0.2, vs 2.1, SD 0.7; \( P < .001 \)) during the ad campaign. The number of 30-day conversions was higher during the ad campaign (100 vs 47; \( P < .001 \)), with an associated lower conversion rate based on the number of sessions (7.1%, 100/1401, vs 15.9%, 42/264; \( P < .001 \); Figure 6).

Detailed website behavior was available for 1400 sessions during the ad campaign. Advertising via display ads and paid searches accounted for 59.9% (839/1400) of the website sessions during the 30-day periods. The behavior of users visiting the website because of advertising differed from that of other visitors: The bounce rate was higher, pages viewed was lower, and visit duration was shorter when users were directed to the site via advertising (Table 3). In addition, 9 of the 839 (1.1%) sessions with one or more conversions were prompted by the Headstrong website ads as compared to 51 of the 561 (9.1%) sessions unprompted by an advertisement during the same 30-day period (\( P < .001 \)).

Acquisition

Website acquisition data were available for 91.8% (1203/1311) of users during and 87.6% (211/241) of users after the 30-day campaign periods. Paid and display ads accounted for 62.7% (754/1202) of site traffic during the ad campaign (Figure 7). The combined number of users from direct, organic search, social media, and referral sources during the 30-day period of the ad campaign was greater than that in the selected 30-day period after the ad campaign (448 users vs 211 users, \( P < .001 \)).
Figure 4. Daily rate of Headstrong website visits. *On January 5, 2018, an Ontario-wide call-in public radio show about insomnia promoted resources available on the Headstrong website, which resulted in a high volume of visits for several days thereafter.

Figure 5. All website visits by all users and return users during and after the ad campaign.*The 30-day period during the ad campaign (January 26, 2018 to February 24, 2018). **The 30-day period after the ad campaign (March 23, 2018 to April 21, 2018).
**Figure 6.** Number of nonbounce users and cumulative conversions during and after the ad campaign.*The 30-day period during the ad campaign (January 26, 2018 to February 24, 2018). **The 30-day period after the ad campaign (March 23, 2018 to April 21, 2018).

<table>
<thead>
<tr>
<th>Source</th>
<th>Sessions, n</th>
<th>Bounce rate, %</th>
<th>Pages per session, n</th>
<th>Mean session duration (seconds)</th>
<th>Sessions with conversions, n (%)a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Google Ads</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Display</td>
<td>437</td>
<td>85.4</td>
<td>1.2</td>
<td>13</td>
<td>6 (1.4)</td>
</tr>
<tr>
<td>Paid Search</td>
<td>402</td>
<td>92.3</td>
<td>1.1</td>
<td>18</td>
<td>3 (0.8)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>164</td>
<td>57.9</td>
<td>2.0</td>
<td>120</td>
<td>21 (12.8)</td>
</tr>
<tr>
<td>Organic search</td>
<td>177</td>
<td>67.8</td>
<td>1.7</td>
<td>70</td>
<td>18 (10.2)</td>
</tr>
<tr>
<td>Social</td>
<td>126</td>
<td>66.7</td>
<td>1.6</td>
<td>52</td>
<td>11 (8.7)</td>
</tr>
<tr>
<td>Referral</td>
<td>94</td>
<td>93.6</td>
<td>1.2</td>
<td>54</td>
<td>1 (1.1)</td>
</tr>
</tbody>
</table>

aSessions can have one or more conversions. Percentages indicate the number of sessions with conversions divided by the total number of sessions.
Figure 7. Website acquisition sources during (n=1203) and after (n=211) the Headstrong website ad campaign.*The 30-day period during the ad campaign (January 26, 2018 to February 24, 2018). **The 30-day period after the ad campaign (March 23, 2018 to April 21, 2018).

Table 4. Devices used to access the Headstrong website during and after the Google Ad campaign.

<table>
<thead>
<tr>
<th>Devices</th>
<th>Bounce rate, %</th>
<th>Pages or session, n</th>
<th>Average session duration, seconds</th>
<th>Conversions, n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During the ad campaign (30 days, n=1195)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td>87.3</td>
<td>1.2</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td>Desktop</td>
<td>57.8</td>
<td>2.0</td>
<td>112</td>
<td>36</td>
</tr>
<tr>
<td><strong>After the ad campaign (30 days, n=206)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td>78.2</td>
<td>1.7</td>
<td>74</td>
<td>6</td>
</tr>
<tr>
<td>Desktop</td>
<td>51.8</td>
<td>2.4</td>
<td>129</td>
<td>23</td>
</tr>
</tbody>
</table>
**Devices**

Data on which device was utilized by website users when accessing the Headstrong website were available for 91.2% of all users (1195/1311) during the 30-day period of the ad campaign and 85.5% of all users (206/241) in the selected 30-day period after the ad campaign. Mobile phones represented the majority of devices used during the 30-day period of the ad campaign (74.0%, 884/1195), followed by desktop computers (19.9%, 238/1195) and tablets (6.1%, 73/1195). After the ad campaign, device use differed substantively ($P < .001$): Desktop computers were used most often (51.5%, 106/206), followed by mobile phones (40.8%, 84/206) and tablets (7.8%, 16/206).

