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Original Paper

Web-Based Cognitive Behavioral Relapse Prevention Program With Tailored Feedback for People With Methamphetamine and Other Drug Use Problems: Development and Usability Study

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Abstract

Background: Although drug abuse has been a serious public health concern, there have been problems with implementation of treatment for drug users in Japan because of poor accessibility to treatment, concerns about stigma and confidentiality, and costs. Therapeutic interventions using the Internet and computer technologies could improve this situation and provide more feasible and acceptable approaches.

Objective: The objective of the study was to show how we developed a pilot version of a new Web-based cognitive behavioral relapse prevention program with tailored feedback to assist people with drug problems and assessed its acceptance and usability.

Methods: We developed the pilot program based on existing face-to-face relapse prevention approaches using an open source Web application to build an e-learning website, including relapse prevention sessions with videos, exercises, a diary function, and self-monitoring. When users submitted exercise answers and their diary, researchers provided them with personalized feedback comments using motivational interviewing skills. People diagnosed with drug dependence were recruited in this pilot study from a psychiatric outpatient ward and nonprofit rehabilitation facilities and usability was evaluated using Internet questionnaires. Overall, website usability was assessed by the Web Usability Scale. The adequacy of procedures in the program, ease of use, helpfulness of content, and adverse effects, for example, drug craving, mental distress, were assessed by original structured questionnaires and descriptive form questions.

Results: In total, 10 people participated in the study and completed the baseline assessment, 60% completed all relapse prevention sessions within the expected period. The time needed to complete one session was about 60 minutes and most of the participants took 2 days to complete the session. Overall website usability was good, with reasonable scores on subscales of the Web Usability Scale. The participants felt that the relapse prevention sessions were easy to use and helpful, but that the length of the videos was too long. The participant who until recently used drugs was satisfied with the self-monitoring, but others that had already maintained abstinence for more than a year felt this activity was unhelpful and were bored tracking and recording information on daily drug use. Feedback comments from researchers enhanced participants' motivation and further insight into the disease. Serious adverse effects caused by the intervention were not observed. Some possible improvements to the program were suggested.

Conclusions: The Web-based relapse prevention program was easy to use and acceptable to drug users in this study. This program will be helpful for drug users who do not receive behavioral therapy. After the pilot program is revised, further large-scale research is needed to assess its efficacy among drug users who have recently used drugs.

KEYWORDS

web-based; drug dependence; relapse prevention; cognitive behavioral therapy; motivational interviewing; self-monitoring; Internet

Introduction

Drug Use Problems and Treatments

Drug abuse is a serious public health problem all over the world. In the latest report, 243 million people, corresponding to 5.2% of the world population ages 15-64, have used an illicit drug at least once in the previous year [1]. In Japan, drug use in the community-based population has been much lower than that of other countries. Lifetime prevalence of drug use was estimated at 2.6% for any drug [2], 6.4% for nonmedical use of prescription drugs, and 1.5% for cannabis [3]. As for twelve-month prevalence, any drug use and drug dependence were reported as very close to zero [2,4]. However, there are high-risk groups with lifetime prevalence of any drug use estimated as 54.7% and 65.0% among HIV positive patients and men who have sex with men, respectively [5]. Lifetime prevalence of cannabis was reported as 24.7% among clubgoers [6]. These numbers for drug use prevalence were about 25 or more times higher than among the general population. The prevalence rate of drug use and drug dependence is considered underestimated because patients and high-risk people are unlikely to answer a nationwide survey. In fact, the numbers for people under arrest due to drug-related crimes and patients with drug dependence has remained stable or slightly increased [2,7].

The most prevalent drug has been methamphetamine in the treatment population, estimated at about 40% of patients who received any treatment in psychiatry with dependence or related disorders [8]. In recent years, health problems have arisen from rapidly increased use of new psychoactive substances (NPS), such as marijuana or stimulants containing synthetic cannabinoid and cathinone, especially among males in their 20s and 30s [8]. Prescription drug abuse has also increased, especially among females suffering from mental distress [8].

Many treatment interventions to prevent relapse have contributed to recovery from drug addiction. One of the most common and evidence-based approaches for several forms of drug addiction is behavioral therapy [9]. Behavioral therapies focus on various behavioral aspects and involve addressing drug users' motivation to change, engage in treatments, handle triggers for drug cravings, acquire skills to resist drug use, replace activities using drug with constructive, and reward activities, and improve ways to handle problems and stress in various situations [10]. In previous meta-analysis, behavioral therapy demonstrated efficacy for abstinence with moderate effect size ($d=0.45$) and for treatment retention [11].

Despite evidence of effective and positive outcomes from behavioral therapies, treatment implementation remains problematic for various reasons. First, proper treatment is hampered by limited availability, rigid session times, inconvenient locations, and cost for service users [12,13].

Additionally, concerns about confidentiality and stigmatization further constrain drug users' motivation to seek and engage in treatment [13]. Finally, the provision of frequent face-to-face validated interventions by well-trained therapists tends to create an economic and human-resource burden [14].

As for the treatment situation in Japan, there is also a gap between potential population-based treatment needs and available treatment services. Only about 16% of people received any psychiatric treatment among those with past alcohol/drug use disorders [15]. If they visit a psychiatrist, only 38.5% received specialized treatment for dependence, including cognitive behavioral therapy (CBT) [7]. This means that most drug users are not likely to visit a psychiatrist, nor would one receive specialized treatment even if treated by a psychiatrist. There are a few available community-based and evidence-based treatments because of a zero tolerance policy [16]. Many psychiatric hospitals have often only provided treatment for detoxification and medication in an acute stage without follow-up and psychosocial treatment [16,17]. Additionally, stigma and prejudice against drug use and drug users is also high among Japanese people including health care professionals [16]. As such, it is necessary to increase the availability and accessibility of evidence-based treatments that drug users can use without concerns about stigmatization and confidentiality.

Intervention Using Computer and Internet Technology

Over the last two decades, interventions using computer technologies and the Internet have rapidly developed and adapted to various health problems, including for substance abuse, to address challenges in treatment implementation [12,14,18,19]. There are various types of Internet-based programs and most previous implementations were developed based on traditional face-to-face approaches and theories [20].

In Western countries, especially, many interventions have been developed to treat drug abuse. Enduring abstinence, engagement in treatment, actual help seeking, and cost effectiveness have been demonstrated by randomized controlled trials [13,14,21-28]. However, previous meta-analysis and systematic review studies revealed that the number of specific studies for drug abuse was fewer than for mental health problems, including alcohol and tobacco use problems [18,29]. Although there have been some Web-based or computerized intervention studies for cocaine or cannabis users, very few addressed users of various drugs including methamphetamine [19,30]. In addition, previous studies were heterogeneous in sample size, participant characteristics, applied technology type, presence and extent of therapist involvement, intervention length and session times, and condition of control group. As such, it has not been clear how to best implement interventions using a computer and Internet technologies for people with problems with various drugs including methamphetamine, especially in Asian countries. In Japan, while the availability of computer

technologies and diffusion of Internet infrastructure has become widespread, technological treatments with validated methods remain underdeveloped.

The aims of this study are: (1) to describe the development of a new Web-based relapse prevention program with tailored feedback from a therapist using evidence-based cognitive behavioral approaches; and (2) to evaluate the acceptance and usability of the pilot program.

Methods

Development of the Pilot Version

Referenced Program

The new Web-based program was based on an existing evidence-based face-to-face relapse prevention program for people with drug use problems in Japan called the Serigaya Methamphetamine Relapse Prevention Program (SMARPP). SMARPP was developed in 2006 based on the Matrix Model as one of various effective behavioral therapies for outpatients with stimulant dependence [31-36]. The Matrix Model is a packaged cognitive behavioral relapse prevention program constructed with treatment elements based on other evidence-based approaches using detailed treatment manuals and demonstrated effectiveness for drug and alcohol reduction and risky sexual behaviors [33-36]. SMARPP inherits principles of the Matrix Model and aims at enhancing motivation for treatment and reducing drug use. The program is versatile and can be used for various drug problems. The program consists of a series of sessions based on educational components and practical relapse prevention exercises using a workbook and is done on a weekly basis [31]. SMARPP has been adapted for use to address different drug user needs and for various service providers, such as: the outpatient ward of psychiatric hospitals, the forensic psychiatric inpatient ward, the public mental health welfare center, nonprofit rehabilitation facilities, and probation offices. There are, however, challenges in implementation, particularly in community-based and outpatient settings.

As continuous drug-use monitoring is one of the important elements of treatment for drug addiction, participants of SMARRP check daily drug use and are encouraged to honestly convey their use to therapists and others. Urine tests and self-monitoring or self-monitoring only are also used depending on the institute and these results are only used to evaluate efficacy of the intervention and are kept confidential.

In previous studies, SMARPP participants showed more enduring abstinence, retention of outpatient treatment, and more

frequent new enrollment in a self-help group than nonparticipants [37,38]. In addition, motivation for treatment and confidence dealing with drug cravings increased during intervention among inmates in a juvenile home and a prison that participated in the program [39,40].

Structure and Website Security

The new Web-based program was named e-SMARPP. The e-SMARPP website and content was developed by the first author primarily through the use of Moodle (version 2.6.1), which is an open-source Web application (app) to build e-learning websites [41]. Moodle has various modules to customize an original website written in PHP, which is a program language to make interactive Web pages, and is designed to support any device, including personal computers (PC), mobile phones, and tablet computers. An original domain name was obtained for the e-SMARPP website and access is encrypted through Secure Socket Layer technology. The e-SMARPP website is closed access. Each user is given an individual account that is created by only the first author using an email address and users create their nickname, identification, and password to log in.

e-Serigaya Methamphetamine Relapse Prevention Program Components

e-SMARPP is comprised of five parts: (1) a relapse prevention course, cognitive behavioral relapse prevention sessions (watching videos, submitting exercises, and a weekly diary on the website); (2) self-monitoring, calendar that displays drug use status by color; (3) information, downloadable PDF information and website links to drug addiction support services; (4) user guide, how to use the system, frequently asked questions, and contact form to researchers; and (5) a survey, questionnaires for baseline and post surveys. Users clicked radio buttons or input brief text when answering.

The main intervention contents are the relapse prevention course and the self-monitoring module. In the relapse prevention course, users are expected to complete each session over a week and in consecutive order. In this tentative study, four sessions were made for four weeks. Each session included a different number of videos and exercises and one weekly diary activity (Table 1). In order to explore what was a suitable number of videos and exercises in each session and length of videos, we provided a different number of videos and exercises sessions in the pilot version. Therefore, the volume of videos varied in each session. The total minutes of videos in each session ranged from approximately 23 to 66 minutes (Table 1).

Table 1. Content for relapse prevention course of e-SMARPP pilot version.

Session	Video	Minutes and seconds of video	Exercise	Weekly diary
1	Mental and physical consequences caused by drug use	8' 39"	Think about your pros and cons for use/quitting drug use.	"How did you spend last week? How about drug use, emotions, events, etc?"
	What is dependence? Changes in the brain	12' 24"	Define drug use situations: when, where, who, why, what, and emotion.	
	How to stop thinking about drugs	7' 56"	Think about how to reduce cravings for drugs.	
2	Process of craving and drug use	6' 38"	Define your triggers. Find your anchors.	"How will you spend next week? How about expected triggers, schedule, goals, etc?"
	Triggers of craving	11' 32"		
	Anchors keeping you from the drug	5' 25"		
3	Process and stage of recovery	13' 34"	Think of your signs of difficult times and barriers to recovery.	
	Safe lifestyle and signs of relapse	10' 54"	Plan a safe holiday schedule without drugs.	
	How to plan a safe schedule	7' 23"		
4	Novel psychoactive substances	11' 13"	Think about how to reduce or quit alcohol.	
	Prescription drug and over the counter drugs	14' 23"		
	Alcohol	12' 32"		
	How to quit or reduce alcohol	15' 24"		
	Cannabis	12' 00"		

Video and Exercise Content

Content for the videos and exercises were mostly taken from the SMARPP workbook. Although SMARPP has a considerable amount of content, we selected core content focused on encouraging drug users who have just started to seek treatment. These contents did not depend on the type of drug. We also added content from relevant books and websites if needed. Videos made in a YouTube format were embedded in each session (Figure 1 shows this). Narration and subtitles helped users understand the content. Exercises were based on the video content and users were expected to complete the exercises after watching the videos. Users wrote their own answers on an Internet text form and submitted the forms (Figure 2 shows this). As for the weekly diary activity, users were expected to write down their condition from the last week, current goals, and how they planned to spend time over the next week. Writing for the diary was also done on the Internet through the system. After submission of exercises and the weekly diary, users received tailored feedback from researchers.

The self-monitoring calendar in e-SMARPP was newly developed, using a plug-in from Moodle, to provide a function similar to the self-monitoring process utilized in SMARPP. Participants clicked on a date in the calendar and selected one

of three colors (red, yellow, or blue), with that color subsequently displayed on the date (Figure 3 shows this). The colors represent drug use: red reflecting abuse of the primary drug; yellow reflecting secondary abuse of other drugs and alcohol use, or alcohol use; and blue indicating no drug or alcohol use. Instructions and a legend for the colors were not displayed on the Web page to avoid concerns about confidentiality. At registration, users were given an explanation about the colors and how to use the calendar. This calendar only attempted to assess daily drug use without quantity or frequency-a-day. Because primary abuse of drugs were considered to vary and could not be adequately compared, we prioritized the development of a user-friendly program, and as such, did not provide several options for drug names and units and involve a complicated calculation system.

The self-monitoring calendar was also similar to the Timeline Followback (TLFB) method that retrospectively assesses drug use [42,43]. Although the TLFB method was developed to obtain self-reports on alcohol use with a paper-and-pencil approach, it has been extended to other behaviors and moreover Web-based versions have been developed with good reliability and usability [44-47]. During the intervention, participants were expected to check daily drug use and submit this at the weekly deadline (each Sunday).

Figure 1. Video page screenshot.

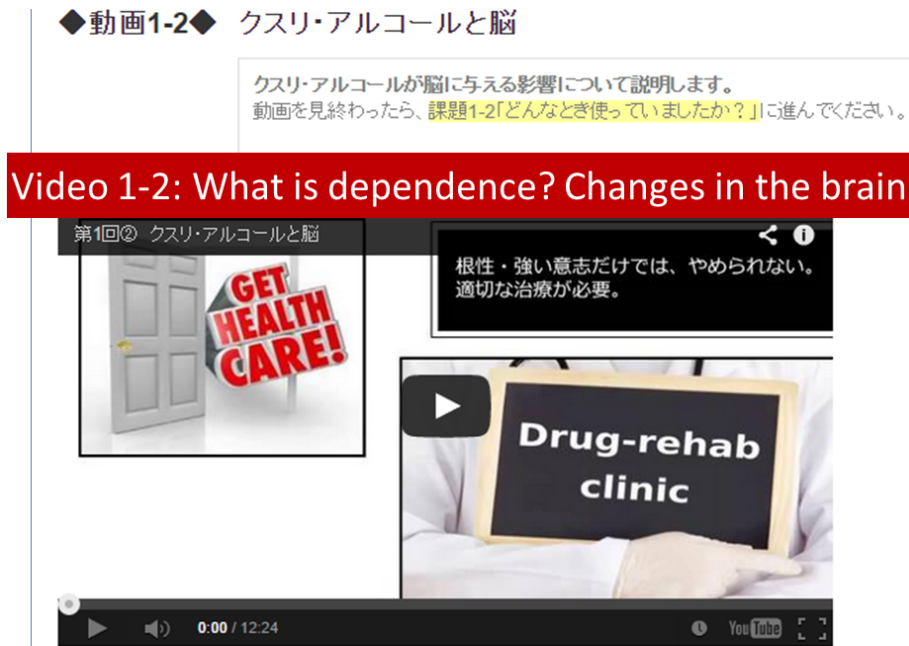


Figure 2. Exercise page screenshot.