During and after the ad campaign, mobile phone users had a higher bounce rate, fewer pages per session, shorter average session duration, and lower number of conversions than desktop computer users. In addition, the number of conversions with mobile phone users was half that of desktop users, although mobile phone users accounted for the majority of users during the ad campaign (Table 4). No differences in device use were observed on the basis of gender (data not shown).

**Table 5.** Analytics of ad groups during the 30-day Google Ads campaign.

<table>
<thead>
<tr>
<th>Google Ad group</th>
<th>Clicks, n</th>
<th>Cost per click, Can $</th>
<th>Bounce rate, %</th>
<th>Conversions, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad Group #1</td>
<td>717</td>
<td>0.53</td>
<td>93.2</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Ad Group #1_Depression</td>
<td>205</td>
<td>0.23</td>
<td>84.5</td>
<td>5 (3.0)</td>
</tr>
<tr>
<td>Ad Group #1_Bipolar</td>
<td>91</td>
<td>0.25</td>
<td>79.6</td>
<td>1 (1.1)</td>
</tr>
<tr>
<td>Ad Group #1_Disorder</td>
<td>84</td>
<td>0.23</td>
<td>84.5</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ad Group #1_Mental</td>
<td>32</td>
<td>0.26</td>
<td>89.7</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ad Group #1_Mental Illnesses</td>
<td>23</td>
<td>0.28</td>
<td>90.9</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ad Group #1_Depression_Causes Depression</td>
<td>11</td>
<td>0.22</td>
<td>100.0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ad Group #1_Smoking</td>
<td>4</td>
<td>0.80</td>
<td>100.0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Ad Group #1_Mental Health</td>
<td>2</td>
<td>0.62</td>
<td>33.3</td>
<td>2 (66.7)</td>
</tr>
<tr>
<td>Ad Group #1_Mental Disorders</td>
<td>1</td>
<td>0.79</td>
<td>100.0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Total</td>
<td>1171</td>
<td>0.42</td>
<td>88.7</td>
<td>9 (1.1)</td>
</tr>
</tbody>
</table>

**Performance of Google Ads Groups**

Ad group performances were relatively low overall, with high bounce rates and few conversions. The most general ad group, “Ad Group #1,” generated the highest number of clicks at 717; however, only one conversion was noted with this group (Table 5). Moreover, for this ad group, “Nova Scotia” was included as a part of the search string in 91.6% (657/717) of clicks and target content terms were included in 6.3% (45/717) of clicks. The search term “men” was included in only 2.1% (15/717) of the search terms but demonstrated the best engagement, with a bounce rate of 80% and the highest number of pages per session (1.4) within this ad group. The more specific “Ad Group #1_Depression” demonstrated the best performance overall, with 205 clicks, lower cost per click compared to “Ad Group #1,” an intermediate bounce rate, and a good conversion rate of 3%.

**Cost Analysis**

The cost of the 30-day period during the campaign was $492.20, with an average cost of $16.40 per day. The click-through rate was 0.1%, with an average cost per click of $0.42 and a conversion rate of 1.1%. A total of 9 sessions had one or more conversions resulting from a Google Ads campaign advertisement. The cost per session with conversion was $54.69. Assuming that the number of conversions per session was 1.67 (100 conversions in 60 sessions with conversions) was the same irrespective of whether the site user was acquired by a paid ad, we estimate that 15 conversions resulted from the ad campaign. This corresponds to $32.81 per conversion.

**Discussion**

**Principal Findings**

A Google Ads campaign substantially increased the number of visits to the Headstrong men’s mental health website. Although there were more user visits because of the ad campaign, the analytics data demonstrated a substantial reduction in user engagement. Higher bounce and lower return visitor rates, lower visit duration, and fewer page views suggested that the ad campaign attracted visits from individuals who were not interested in Headstrong’s purpose or web content. Targeting men, in general, through an online ad campaign that encouraged them to find support and resources for depression, anxiety, insomnia, and other mental health issues was not successful. This could be, in large part, due to the use of nonspecific keywords along with content-specific keywords for the ad campaign. Our results showed that this approach was not efficient, despite a relatively high prevalence of depression, anxiety disorders, insomnia, and tobacco and alcohol use problems in men. It is also possible that the nonspecific group of online users who saw and clicked on the Google Ad, thus using a portion of the daily spending limit of $15, prevented the ad from being viewed by someone more specifically targeted on the same day.