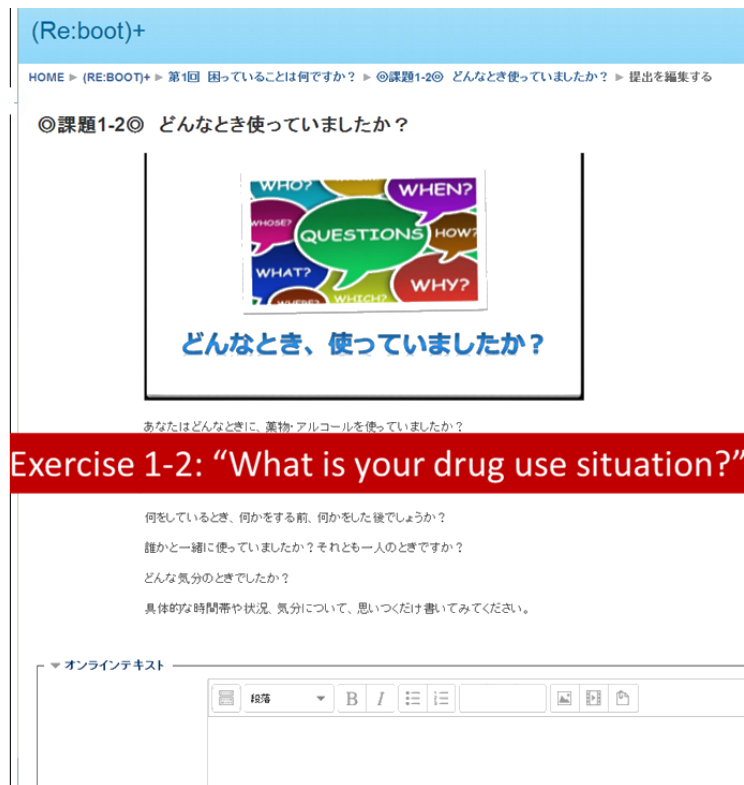
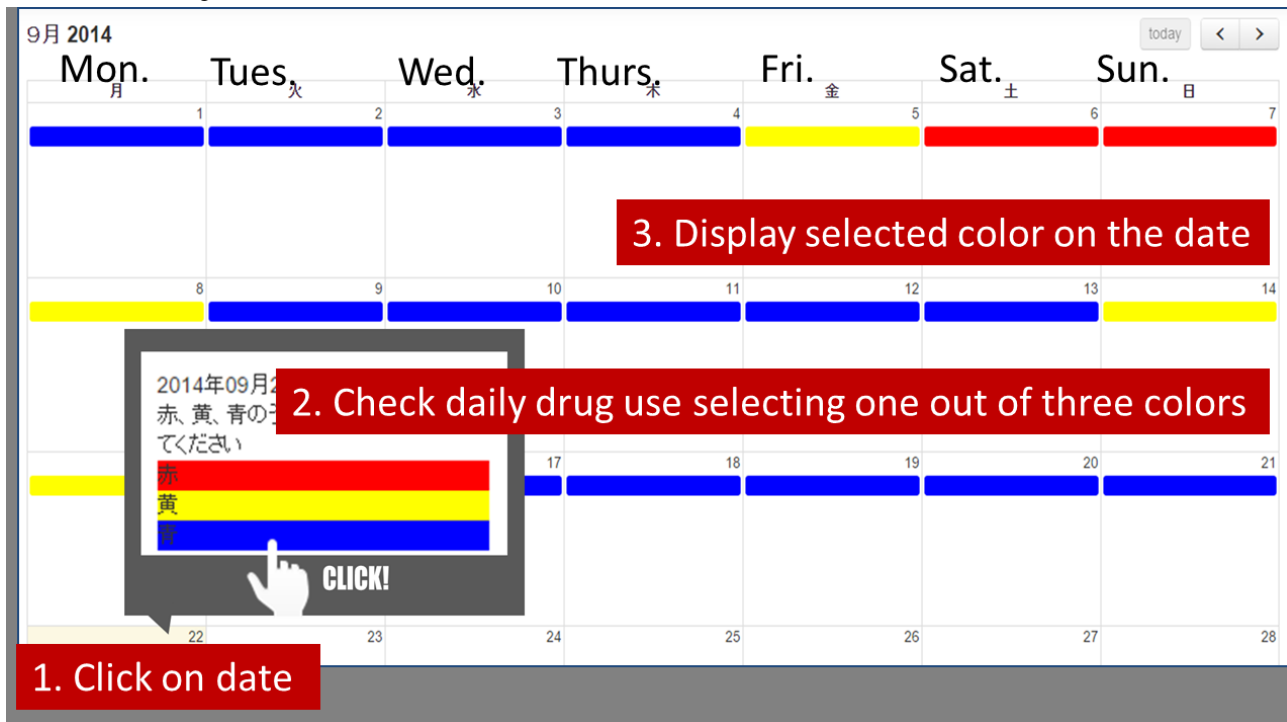


Figure 3. Self-monitoring calendar.



Human Involvement and Automated Functions

Researchers qualified as health care professionals (registered nurse or medical doctor) and trained to support substance use disorders, provide personalized feedback comments within one or two days every time participants submitted exercises and the weekly diary. Feedback comments were based on motivational interview skills to enhance user motivation and to provide individual support. The researchers would send the users an email reminder on Monday if the users did not submit their exercises, diary, and self-monitoring calendar by each Sunday deadline.

e-SMARPP had some automated functions, including tracking progress for users, and a notification email for users when they received feedback, and for researchers when users submitted an exercise, diary, and questionnaire. In the notification emails, a related Web page link, for example, feedback comments page, is shown and users can access the Web page directly.

Acceptance and Usability Study

Participants

We enrolled adults 20 years old and older who had been diagnosed in the past with substance use disorders, excluding alcohol, at the outpatient ward of the National Center of Neurology and Psychiatry (NCNP) and at nonprofit rehabilitation Drug Addiction Rehabilitation Center (DARC) institutes located in the Kanto region of Japan from March to April in 2014. DARC is operated by peer staff that have experienced drug dependence problems and are recovering at DARC. Additional inclusion criteria were: (1) those who could access the Internet via PC, mobile phone, and tablet, or tablet computer and exchange emails; (2) those without serious physical and psychiatric symptoms; and (3) with permission for participation in this study by psychiatrists at the NCNP or

from DARC staff. Participants were given an explanation about this study with flyers provided by the researchers. At DARC, we asked DARC staff to refer DARC users to researchers and to participate in the study voluntarily. Because this study was a pilot and a first trial, we sought out a variety of comments from people dealing with drug problems at different stages of recovery. We thought opinions of people who had experience with drug use and recovery from drug dependence were of some help to developing an effective and user-friendly program. Therefore, we also invited DARC staff that had quit using drugs for more than a year to participate. In total, 12 people (the NCNP=3 and DARC=9) volunteered to participate.

Procedure

Applicants were given an explanation about the aims and procedures of this study. If they agreed to participate, they were registered at the e-SMARPP website by the first author and given an explanation about how to use e-SMARPP and participate in the tasks in this study. Then, they were asked to complete the baseline assessment on e-SMARPP and received a prepaid card for 1000 yen as a reward.

Participants participated in the program over four weeks. During each week, they were to go through a session and submit self-monitoring data on Sunday. If they did not complete the session and the self-monitoring by each deadline, researchers sent emails once or twice as a reminder. Information and a user guide were optional content. After the four weeks, participants completed a post survey.

The Ethics Committee of The University of Tokyo and the Ethics Committee of the NCNP approved this study. We received approval from the staff director of DARC before recruitment.

Measures

Baseline Assessment

Sociodemographic information was gathered including age (years), sex, marital status, cohabiter, educational history, employment status, and condition of Internet use (use days per week, hours per day, and main devices to access).

Information about history of drug use was also gathered. Primary drug of problems was assessed with the optional category of drug (methamphetamine, cannabis, NPS, prescription drug, organic solvent, cocaine, lysergic acid diethylamide: LSD, 3, 4- methylenedioxymethamphetamine: MDMA, heroine, over-the-counter drug, and other). If participants answered NPS as a primary drug, we also asked about its form (herb, liquid, and powder). Drug use in the past 28 days was collected using the self-monitoring calendar based on the TLFB method. In addition, we assessed multi-substance abuse (yes/no), onset age (years), first-abused drug as in the same category as the primary-abused drug, abstinence duration calculated from the day when they last used a drug, experience of past arrest (yes/no), past experience in a correctional facilities (yes/no), and self-reported psychiatric comorbidity with an option to select a diagnosis based on the International Classification of Diseases-10. Similarly, we evaluated history of treatment in several ways: duration of psychiatry outpatient ward, number of psychiatry hospitalization, specialized treatment for drug problems in the past (yes/no), and self-help group use (yes/no).

In order to assess severity of drug use problems in the past year, we used the Japanese version of the Drug Abuse Screening Test (DAST-20), which consists of 20 binary items [48,49]. Total score ranges from 0 to 20 and a high score represents a severe condition. The total score was classified into the following five levels: None (0), Low (1-5), Intermediate (6-10), Substantial (11-15), and Severe (16-20). Furthermore, the Kessler-6 (K6) scale consisting of six items measured on a 5-point scale was used to assess psychological distress [50,51]. Total score ranged from 0 to 24 and a high score indicates severe distress. The optimal cut-off point is considered 4/5 for a mood and anxiety disorder [52].

Acceptance Outcome

The compliance rate for the intervention and surveys among applicants was evaluated. The post survey asked participants about devices used and where they most frequently accessed

e-SMARPP. Self-reported time needed to complete one exercise and one weekly diary and days needed to complete one session were assessed. We also asked about user experiences through four original questions: (1) “Do you think that number of session times was suitable?”, (2) “Do you think that the length of the videos was suitable?”, (3) “Do you think that exercises and the diary were difficult to answer?”, and (4) “Did you feel any harmful effects, for example, craving drugs or mental distress while using e-SMARPP?”

Usability Outcome

The Web Usability Scale was used to assess the overall usability of the e-SMARPP website. The Web Usability Scale consists of 21 items on a 5-point scale (1=disagree, 5=agree) and subscales: ease of use, ease in understanding structure, ease in reading, response speed, favorable, helpfulness, and credibility [53]. The average scores of each subscale were calculated and compared to each other. The Cronbach alpha coefficient in this study was .90, which meant the scale had good internal consistency. Next, to evaluate content usability in detail, the original 5-point scales (difficult, unhelpful, inadequate-easy, helpful, or adequate) were used as follows: degree of ease of use and helpfulness of content, degree of adequacy of feedback comments, and the most helpful/unhelpful content and their reasons. Finally, we gathered comments using description form questions to qualitatively evaluate content.

Statistical Analysis

Descriptive statistics were used to examine the characteristics of participants and outcomes related to acceptance and usability of e-SMARPP. Data were analyzed using Microsoft Excel (Office 2010). The answers from the description form questions were summarized according to e-SMARPP content.

Results

Participant Characteristics

Of the 12 eligible applicants, 83% (10/12) completed the baseline assessment. There were two that were excluded because of bad health and an unknown reason. Sociodemographic characteristics of the ten participants are shown in Table 2. Most of the participants were male and recruited from DARC. About 70% (7/10) graduated high school or college and had a full-time or part-time job. Most accessed the Internet everyday primarily from a mobile phone (70%; 7/10) or PC (30%; 3/10).

Table 2. Participant demographic characteristics at baseline (n=10).

Demographic characteristics	n	%
Sex		
Male	9	90
Age, mean (SD)	38.3	(5.6)
Recruitment setting		
Outpatient ward of psychiatry	1	10
Rehabilitation facility	9	90
Marital status		
Married	3	30
Never married	7	70
Divorced/widowed	0	0
Cohabiter		
Alone	3	30
Partner/parent/child/other	7	70
Years of education		
0-11 (< high school)	3	30
12 (high school)	3	30
13-15 (college)	4	40
16+	0	0
Employment		
Working (full-time)	4	40
Working (part-time)	3	30
Leave of absence	1	10
Unemployed (employed in the past)	1	10
Unemployed (never employed in the past)	0	0
Student/homeworker	0	0
Other	1	10
Internet use outside of job (days per week)		
1/ 2/ 3/ 4	0	0
5	1	10
6	1	10
7	8	70
Internet use outside of job (hours per day)		
0-1	1	10
1-2	5	50
2-3	0	0
3-4	2	20
4-5	1	10
5-6	0	0
6-7	1	10
7+	0	0
Internet access devices (most used)		
PC	3	30

Demographic characteristics		n	%
	Mobile phone	7	70
	Tablet computer	0	0

History of Drug Use and Treatment

Table 3 shows history of drug use and treatment among participants. Primary drugs were methamphetamine (80%), cannabis (10%), and NPS (10%). The first-abused drugs were different and most participants used various drugs at the same time. Average age of onset for drug abuse was at 17.7 years old (SD 4.8, range: 12-29 years old). Most of the participants had maintained drug abstinence for more than a year and had been involved in a self-help group. Meanwhile, their severity of drug abuse and psychological distress tended to be relatively serious.

Acceptance

Compliance Rate

Among ten participants who completed the baseline assessment, (60%) 6/10 completed all four sessions and (30%) 3/10 completed three or fewer sessions over the expected four weeks. Reasons for not completing sessions over the entire expected period were due to a full work schedule or reluctance. There was one participant (10%) that did not use e-SMARPP at all after the baseline assessment because of a recent family member death.

Of the ten participants who completed the baseline assessment, (80%) 8/10 responded to the post survey. However, there were missing variables because one participant (10%) did not complete a questionnaire.

User Experience

The device most commonly used to access e-SMARPP was a PC. Participants accessed most frequently from their home. The average minutes needed to complete one exercise and make diary entries were 9.5 (SD 5.6) and 9.3 (SD 5.7), respectively. This means that one session took about 43 to 86 minutes (average: about 60 minutes). Regarding days needed to complete one session, average days were 2.15 (SD 0.9) and median was 2.

Table 4 shows perceptions about e-SMARPP acceptance among the participants. More than half felt that the number of session times, one session per week, was suitable. However, many of them thought that the length of a video was too long. As for difficulty in responding to exercises and keeping a diary, more than half felt that this was basically easy. There were no participants that felt harmful effects while using e-SMARPP.

Usability

Overall Usability of the e-Serigaya Methamphetamine Relapse Prevention Program Website

Table 5 shows the scores of each subscale of the Web Usability Scale used for assessing the overall usability of the e-SMARPP website. All average scores of the subscales were over 3 points. The highest score among the subscales was credibility and the worst was favorability.

Table 3. History of drug use and treatment among participants at baseline (n=10).

History of drug use and treatment	n	%
Primary drug use problem (at baseline/ last drug problem)		
Methamphetamine	8	80
Cannabis	1	10
Novel psychoactive substances	1	10
Other ^a	0	0
Multi-substance abuse	Yes	9 90
Onset age of drug abuse, mean (SD)	Range: 12-29	17.7 (4.8)
First-abused drug		
Methamphetamine	1	10
Cannabis	3	30
Organic solvent	3	30
Other	3	30
Prescription/ designer drugs etc ^b	0	0
Abstinence duration		
< 1 month	1	10
1 month-1 year	0	0
1 year-3 years	6	60
> 3 years	3	30
Past arrest	Yes	7 70
Correction facility in the past	Yes	3 30
Comorbidity (multiple answers)		
No	7	70
Mood disorder	3	30
Sleep disorder	1	10
Psychiatry outpatient	Yes	6 60
Psychiatry outpatient length		
< 1 month	1	10
< 6 month	2	20
< 1 year	1	10
> 1 year	6	60
Past psychiatry admission	Yes	4 40
Past CBT	Yes	3 30
Self-help group use	Yes	9 90
Severity of drug abuse^c DAST-20 scores, mean (SD)		
Range: 13-19	15.5	(2.0)
None: 0/Low: 1-5/Intermediate: 6-10, n, (%)	0	(0)
Substantial: 11-15, n, (%)	6	(60)
Severe: 16-20, n, (%)	4	(40)
Psychological distress ^d , mean (SD)	Range: 1-16	7.3 (4.5)

^a Prescription, organic solvent, cocaine, LSD, heroin, MDMA, over-the-counter drugs and other.^b Prescription, novel psychoactive substances, cocaine, LSD, heroin, MDMA, and over-the-counter drugs.