**Overview**

A primary aim of the Headstrong initiative was to help men access self-help resources for anxiety, depression, insomnia, and tobacco and alcohol use problems and to directly seek help...
for thoughts of suicide. For each mental health and addictions issue, a limited set of vetted and recommended resources were described succinctly with video overviews. Outbound clicks (conversions) to these resources indicated that users were engaged and potentially interested in accessing the resource. There were more conversions during the paid ad campaign, but a closer examination of user behavior per session demonstrated that the ads had little impact on conversions. Only 9 of the 60 sessions (15%) with conversions during the specified 30-day period of the ad campaign were from users who accessed the Headstrong website via an ad.

Most conversions were from sessions initiated independent of the paid ads via a variety of mechanisms, including the in-pharmacy Headstrong initiative. The number of conversions during the ad campaign was higher than that after the ad campaign due to a higher number of visitors who sought out the Headstrong website intentionally. This may, in part, be a remnant of the increased traffic that followed the call-in public radio show that brought attention to the website and more activity within participating pharmacies in the early stages of the Headstrong initiative.

The majority of responses to the ad campaign were from mobile device users, suggesting that they were more plentiful or more sensitive to the ads than desktop users. The higher proportion of mobile device users during the ad campaign is consistent with the findings of Birnbaum (2017), who reported a higher responsiveness to ads from mobile device users than from desktop users [16]. Independent of the ad campaign, we observed lower website engagement by mobile device users than by desktop users. The reasons for higher responsiveness and lower engagement from the mobile users is unclear. We believe this may be due to the volume of online searches using mobile devices as compared to desktop devices and differences in the website appearance among devices. Our observations reinforce the importance of developing engaging, mobile-friendly websites. Further work is needed to determine how to best improve engagement of mobile device users in response to the global trend of increasing mobile device use [25].

A common method to characterize the cost of a Google Ads campaign is to report the cost per conversion of a webpage. For the Headstrong webpage, the desired outcome was for users to click on one of the several outbound links to the recommended mental health resources. We estimate the investment per conversion to be $33 or $55 per session. The cost data for other Google Ads health-related campaigns are considerably varied, with cost per desired outcome ranging between US $6.70 [26] to Aus $495 [15]. Although the cost of our ad campaign was on the higher end, it was favorable as compared to other advertisement campaigns [11,13,15-17,20,22,26,27]. However, for an initiative that does not generate revenue, the cost of the ad campaign as currently designed is unsustainable.

Our experience with this Google Ads campaign highlights the importance of regular evaluation and modification of a campaign’s keywords to optimize the impact of the investment. Keywords that lead to a high volume of clicks but undesired behaviors (ie, high bounce rates, brief visit durations, and few conversions) will result in the inefficient use of a campaign’s daily budget and thereby limit advertising to more appropriate, targeted online users. However, it is important to recognize that focusing the ad campaign on a narrower target user changes the purpose of the campaign. For our campaign, narrowing the keywords would increase our ability to support men who are actively searching for information and resources on mental health and addiction. However, it would reduce the ability to reach men who may benefit from such information and resources even though they were not actively looking for such information [11].

Limitations

A substantial proportion of the demographic details of website users were unavailable, and users were able to prevent tracking of their general location, age, and gender. This limited our ability to determine differences in user behavior based on these variables. The desired behavior of users of the Headstrong website was the use of the recommended resources. Our proxy measure for identifying this behavior is determining conversions based on the use of outbound links to the recommended resources. We were unable to determine whether the user actually benefited from the resource.

Conclusions

A Google Ads campaign designed to direct men to Headstrong website, which presents a curated collection of print and online recommended resources for depression, anxiety, insomnia, tobacco and alcohol use problems, and suicide risk, increased the number of user visits by more than five-fold. People using mobile devices were most responsive to the campaign. Engagement by users responding to the ad campaign was substantially lower than that by users who visited the website via other acquisition methods. The use of nonspecific keywords accounted for most visits but may have failed to attract men interested in accessing resources focused on mental health and specific substance use problems. Narrowing the keywords may result in more efficient use of ad campaign funds with greater user engagement.

Acknowledgments

This study was funded by the Movember Foundation. We would like to acknowledge Drs Ruth Martin-Misener and Stan Kutcher who were part of the successfully funded project application.

Conflicts of Interest

None declared.
Authors' Contributions
ALM and DMG conceptualized the project, research design, and analysis plans. SP collated the data for the analysis and contributed to data analysis under the supervision of ALM and DMG. SP prepared initial drafts of the manuscript including figures. ALM and DMG revised all drafts for content. All authors approved the final version.