^c DAST-20, range: 0-20.

^d K6, range: 0-24.

Table 4. Perceptions about e-SMARPP acceptance (n=8).

Questions	n	%
Number of session times		
Suitable	5	63
Less is better	0	0
More is better	0	0
No opinion	3	38
Length of a video		
Suitable	1	13
Shorter is better	6	75
Longer is better	0	0
No opinion	1	13
Difficulty in responding to exercise		
Difficult	0	0
Slightly difficult	2	25
No opinion	1	13
Slightly easy	3	38
Easy	2	25
Difficulty diary entries		
Difficult	0	0
Slightly difficult	2	25
No opinion	1	13
Slightly easy	2	25
Easy	3	38
Harmful effects		
No	7	88
Yes	0	0
Unknown	1	13

Table 5. Scores on Web Usability Scale to assess overall usability of e-SMARPP (n=7).

Subscales ^a	Mean	SD
Ease of use	3.48	0.92
Ease in understanding structure	3.43	0.68
Ease in reading	3.62	0.49
Response speed	3.43	0.95
Favorability	3.10	0.66
Helpfulness	3.71	0.60
Credibility	4.29	0.55

^a Each subscale consisted of 3 items on 5-point scale, 1=disagree, 5=agree.

Evaluation of Contents Usability

Tables 6 and 7 show data for the evaluation of usability of content and feedback comments. Videos were appreciated, however, some participants were not satisfied. Evaluation of exercise and diary was reasonable because some participants felt that these contents were helpful, but not easy to use.

Evaluation of self-monitoring tended to be slightly negative. As for the evaluation of feedback comments from researchers, most of the participants thought that feedback comments were necessary and more than half of them felt that feedback comments were adequate and helpful. The most helpful content varied among participants and the least helpful content was self-monitoring.

Table 6. Evaluation of usability of e-SMARPP content (n=8).

Contents	Ease of use			Helpfulness		
	Easy, n (%)	Neutral/Unknown, n (%)	Difficult, n (%)	Helpful, n (%)	Neutral/Unknown, n (%)	Unhelpful, n (%)
Video	5 (63)	2 (25)	1 (13)	6 (75)	1 (13)	1 (13)
Exercise	4 (50)	2 (25)	2 (25)	7 (88)	0 (0)	1 (13)
Diary	5 (63)	2 (25)	1 (13)	7 (88)	0 (0)	1 (13)
Self-monitoring	2 (25)	4 (50)	2 (25)	2 (25)	2 (25)	4 (50)

Table 7. Evaluation of adequacy of feedback comments from therapists (n=8).

Feedback/comments	Adequacy			Helpfulness		
	Adequate, n (%)	Neutral, n (%)	Inadequate, n (%)	Helpful, n (%)	Neutral, n (%)	Unhelpful, n (%)
For exercise	5 (63)	3 (38)	0 (0)	5 (63)	2 (25)	1 (13)
For diary	5 (63)	3 (38)	0 (0)	5 (63)	2 (25)	1 (13)
Necessity, n (%)	7 (88)	1 (13)	0 (0)			

Qualitative Evaluation of Content

Both positive and negative comments for content were gathered using descriptive form questions. Overall, participants felt e-SMARPP was effective because cognitive behavioral approaches had different therapeutic elements from a self-help program or typical outpatient treatment, even if they had received some previous treatment and support.

Videos were well received, however, many participants felt the length was too long and hard to view on a small mobile phone screen,

The information was new and easy to understand. I learned some things that I didn't know about. The videos were long, especially the one about people using drugs and having withdrawal symptoms. It was ambiguous that alcohol was included in drugs. [Male, an outpatient, DARC staffs and users]

As for exercises and the weekly diary, many participants felt it valuable to have time to think about their problems and drug-use/nonuse schedule. They recognized that they were motivated and felt connected with supporters by feedback comments from the researchers. However, there was a comment that interaction with the researchers was limited. Some participants had some difficulty using the system and some Moodle functions over a mobile phone; for example, it was awkward to write long sentences. There was one participant that could not see feedback comments because he received garbled notification emails on the iPhone and could not access the Web page of the feedback comments directly. Although

there were problems with compatibility in the character code on the iPhone email app, garbled characters were not found when he accessed the e-SMARPP website via a Web browser. Regarding the exercises,

I was able to think about my disease again. It was a good opportunity. I was motivated to see the videos because there were exercises. The feedback comments were good and encouraged me. It would be easier to respond if the questions were more focused and detailed. [Male, DARC staffs and users]

Regarding the weekly diary,

I was able to review my life every week and confirm goals for the next week. It was valuable because it was the only part where I could freely write down some of my thoughts. Feedback comments gave me some calm and different ways of thinking. [Male, DARC staff and users]

The comments about self-monitoring tended to be critical. There was one participant who just started to receive treatment that felt that it was helpful. On the other hand, participants who had received various support and were able to maintain drug abstinence for several years felt that it was not necessary to check their condition every day.

In addition, some participants mentioned technical and user interface difficulties, such as slow response speed or being likely to forget to check sometimes because the self-monitoring was put on a different Web page from the relapse prevention course. Some comments included,

It was not necessary for me because I have been able to maintain my drug abstinence. I did not feel that it was helpful because I checked the same color condition all at once. It was troublesome to input my daily condition. Batch input would be better if possible. [Male, DARC staffs]

Discussion

Principal Results

We developed a pilot version of a Web-based cognitive behavioral relapse prevention program to assist people who want to address their drug problems. This e-SMARPP program was piloted and reasonably accepted, although the sample size of the study was small and participants' ideas were a subset of all the ideas of the participants. The participants were satisfied with the relapse prevention sessions including videos, exercises, and diary activity; however, the self-monitoring was not favorably considered.

There were critical functional defects, although serious adverse events were not observed during the intervention. Further improvements are suggested.

Development of the Pilot Version

When we developed the website and content, we tried to match the system to the needs of our target population. We discussed what a usable system would look like with drug users and therapists and incorporated their ideas into e-SMARPP. In one instance, we made videos with narrations and subtitles because some of those surveyed said they did not want to read Web pages with too much text and difficult Kanji characters. We decided to make content that was easy to understand and strived for favorable impressions by using videos. Additionally, we developed an accessible website and content that could be viewed via any device because mobile devices are very common in Japan for personal Internet use [54]. The Internet penetration rate is more than 90% among people age 13 to 59 in Japan and it has been increasing year by year [54]. Mobile phones have been more popular among young-middle age people, including drug users. In contrast, the Internet penetration rate is low among people with a low household income. Drug users who have withdrawal symptoms and mental disease comorbidity are considered to have difficulty with concentration and use of a Web-based program. Therefore, it is important to provide user-friendly content with a low cost. This will require further consideration in future revisions of the program.

We utilized an existing evidence-based face-to-face relapse prevention program to develop the new Web-based program based on previous studies [13,14,24,26]. The new Web-based program has key elements of a typical relapse prevention program and is promising in terms of efficacy for addressing drug use problems. In Japan, most face-to-face programs for drug users deal with problems of various drugs. Accordingly, e-SMARPP was developed with versatility to assist in handling common problems among drug users. We think e-SMARPP will be useful for researchers who want to know about programs for various substances, including methamphetamine.

Although a program with feedback from Web-therapists raises concern about scalability, we thought these functions to motivate users were necessary because treatment retention is very important for abstinence and recovery. Drug users mostly have ambivalent thoughts and it is essential to have motivational enhancement. A complete self-guided program requires more automated functions with complicated algorithms to support a personalized program. In addition, if we create a complete self-guided program and recruit drug users who do not receive any treatment and support by Internet or offline methods, we have to add a system to confirm the eligibility of people with drug problems and develop a different recruitment strategy. At this time, this was felt to be unrealistic for our study. We think e-SMARPP will be used as an extension of care or a partial replacement of standard treatment, similar to the work by Marsch et al [55], especially as at this point it might be difficult to recruit drug users who do not receive any treatment and support. Our program was similar to previous interventions in terms of intervention approach and adjunct treatment; however, there were some differences as our system was location independent and included human involvement by Web-therapists. The participants could use e-SMARPP anywhere, which was a more real world setting. They also obtained personalized feedback from researchers in a manner similar to real counseling. We plan to do a randomized controlled trial to assess the efficacy of our program, and then we hope to add a Web-recruitment system and recruit drug users who do not receive any treatment and support. If we can collaborate with primary care settings and community-based support, e-SMARPP will be widely used and helpful for those who are not receiving behavioral therapy.

Acceptance and Usability Study

There are two thirds of the participants that completed all of the sessions and most felt that the frequency, one session a week, was suitable. There was one third that did not complete all the sessions because of other work commitments and low motivation. Participants took a total of approximately 60 minutes over two days to complete one session. This was not overly protracted, as the time needed to complete one session in this study was similar to times in other previous studies, where for example, in another program, one session took 45 minutes with a total of six sessions [14,24] and in another program, 60 minutes with a total of nine sessions [26]. In general, the session time of the Web-based interventions ranged from 20 to 60 minutes and tended to be shorter if the number of sessions was more frequent [12,19]. The number of sessions in an intervention study tends to be limited and session time tends to be longer than in a real setting because it is difficult to conduct frequent sessions over a long period, although intensive and long-term intervention is necessary to recover from drug dependence. For this reason, many participants felt the length of the videos were too long and also had difficulty watching them on a small mobile phone screen. In order to motivate busy and reluctant drug users to engage in the program, the videos should be shorter and include content focused on skills to avoid relapse, rather than educational content to provide knowledge about the dangers of drugs. Additionally, it is necessary to make improvements that facilitate a user-friendlier mobile phone interface. Measures to

prevent drop out may also be necessary with a more suitable session time and improved content because the attrition rate of Web-based studies is likely to be higher than that of face-to-face interventions [56].

Most of the participants felt that the relapse prevention sessions were useful and helpful. They felt that there were new elements in the Web-based cognitive behavioral relapse prevention program even if they had gone through the 12-step program and/or psychiatric treatment. In contrast, except for one participant that was still currently using drugs, the majority of participants were not satisfied with the self-monitoring because it was boring for those who already had maintained a lengthy period of drug abstinence. The self-monitoring may be more important for drug users that currently or have recently used drugs. As such, the helpfulness and efficacy of the self-monitoring needs further study. While using the e-SMARPP, none of the participants felt an increased craving for drugs or added mental distress. This individual Web-based program may be suitable for drug users who are likely to be negatively influenced by others.

The results of the Web Usability Scale suggested that the overall usability of the website was reasonable. Most of the participants felt that the website and content were easy to use. However, one participant who used an iPhone received emails with unreadable characters because the characters were device-dependent. Functional defects, including garbled characters and the user interface for moving between Web pages, need to be considered and revised.

Future Directions

In accordance with the results of the acceptance and usability study, five key improvement items were identified: (1) simplify the content of the relapse prevention sessions; (2) improve usefulness of the self-monitoring; (3) prevent noncompletion of the intervention; (4) address functional defects; and (5) obtain real comments and ideas from participants and drug users through a focus group interview.

Limitations

There were some limitations to this study. First, the generalizability of the results is limited due to the small sample size and some participants had previously received treatment and support, including CBT. Additionally, recruitment was done at only three settings. Second, usability and compliance in terms of Web-based programs depends on individual Internet literacy and computer skills [57,58], but we did not assess this. Finally, all outcome measures were self-reported, and not based on access logs, and as such, actual times needed to complete sessions may not be accurate.

Conclusions

A new Web-based cognitive behavioral relapse prevention program for drug-abuse treatment, named e-SMARPP, was implemented and considered usable. Challenges were addressed and improvement points suggested. Although there are challenges to address in further development, this program and similar technology implementations are promising approaches for treatment in Japan, especially as drug-use stigma is strong in this society. After updates to the pilot version, further research is necessary to confirm its efficacy.

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Authors' Contributions

AT conceived the study, developed the piloted program, and drafted the manuscript. YM and NK contributed to the study design and helped to draft the manuscript. TM supported to develop program and recruit participants and advised about responses to participants.

Conflicts of Interest

None declared.

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Abbreviations

- app:** application
- CBT:** cognitive behavioral therapy
- DARC:** Drug Addiction Rehabilitation Center
- DAST:** Drug Abuse Screening Test
- K6:** Kessler-6 scale
- NCNP:** National Center of Neurology and Psychiatry
- NPS:** new psychoactive substances
- PC:** personal computers
- SMARPP:** Serigaya Methamphetamine Relapse Prevention Program
- TLFB:** Timeline Followback

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Original Paper

Automated Remote Monitoring of Depression: Acceptance Among Low-Income Patients in Diabetes Disease Management

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Abstract

Background: Remote patient monitoring is increasingly integrated into health care delivery to expand access and increase effectiveness. Automation can add efficiency to remote monitoring, but patient acceptance of automated tools is critical for success. From 2010 to 2013, the Diabetes-Depression Care-management Adoption Trial (DCAT)—a quasi-experimental comparative effectiveness research trial aimed at accelerating the adoption of collaborative depression care in a safety-net health care system—tested a fully automated telephonic assessment (ATA) depression monitoring system serving low-income patients with diabetes.

Objective: The aim of this study was to determine patient acceptance of ATA calls over time, and to identify factors predicting long-term patient acceptance of ATA calls.

Methods: We conducted two analyses using data from the DCAT technology-facilitated care arm, in which for 12 months the ATA system periodically assessed depression symptoms, monitored treatment adherence, prompted self-care behaviors, and inquired about patients' needs for provider contact. Patients received assessments at 6, 12, and 18 months using Likert-scale measures of willingness to use ATA calls, preferred mode of reach, perceived ease of use, usefulness, nonintrusiveness, privacy/security, and long-term usefulness. For the first analysis (patient acceptance over time), we computed descriptive statistics of these measures. In the second analysis (predictive factors), we collapsed patients into two groups: those reporting "high" versus "low" willingness to use ATA calls. To compare them, we used independent *t* tests for continuous variables and Pearson chi-square tests for categorical variables. Next, we jointly entered independent factors found to be significantly associated with 18-month willingness to use ATA calls at the univariate level into a logistic regression model with backward selection to identify predictive factors. We performed a final logistic regression model with the identified significant predictive factors and reported the odds ratio estimates and 95% confidence intervals.

Results: At 6 and 12 months, respectively, 89.6% (69/77) and 63.7% (49/77) of patients "agreed" or "strongly agreed" that they would be willing to use ATA calls in the future. At 18 months, 51.0% (64/125) of patients perceived ATA calls as useful and 59.7% (46/77) were willing to use the technology. Moreover, in the first 6 months, most patients reported that ATA calls felt private/secure (75.9%, 82/108) and were easy to use (86.2%, 94/109), useful (65.1%, 71/109), and nonintrusive (87.2%, 95/109).

Perceived usefulness, however, decreased to 54.1% (59/109) in the second 6 months of the trial. Factors predicting willingness to use ATA calls at the 18-month follow-up were perceived privacy/security and long-term perceived usefulness of ATA calls. No patient characteristics were significant predictors of long-term acceptance.

Conclusions: In the short term, patients are generally accepting of ATA calls for depression monitoring, with ATA call design and the care management intervention being primary factors influencing patient acceptance. Acceptance over the long term requires that the system be perceived as private/secure, and that it be constantly useful for patients' needs of awareness of feelings, self-care reminders, and connectivity with health care providers.

Trial Registration: ClinicalTrials.gov NCT01781013; <https://clinicaltrials.gov/ct2/show/NCT01781013> (Archived by WebCite at <http://www.webcitation.org/6e7NGku56>)

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KEYWORDS

technology assessment; telecommunications; telemedicine; patient care management; clinical decision support systems; depression; diabetes mellitus; safety-net clinics

Introduction

In late 2014, the Centers for Medicare and Medicaid Services (CMS) issued new rules that expanded provider reimbursements beginning in 2015 for remote monitoring of Medicare beneficiaries [1]. Telemedicine and telehealth—or, what Kvedar and colleagues refer to collectively as “connected health”—capitalize on advances in health information technology (HIT) to remotely provide health care services, information, health education, and self-management support [2]. A number of studies have demonstrated the potential of these technologies to increase access and quality of care while decreasing health care costs [3-8].