References


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A Schema Therapy–Based eHealth Program for Patients with Borderline Personality Disorder (priovi): Naturalistic Single-Arm Observational Study

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1GAIA AG, Hamburg, Germany
2Department of Psychiatry and Psychotherapy, University of Lübeck, Lübeck, Germany

Abstract

Background: Electronic health (eHealth) programs have been found to be effective in treating many psychological conditions. However, regarding borderline personality disorder (BPD), only a few eHealth programs have been tested, involving small interventions based on the dialectical behavior therapy treatment approach. We investigated priovi, a program based on the schema therapy (ST) approach. priovi is considerably more comprehensive than prior programs, offering broad psychoeducation content and many therapeutic exercises.

Objective: We tested the acceptability and feasibility of priovi in 14 patients with BPD as an add-on to individual face-to-face ST.

Methods: Patients received weekly individual ST and used priovi over a period of 12 months. We assessed BPD symptom severity using self-reported and interview-based measures. Qualitative interviews were conducted with both patients and therapists to assess their experiences with priovi.

Results: BPD symptoms improved significantly (Cohen d=1.0). Overall, qualitative data showed that priovi was positively received by both patients and therapists. Some exercises provoked mild anxiety; however, no serious threat to safety was detected.

Conclusions: priovi is a potentially helpful and safe tool that could support individual ST. It needs to be further tested in a randomized controlled study.

Trial Registration: German Clinical Trials Register DRKS00011538; https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00011538 (Archived by WebCite at http://www.webcitation.org/74jb0AgV8)

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KEYWORDS

borderline personality disorder; eHealth; mHealth; psychotherapy; schema therapy

Introduction

Electronic health (eHealth) applications have been found to be helpful in treating many psychological conditions. They have been extensively studied for common disorders (eg, depression or anxiety disorders) [1,2] and a broad spectrum of less frequent conditions, such as eating disorders [3,4] or posttraumatic stress disorder [5]. However, only a few studies have so far investigated eHealth applications in relation to people with borderline personality disorder (BPD).

BPD is a severe, often chronic psychological condition. Affective instability, self-injuring behavior, impulsivity, and identity problems are the hallmark symptoms of BPD. Those affected suffer severely, use a lot of psychological and psychiatric treatment, and are often severely impaired in their social and professional functioning. BPD also constitutes a high...
economic burden on society [6,7], with disease prevalence in the general population estimated to range from 1.2% to 2% [8,9].

Several psychological treatments for BPD have been developed and positively tested, including dialectical behavior therapy (DBT), schema therapy (ST), mentalization-based therapy (MBT), and transference-focused psychotherapy [10]. These treatments notably take a long time to administer, requiring several years for completion. Meanwhile, implementation and dissemination are slow, and most patients with BPD do not receive these treatments [11]. eHealth applications may offer innovative, cost-effective ways to provide evidence-based treatment for more patients with BPD [12].

All existing digital interventions for BPD are related to teaching DBT skills. The DBT Coach mobile phone app offers coaching for skills use and has been studied in 2 small uncontrolled pilot studies [13,14]. Results showed good feasibility, acceptability, and subjective patient evaluations of the DBT Coach as part of a standard DBT program. The EMOTEO (emotion–meteo [weather forecast]) mobile phone app has been tested for usability and efficiency with regard to the reduction of inner tension over 6 months in 16 patients with BPD. It was found to be user-friendly and efficient in reducing aversive tension [15]. Pocket Skills is another mobile app that teaches DBT skills. It was studied over a 4-week period in 73 individuals with mixed diagnoses (mainly depression, anxiety, and BPD) and enrolled in psychotherapy. It helped participants to engage in their DBT. They reported decreased depression and anxiety and increased DBT skill use [16]. Meanwhile, an internet-delivered DBT skills training intervention has been investigated over a 4-month period in a randomized controlled trial (RCT) with suicidal individuals who engaged in heavy episodic drinking. Compared with the waitlist, individuals in the internet-delivered DBT skills training intervention condition showed faster reductions in alcohol consumption [17]. Another pilot study examined the feasibility of 4 sessions of avatar therapy in virtual reality as an add-on to MBT in BPD [18]. Qualitative data suggest that avatar-MBT is acceptable to patients with BPD and has a positive impact. For ST, no Web-based intervention has been tested yet.