Given the mounting evidence for the clinical and cost effectiveness of connected health, the CMS ruling is likely to boost interest in its adoption. Attempts to improve patient care with connected health, however, will be futile unless patients accept these technologies. Prior studies suggest that individuals who do not accept technologies simply will not use them [9,10]. Indeed, so critical is user acceptance that it has been regarded as “the pivotal factor in determining the success or failure of an information system” [11]. In an editorial review of connected health technologies to support behavior changes for self-management, Piette [12] remarks that patients' discontinued use, which results from a lack of acceptance, has largely hindered large-scale implementation. Therefore, it is clear that patient acceptance has important implications for the broader domain of connected health, since patients who do not accept (and thus do not use) these technologies will not realize the full benefits of them, resulting in a loss for both patients and payers.

This study investigates patient acceptance of an automated telecommunications system designed to facilitate depression care management of low-income patients with diabetes in a safety-net care system [13,14]. There is evidence of significant disparities in receipt of depression treatment in low-income, uninsured, and minority populations. These groups are less likely to receive depression care [15-19], show greater treatment discontinuation [20], and experience higher rates of clinically significant depression. Patient barriers to depression care influence detection and treatment processes. For example, minority patients are less likely to voluntarily report depressive

symptoms, may view depression as a moral weakness or character flaw instead of an illness, may be more likely to ascribe symptoms of depression to a physical illness [21,22], and may refuse or discontinue treatment due to stigma [23]. Nonadherence to depression treatment in minority groups with diabetes is common, due in part to side effects of diabetes medications [24-26]. Further exacerbating the challenges are cost and complex patient-provider interactions inherent in caring for patients with comorbid chronic illnesses. For instance, prioritizing among competing demands may negatively affect initiation and long-term follow-up of depression management in primary care [27-34].

To address these issues in order to accelerate the adoption of evidence-based depression care [24,35], we designed an advanced automated telephonic assessment (ATA) system. It had the capability to inquire—via periodic telephone calls to patients—about important aspects of depression care using a combination of the following six modules: monitoring for depression, assessing pain, assessing adherence to antidepressant medications, assessing psychotherapy practice, prompting depression self-care activities, and allowing patients to request contact from a clinician [14]. The ATA system was fully integrated into an existing disease management registry (DMR), which allowed it to automatically select these modules and the frequency of calls depending on individual patient clinical data: results from previous ATA calls or clinical assessments (depressed patients were called monthly, nondepressed patients quarterly), whether patients had an active antidepressant medication prescription, and whether patients were receiving psychotherapy. It also allowed patients to indicate their preferences for language (English or Spanish), call days and times, and receiving human calls instead of machine calls. If a call was not answered, the ATA system attempted again three times per day for 7 days (morning, afternoon, and evening). As a whole, the design allowed the ATA system to individually customize calls to focus on patients' specific needs and preferences rather than having patients adapt to standard comprehensive assessments, in essence illustrating the philosophy of patient-centered care.

Moreover, the ATA system facilitated timely, proactive follow-up by clinicians and staff. Data captured on the ATA calls were automatically assessed and the results sent to the

DMR for clinician and staff review [14]. Notifications, tasks, and alerts were triggered in response to specific issues identified from the ATA calls: patient requests for contact, high depression scores, nonadherence to antidepressant medications, or suicidal ideation.

The ATA system was tested in the Diabetes-Depression Care-management Adoption Trial (DCAT) [13]. DCAT was a 12-month, quasi-experimental comparative effectiveness research trial conducted in collaboration with the Los Angeles County Department of Health Services (LACDHS) with the aim of comparing different approaches for accelerating the adoption of collaborative team depression care in routine safety-net primary care practice. The study was conducted in its ambulatory care clinics serving low-income, racially/ethnically diverse (but primarily Hispanic/Latino) patients. It tested three depression care delivery models: usual care (UC), supported care (SC), and technology-facilitated care (TC). UC represented the status quo, whereby primary care providers (PCPs) and their staff initiate the translation and adoption of depression care evidence. Both SC and TC included care teams of the LACDHS disease management program (DMP) for the first 6 months of the trial to support diabetes care as well as depression care using evidence-based protocols [36]. After 6 months, patients returned to their PCPs for care. The difference between SC and TC was that the latter utilized the ATA system for 12 months to facilitate automated depression screening and monitoring, and timely follow-up by clinicians and staff. The provider notifications, tasks, and alerts generated by the ATA system were sent to DMP teams during the first 6 months of DCAT and to PCPs and their staff during the second 6 months.

If such automated remote screening and monitoring of depression—and more broadly, connected health—is to be integrated into mainstream health care delivery to help reach the important policy goal of expanding access to high-quality, effective, and efficient care, an understanding of patient technology acceptance is urgently needed. Studies on remote assessment and monitoring via connected health, however, continue to overlook this important research area [35,37]. Those that do touch upon elements of patient acceptance tend to be cross-sectional and operationalize the construct using measures

of patient satisfaction with care, which in itself reveals little about technology acceptance or how to design the system to improve patient acceptance.

The present study echoes the information technology literature [38-40] by measuring technology acceptance as patients' willingness to use ATA calls as part of their depression care. Moreover, this study is longitudinal, which allows for an understanding of how patient acceptance may change over time. Finally, to inform future design choices for automated remote depression monitoring technology, the evaluation includes several system characteristics that may explain why patients accept or reject the technology. Thus, in sum, the study was undertaken to (1) determine patient acceptance of ATA calls for remote depression screening and monitoring over time, and (2) identify what factors predict long-term patient acceptance of ATA calls.

Methods

Study Design and Participants

To answer the research questions, we analyzed data collected from patients in the TC arm of DCAT. English-Spanish bilingual interviewers administered assessments of technology acceptance at 6, 12, and 18 months. Thus, patients received two assessments during the study and one assessment 6 months after the study had ended.

Survey-Based Measures of ATA Call Acceptance

DCAT defined technology acceptance as patients' reported willingness to use ATA calls in the future as part of their depression care. The measurement was administered at 6, 12, and 18 months. DCAT also assessed additional measures of ATA call design characteristics: perceived ease of use (7 items), perceived usefulness (6 items), perceived nonintrusiveness (3 items), and perceived privacy/security (1 item). DCAT administered these assessments at 6 and 12 months. Moreover, patients' preference for mode of reach (1 item) was assessed at 6, 12, and 18 months. Finally, at 18 months, patients were asked about their long-term perceived usefulness of ATA calls (3 items). All measures were assessed on a 5-point Likert scale. [Table 1](#) provides the exact wording used in the DCAT assessments.

Table 1. Measures of patient ATA call acceptance.

Domain of measurement	Items	Administration
Willingness to use ATA calls ^a	To what extent do you agree or disagree with the following statement?	6, 12, and 18 months
	You would not mind receiving automated calls as part of your depression care in the future.	
Perceived ease of use ^{b,c}	“How often would you say...”	6 and 12 months
	The language used by Amy ^c in the calls was easy for you to understand?	
	Amy’s voice on the call was loud enough to hear without straining?	
	Amy was speaking too fast on the automated call?	
	You were clear on how to respond to Amy’s questions?	
	You had difficulty answering the questions when asked to press buttons on your phone?	
	Giving answers to a real person would have been easier than giving answers to the automated operator Amy?	
Perceived usefulness ^{b,c}	“How often would you say...”	6 and 12 months
	The call made you feel confident that your nurse or social worker knew how you were doing?	
	The calls made you feel like your nurse or social worker was more accessible?	
	The calls by Amy were just as effectiveness in reporting your feelings as an in-person visit with your care provider?	
	The antidepressant medication questions asked by Amy reminded you to take your medications?	
	The problem-solving skills questions asked by Amy reminded you to use these skills?	
Perceived nonintrusiveness ^b	“How often would you say...”	6 and 12 months
	You enjoyed receiving the calls?	
	You felt the calls were a bother?	
Perceived privacy/security ^a	To what extent do you agree or disagree with the following statement?	6 and 12 months
	You feel automated calls are private and/or secure.	
Preferred mode of reach	To what extent do you agree or disagree with the following statement?	6, 12, and 18 months
	Instead of receiving automated calls, you would prefer to call the automated service at your convenience.	
Long-term perceived usefulness ^a	To what extent do you agree or disagree with the following statements?	18 months
	The automated calls helped you be more aware of how you are feeling.	
	The automated calls reminded you to take care of your health, such as doing exercise.	
	The automated calls helped you stay better connected with your doctors, nurses or social worker.	