Thus, we developed priovi, which is based on ST. In ST, problematic BPD behaviors and symptoms are linked with “schema modes,” (ie, emotional states related to dysfunctional schemas such as mistrust or abuse or abandonment). The typical schema modes of patients with BPD are the vulnerable child mode (related to intense feelings of abandonment, sadness, anxiety, and mistrust), the angry or impulsive child mode (related to anger outbursts and impulsive behaviors), the punitive parent mode (related to self-devaluation and self-punishment), and the detached protector mode (related to problematic emotion-avoidance strategies such as dissociation, substance abuse, binge eating, and social withdrawal). The healthy adult mode (related to healthy functioning and relationships) is usually weak at the beginning of treatment. In the first part of treatment, patients learn to identify their schema modes and to understand their biographical background. Treatment goals in the following phase of therapy are also related to modes (ie, support and comfort the vulnerable child mode, help the angry child mode find better ways to deal with anger, control the punitive parent mode, and reassure the detached protector mode), so that patients can reduce their emotional avoidance and learn healthier ways to deal with emotions and relationships. To achieve these goals, mode-specific cognitive, experiential, and behavioral interventions are used. In addition, the therapy relationship, which is conceptualized as limited reparenting, is warm, caring, directive, and often non-Socratic. Several RCTs have shown the tremendous efficacy of ST in treating BPD [19]. It is currently recognized as one of the most promising approaches for treating severe disorders such as various personality disorders (PDs) [20] or forensic patients [21]. ST has shown low treatment dropout and high acceptance in both patients and therapists [19,22].

With priovi, we have developed the first ST-based Web-based intervention comprising broad psychoeducational content and several therapeutic exercises. If feasible, priovi could offer a lot of therapeutic content to patients with BPD and relieve therapists from discussing all the content in detail themselves, thereby saving therapy time and speeding up therapy substantially.

In this first pilot study on a Web-based ST intervention, we offered priovi to patients as an add-on to face-to-face ST. We investigated whether priovi is feasible and acceptable to patients and whether both patients and therapists found it helpful. The study was approved by the ethical committee of the University of Lübeck, Germany (AZ 14-038) and has been registered in the German Clinical Trials Register (DRKS-ID: DRKS00011538).

Methods

Subjects

We recruited patients from people asking for treatment in the outpatient center of the Department of Psychiatry and Psychotherapy at Lübeck University, Germany. The outpatient center treats chronic and severely ill patients. Textbox 1 show the inclusion and exclusion criteria. Regarding substance use, patients were included when they fulfilled only the criteria of substance abuse or were abstinent for >2 months.

There were 14 patients with BPD who began the trial. Of these, 1 patient was soon excluded, as she developed a psychotic episode shortly after the start of the trial, which was not related to ST treatment or priovi. Of the remaining 13 study participants, 9 completed all 4 assessments, 2 each missed assessments after 6 and 12 months, and 4 missed the assessment after 18 months.

Of the 13 study participants, 11 were females. The mean age was 28.4 (SD 8.3) years. There were 4 patients who had children, and 8 lived with a spouse. The average level of education was 10.8 years. Regarding the job situation, 4 were on long-term sick leave, 7 worked in a regular job, and 2 were unemployed. The patients had a high number of comorbid psychiatric conditions including on Axis I a current major depressive disorder (11/13, 85%), posttraumatic stress disorder (10/13, 77%), social phobia (6/13, 46%), agoraphobia with panic disorder (5/13, 38%), generalized anxiety disorder (2/13, 15%), specific phobia (5/13, 38%), obsessive-compulsive
disorder (3/13, 23%), bulimic disorder (6/13, 46%), and substance abuse (5/13, 38%). On Axis II, the comorbidities included obsessive-compulsive PD (5/13, 38%), avoidant PD (5/13, 38%), paranoid PD (3/13, 23%), and narcissistic PD (1/13, 8%). There were eleven patients (11/13, 85%) on psychopharmacological medication. All of them took antidepressants, 6 had an additional antipsychotic medication, and 1 patient used zopiclone.

With regard to prior treatments, only 2 patients were treatment-naïve, 11 patients had received prior medication (mean 8.5 [SD 5.9] different medications) and individual psychotherapy, and 9 had received group psychotherapy. Patients with prior treatments reported a mean of 5.5 inpatient treatments and 3.8 outpatient treatments. Note that not all these treatments necessarily focused on BPD, since many patients had also been treated for comorbid conditions, mainly depression and eating disorders.

**Intervention**

All patients received weekly individual face-to-face sessions and priovi for 1 year. priovi is a dialogue-based program; all content is presented to the user in (written) therapeutic dialogue. The program is highly tailored to the individual user, with the therapeutic conversation evolving based on the user’s responses in the dialogue. Within the dialogue format, priovi communicates psychoeducational content, explains therapeutic techniques, and guides the user through exercises. Users can pause and continue sessions anytime they want. Apart from written text, priovi contains several audio guides and illustrations.

**Textbox 1. Inclusion and exclusion criteria.**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary borderline personality disorder diagnosis</td>
</tr>
<tr>
<td>Borderline Personality Disorder Severity Index ≥ 20</td>
</tr>
<tr>
<td>Age ≥ 18 years</td>
</tr>
<tr>
<td>Fluency in German</td>
</tr>
<tr>
<td>Willingness to participate</td>
</tr>
<tr>
<td>Written informed consent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current psychotic disorder</td>
</tr>
<tr>
<td>Alcohol or benzodiazepine dependency requiring immediate detox treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exercise type</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercises to overcome avoidant coping modes</td>
<td>Collecting individual pros and cons of these modes by selecting options from lists with typical pros and cons; imagery of nonavoidant behaviors with audio instructions</td>
</tr>
<tr>
<td>Exercises to soothe the vulnerable child mode</td>
<td>Collecting positive feedback from others and writing it into a personal diary; imagery exercises of caring for the inner child in a safe place, guided by audio instructions</td>
</tr>
<tr>
<td>Exercises to control the punitive parent mode</td>
<td>Collecting arguments against this mode by selecting options from a list with typical arguments; developing counter-arguments</td>
</tr>
<tr>
<td>Exercises to strengthen the healthy adult mode</td>
<td>Implementing healthy and pleasant behavior in real life, supported by audio instructions; dealing with conflicts and problems in real life, supported by audio instructions</td>
</tr>
</tbody>
</table>
priovi can be used on all Web-enabled screen devices. Once registered, access to the program lasts for 1 year. We recommend using it twice weekly for about half an hour. If the user complies with this recommendation, it takes them about 6 months to work through all dialogues. A more detailed description of priovi including some screenshots can be found elsewhere [12].

Assessments
Assessments took place before the start of treatment and after 6, 12, and 18 months. We mainly report on the 1-year outcome, since priovi ended after 1 year, while individual treatment might have been continued.

Borderline Personality Disorder Interview and Questionnaire
BPD severity was assessed with the Borderline Personality Disorder Severity Index (BPDSI)-IV, a well-established semistructured interview representing the severity and frequency of BPD manifestations over the last 3 months according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition [23-25]. In addition, we used the BPD Checklist short version, a 47-item self-report questionnaire assessing BPD symptom severity in the last month [26].

Qualitative Patient Interviews
In-depth qualitative semistructured guideline interviews were conducted to get more detailed insight into the patient’s experience with priovi. We interviewed 11 patients at the end of treatment. Interviews were conducted by 1 of the authors (SK) and 2 research assistants, digitally recorded and pseudonymized. A protocol paraphrasing the major information was typed out. There was no fixed time set for the interviews; the duration varied from 9 to 39 minutes.

Qualitative Therapist Interviews
In a similar way, all 6 study therapists (4 females, 2 males, mean age 34.7 [SD 3.7] years) were also interviewed. These interviews lasted on average 42 minutes (range 28-52 minutes).

Table 2. Borderline Personality Disorder Severity Index and Borderline Personality Disorder Checklist results.

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>18 months</th>
<th>(F_{3,36})</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPDSI(^b), mean (SD)</td>
<td>33.3 (7.4)</td>
<td>26.6 (9.5)</td>
<td>23.6 (11.3)</td>
<td>22.3 (11.9)</td>
<td>6.62</td>
<td>.001</td>
</tr>
<tr>
<td>BPD-CL(^c), mean (SD)</td>
<td>129.0 (21.8)</td>
<td>106.7 (26.7)</td>
<td>98.8 (31.1)</td>
<td>95.1 (28.4)</td>
<td>7.21</td>
<td>.001</td>
</tr>
</tbody>
</table>

\(^a\)F and \(P\) values of repeated measurements analysis of variance. 
\(^b\)BPDSI: Borderline Personality Disorder Severity Index. 
\(^c\)BPD-CL: Borderline Personality Disorder Checklist.

Analysis
We analyzed quantitative data using SPSS software with repeated measures analysis of variance with the last observation carried forward. Effect sizes were calculated using Cohen \(d\). Correlations were calculated with Excel. Qualitative data were thematically analyzed, and interviews were interpreted by means of the qualitative content analysis sensu Mayring [27], extracting the core messages of the interviews.

Results
Principal Results
All patients used the program to a significant extent. The mean days of usage were 80.7 (SD 72, range 12-288), and total mean usage time was 19 (SD 10.9, range 6.2-40.3) hours. Patients tended to use the program over the entire year of treatment (range 68-365 days, mean 304 [SD 93] days).

Borderline Personality Disorder Symptoms
Table 2 shows BPDSI and BPD-CL results over time. The last observation was carried forward in cases of missing data. BPDSI scores were reduced by 9.6 points over 1 year, equaling about Cohen \(d=1.0\) (taking the mean [SD] of all assessments=9.7 as a reference). The BPD-CL was reduced by 29.9 (SD 25.6) points, equaling Cohen \(d=1.2\). All changes were significant over time. Symptom changes were not correlated with usage time \((r=.067)\).

Qualitative Results
In the interviews, patients related to 6 positive and 5 negative categories regarding their experience with priovi (Table 3). Therapists reported helpful functions of priovi and mentioned both positive and negative effects on the therapist, the therapy process, and the patients’ progress (Table 4).
Table 3. Positive and negative categories reported by 11 patients with regard to their experiences with priovi.

<table>
<thead>
<tr>
<th>Category type</th>
<th>Category</th>
<th>n (%)</th>
<th>Patient experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Local and temporal flexibility</td>
<td>6 (55)</td>
<td>The constant availability of priovi made patients feel safe, helped them to optimize their learning process, and made them feel less dependent on their human therapist</td>
</tr>
<tr>
<td>Positive</td>
<td>Validation</td>
<td>10 (91)</td>
<td>The tone of priovi was experienced as validating, which made patients feel understood and improved their self-esteem. This was supported by priovi’s comforting daily text messages and validating case examples</td>
</tr>
<tr>
<td>Positive</td>
<td>Psychoeducation</td>
<td>10 (91)</td>
<td>The content was perceived as helpful, understandable, relevant, and conclusive</td>
</tr>
<tr>
<td>Positive</td>
<td>Specific elements</td>
<td>10 (91)</td>
<td>Some elements were mentioned as particularly helpful, including audio exercises, the regular mood check, case examples, pro-con lists, and some specific exercises</td>
</tr>
<tr>
<td>Positive</td>
<td>Structure</td>
<td>6 (55)</td>
<td>Positive experiences with the program’s structure related to the clear step-by-step approach, the increasing exercise difficulty, the comprehensive sequence of contents, and the easy-to-understand menu</td>
</tr>
<tr>
<td>Positive</td>
<td>Pleasant emotions</td>
<td>6 (55)</td>
<td>Positive emotions were, for example, induced by the nice and funny illustrations or the soothing voice of the audio speaker. Patients felt that priovi was at their side, did not abandon them, and did not force them to do anything they did not like</td>
</tr>
<tr>
<td>Negative</td>
<td>Technical difficulties during the pilot phase</td>
<td>7 (64)</td>
<td>These included bugs such as audio files being unavailable as text, incorrect feedback of the mood check, and temporary breakdown of the text message service</td>
</tr>
<tr>
<td>Negative</td>
<td>Usability problems</td>
<td>8 (73)</td>
<td>Some patients did not like specific functions, such as the duration (either too short or too long), the menu, or the voice of the audio speaker. Some patients suggested additional features, such as other items in the mood check or changes in the menu</td>
</tr>
<tr>
<td>Negative</td>
<td>Lack of connection with priovi</td>
<td>7 (64)</td>
<td>Some patients reported problems in relating to certain aspects of priovi, such as the digital medium in general, the comics, or the case examples. This usually improved over time—at least to some degree</td>
</tr>
<tr>
<td>Negative</td>
<td>Aversive emotions</td>
<td>5 (45)</td>
<td>Negative emotions occurred when patients felt confused or overwhelmed by emotionally difficult topics. Bugs or limitations of the program made some patients feel angry</td>
</tr>
<tr>
<td>Negative</td>
<td>Rigidity</td>
<td>1 (9)</td>
<td>There was 1 patient who found priovi too rigid and not individual enough. She felt it could not respond to her current issues well</td>
</tr>
</tbody>
</table>

aValue indicate the numbers and percentage of patients referring to the respective category.

Table 4. Functions and effects of priovi as reported by 6 therapists.

<table>
<thead>
<tr>
<th>Function or effect</th>
<th>Category</th>
<th>n (%)</th>
<th>Therapist experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helpful functions</td>
<td>Working materials</td>
<td>6 (100)</td>
<td>priovi was used for homework assignments and deepening the understanding of psychoeducational content</td>
</tr>
<tr>
<td>Helpful functions</td>
<td>Monitoring</td>
<td>3 (50)</td>
<td>The “cockpit” function was used to monitor the patients’ progress by half of the therapists</td>
</tr>
<tr>
<td>Helpful functions</td>
<td>Therapist representation</td>
<td>2 (33)</td>
<td>Patients could use priovi as an alternative to personal therapy in between sessions or when the therapist was on vacation</td>
</tr>
<tr>
<td>Effects of priovi</td>
<td>Positive effects on the therapist</td>
<td>6 (100)</td>
<td>Improved knowledge about ST, feeling supported with regard to psychoeducation, emotional relief due to priovi being there for their patients</td>
</tr>
<tr>
<td>Effects of priovi</td>
<td>Negative effects on the therapist</td>
<td>2 (33)</td>
<td>Obligation to motivate the patient for priovi and time burden to get familiar with priovi themselves</td>
</tr>
<tr>
<td>Effects of priovi</td>
<td>Positive effects on the therapy process</td>
<td>6 (100)</td>
<td>Better understanding of ST by the patient, more time for individual issues and experiential exercises, a better overall structure of therapy, improved patient responsibility</td>
</tr>
<tr>
<td>Effects of priovi</td>
<td>Negative effects on the therapy process</td>
<td>2 (33)</td>
<td>Discussing priovi needed therapy time</td>
</tr>
<tr>
<td>Effects of priovi</td>
<td>Positive effects on the patient</td>
<td>6 (100)</td>
<td>Patients learned more, learning occurred more quickly, and patients were more autonomous</td>
</tr>
</tbody>
</table>

aValue indicate the numbers and percentage of therapists referring to the respective category.
Discussion

In this uncontrolled pilot study, we tested the feasibility and acceptability of priovi as an add-on to individual ST in 13 patients with BPD. To our knowledge, this is the first study to explore a Web-based ST tool. BPD symptoms showed improvements equaling Cohen $d=1.0$ on both BPD measures used in the study. This is rather similar to the 1-year outcome found in another study conducted in the same outpatient clinic, piloting a combination of individual and group ST [28]. In this study, mean BPDSI at baseline was 35.7 (SD 9.3), and after 1 year, it was 24.2 (SD 10.2), showing a reduction of Cohen $d=1.2$. Given these results, one could cautiously hypothesize that priovi might replace group sessions in a combined treatment format. An RCT comparing these 2 programs would be of great importance.

Most qualitative comments indicate that patients experience priovi as helpful, informative, available, and caring. Only a few adverse reactions to priovi were reported, and none of them seemed particularly severe. The majority of negative comments related to technical problems and bugs, which were immediately fixed. Therapist feedback was overall positive as well. priovi seems to be feasible, acceptable, and potentially helpful for people with BPD.

Patients used priovi intensively, but usage time was not related to clinical improvement. This is consistent with previous studies, which have suggested that usage time tends to correlate poorly with the outcome, possibly because dose-response relationships are not linear and other usage indicators, such as the number of tasks completed, might better reflect patient engagement [29]. Similarly, a linear dose-response relationship is rarely seen in psychotherapy because treatment responders may discontinue relatively early (the “good enough” effect), whereas those who are relatively treatment-resistant actually remain in treatment for longer [30]. More research is needed to disentangle the complex relationships between engagement with Web-based interventions and response.

This was mainly a qualitative study, investigating both patients’ and therapists’ experience with priovi. More structured and validated quantitative tools, such as the Client Satisfaction Questionnaire [31], would have been another option. However, we chose the interview format, since we also aimed to find unexpected or individual experiences that are not covered by the aforementioned instruments. Notably, we did not employ an elaborate qualitative methodology, such as interpretative phenomenological analysis [32], because our aim was not to understand specific experiences in great detail but rather to get a broad overview of patients’ experiences. The ultimate goal of the interviews was to improve priovi based on patient feedback and to test the acceptability and safety of priovi.

This study had several limitations. The number of subjects was small, we did not study a control group, and we only investigated priovi in combination with individual ST. Thus, we cannot make any conclusion regarding the actual efficacy of priovi on its own. Improvement in BPD symptoms might have been caused by anything, including improvement in BPD symptoms over time as has been seen in long-term studies on the course of BPD [33]. The actual efficacy of priovi needs to be demonstrated in a larger randomized controlled study.

Qualitative interviews may have elicited socially accepted response behavior since interviewers were research assistants of the study and probably positively biased toward priovi. All but 2 subjects were women, and results cannot be generalized to male patients. In general, the outpatient center in Liibeck treats severely and chronically ill patients. Thus, results cannot be generalized to patients in, for example, private practices who are often less severely ill.

Acknowledgments

We thank our study patients for their willingness to share their priovi experiences with us. We also thank all the students and therapists who helped conduct this study.

Conflicts of Interest

AH and GAJ are employees at GAIA, the developer and owner of priovi. GAJ, EF, and US received financial support for training in ST and have published books and DVDs on ST.

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Abbreviations

BPD: borderline personality disorder
BPDSI: Borderline Personality Disorder Severity Index
DBT: dialectical behavior therapy
eHealth: electronic health
MBT: mentalization-based therapy
PD: personality disorder
RCT: randomized controlled trial
ST: schema therapy

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Reference Correction: Preliminary Evaluation of a Web-Based Psychological Screening Tool in Adolescents Undergoing Minimally Invasive Pectus Surgery: Single-Center Observational Cohort Study

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Related Article:
Correction of: https://mental.jmir.org/2018/2/e45/
doi:10.2196/11608

The authors of “Preliminary Evaluation of a Web-Based Psychological Screening Tool in Adolescents Undergoing Minimally Invasive Pectus Surgery: Single-Center Observational Cohort Study” (JMIR Ment Health 2018;5(2):e45) made two errors in the References section.

Rather than Rugo et al (2010), reference 6 should be as follows:

Rather than Vigna et al (2006), reference 51 should be as follows:

The correction will appear in the online version of the paper on the JMIR website on November 12, 2018, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article also has been resubmitted to those repositories.

References
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