^aPatients responded using a 5-point Likert scale of agreement (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree).

^bPatients responded using a 5-point Likert scale of frequency (1=never, 2=rarely, 3=about half the time, 4=usually, and 5=always).

^c“Amy” was the persona of the ATA calls

ATA Call Completion Rates

We assessed the rate of completed ATA calls for three periods: 0-6 months, 7-12 months, and 0-12 months. An ATA call was defined as complete if it reached the patient and recorded answers to the depression assessment questions: PHQ-2 or PHQ-9, whichever was asked.

Statistical Analysis

We conducted two analyses: one to determine patient acceptance of ATA calls for remote depression screening and monitoring

over time, and the other to identify what factors predict long-term patient acceptance of ATA calls. Sample characteristics and sample sizes for each analysis are shown in the Results section (Table 2).

For the first analysis (patient acceptance over time), we included the DCAT TC arm patients who provided responses for a given survey-based measure at each of the measurement periods. By excluding patients who did not meet this criterion, we were able to estimate changes more accurately for each measure over time. We computed descriptive statistics of all measures. For those

measures consisting of multiple items, we computed the average points across items and rounded the average to the nearest integer. Furthermore, we conducted a paired *t* test to determine if there was a significant difference between the ATA call completion rates from 0 to 6 months and from 6 to 12 months. We also used Spearman rank correlation to test the association between the ATA call completion rate of months 0 to 12 and the survey-based measures of ATA call acceptance.

In the second analysis (predictive factors), we used a different criterion to select patients from among the pool of TC arm patients: patients who responded to the question of willingness to use ATA calls at 18 months and at least once at 6 or 12 months or both. If patients answered the question at both 6 and 12 months, we computed the average for use in the analysis. The 125 patients in this sample were collapsed into two groups: those reporting “high” willingness to use ATA calls at 18 months (Likert scale response of 4 or higher) and those reporting “low” willingness to use ATA calls at 18 months (all other response categories). We compared the descriptive statistics for the two groups: patient sociodemographic characteristics, health conditions, health care utilization, and ATA call completion rate. We also compared their responses for perceived ease of use, perceived usefulness, perceived nonintrusiveness, perceived privacy/security, preference of ATA call mode, and long-term perceived usefulness. If patients completed assessments of these measures at both 6 and 12 months, we computed the average of the two for use in the analysis. To compare the two groups of patients, we used independent *t* tests for continuous variables and Pearson chi-square tests for categorical variables. Next, we

jointly entered independent factors found to be significantly associated with 18-month willingness to use ATA calls at the univariate level into a logistic regression model with backward selection to identify predictive factors. Then, we performed a final logistic regression model with the identified significant predictive factors and reported the odds ratio estimates and 95% confidence intervals. All analyses were conducted at 0.05 significance level (2-tailed) using IBM SPSS software, version 22.0.

Results

Sample Characteristics

Table 2 provides the characteristics of patients in the two samples used in the two analyses. The majority of patients were female, Hispanic/Latino, and preferred Spanish as their primary language. The characteristics of the two samples were not significantly different from one another. A comparison of these samples with the rest of the patients in DCAT TC excluded from the analyses did reveal significant differences in characteristics (see Tables A-1 and A-2 in [Multimedia Appendix 1](#)). Compared to the rest of DCAT TC, the two samples had a greater proportion of Hispanics/Latinos, reported a higher willingness to use ATA calls at 6 and 12 months, and had a higher ATA call completion rate. The sample for the second analysis also had lower blood sugar values, better diabetes self-care, and reported higher perceived ease of use and perceived nonintrusiveness at 6 and 12 months compared to the rest of patients in the TC arm of DCAT.

Table 2. Patient characteristics for samples in the two analyses (no statistically significant difference between the two samples).

Characteristic	Sample for first analysis		Sample for second analysis	
	N	Statistics ^a	N	Statistics ^a
Female	109	72 (66.1%)	125	80 (64.0%)
Age	109	51.94 (9.01)	125	51.31 (8.81)
Hispanic/Latino	109	105 (96.3%)	125	116 (92.8%)
Spanish as preferred language	109	93 (85.0%)	125	104 (83.2%)
Married	109	49 (45.0%)	125	55 (44.0%)
PHQ-9 (range 0-27, higher=more severe depression) ^{b,c}	109	5.73 (4.93)	125	5.65 (4.60)
Total number of socioeconomic stressors ^c	109	2.28 (1.56)	125	2.37 (1.46)
SCL-20, mean score ^{c,d}	109	0.54 (0.53)	125	0.51 (0.48)
SF-12 mental (general population=50, higher=better) ^{c,e}	109	50.54 (9.15)	125	51.08 (9.03)
Time with diabetes in years	107	10.15 (7.42)	124	9.98 (7.05)
On insulin treatment ^c	109	82 (75.2%)	125	89 (71.2%)
BMI ^{c,f}	109	32.93 (6.55)	125	32.75 (6.16)
A1C value ^{c,g}	108	8.87 (1.39)	124	8.72 (1.39)
Low-density lipoprotein cholesterol ^c	108	167.08 (36.20)	124	168.44 (36.60)
Whitty-9 diabetes symptoms (range 1-5, 1=none to 5=every day) ^c	109	1.64 (0.54)	125	1.62 (0.49)
Number of diabetes complications ^c	109	1.26 (0.89)	125	1.22 (0.79)
Toolbert diabetes self-care in the past 7 days (range 0-7) ^c	109	4.63 (0.98)	125	4.65 (1.01)
Diabetes emotional burden (range 1-5, 1=not a problem to 5=very burdensome) ^c	109	2.53 (1.35)	125	2.48 (1.37)
Diabetes regime distress (range 1-5, 1=not a problem to 5=very burdensome) ^c	109	2.19 (1.14)	125	2.13 (1.17)
Self-rated health (range 1-5, 1=poor to 5=excellent) ^c	109	2.29 (0.60)	125	2.34 (0.60)
Chronic pain ^c	109	17 (15.6%)	125	24 (19.2%)
SF-12 physical (general population=50, higher=better health) ^{c,e}	109	43.18 (9.62)	125	43.17 (9.49)
Sheehan disability scale (range 0-10, 0=none to 10=extremely) ^c	109	2.21 (2.34)	125	2.14 (2.26)
Number of ICD-9 diagnosis ^{c,h}	108	8.60 (4.50)	124	8.46 (4.46)
Number of clinic visits ^c	107	10.44 (5.61)	124	10.56 (5.64)
Number of emergency room visits ^c	41	1.33 (0.61)	44	1.33 (0.60)
Number of hospitalizations ^c	15	1.47 (0.83)	18	1.39 (0.78)
Willingness to use ^c	109	4.02 (0.93)	125	4.00 (1.08)
Perceived ease of use ^c	109	4.05 (0.56)	125	4.12 (0.50)
Perceived usefulness ^c	109	3.63 (0.89)	125	3.69 (0.90)
Perceived nonintrusiveness ^c	109	4.20 (0.87)	125	4.29 (0.84)
Perceived privacy/security ^c	109	4.10 (1.11)	125	4.17 (1.08)
Preference of ATA call mode ^c	109	3.82 (1.06)	125	3.58 (1.32)
Long-term perceived usefulness	76	3.71 (0.92)	125	3.74 (0.99)
ATA call completion rate ^c	108	0.70 (0.26)	123	0.74 (0.24)

^aValues are numbers (column percentages) for categorical variables and mean (SD) for continuous variables.

^bPatient Health Questionnaire, 9 items

^cAssessment at 6 or 12 months. If both were available, then the average was taken.

^dSymptoms CheckList, 20 items

^eShort-Form Health Survey, 12 items

^fBody mass index

^gGlycated hemoglobin test

^hInternational Classification of Diseases, 9th revision

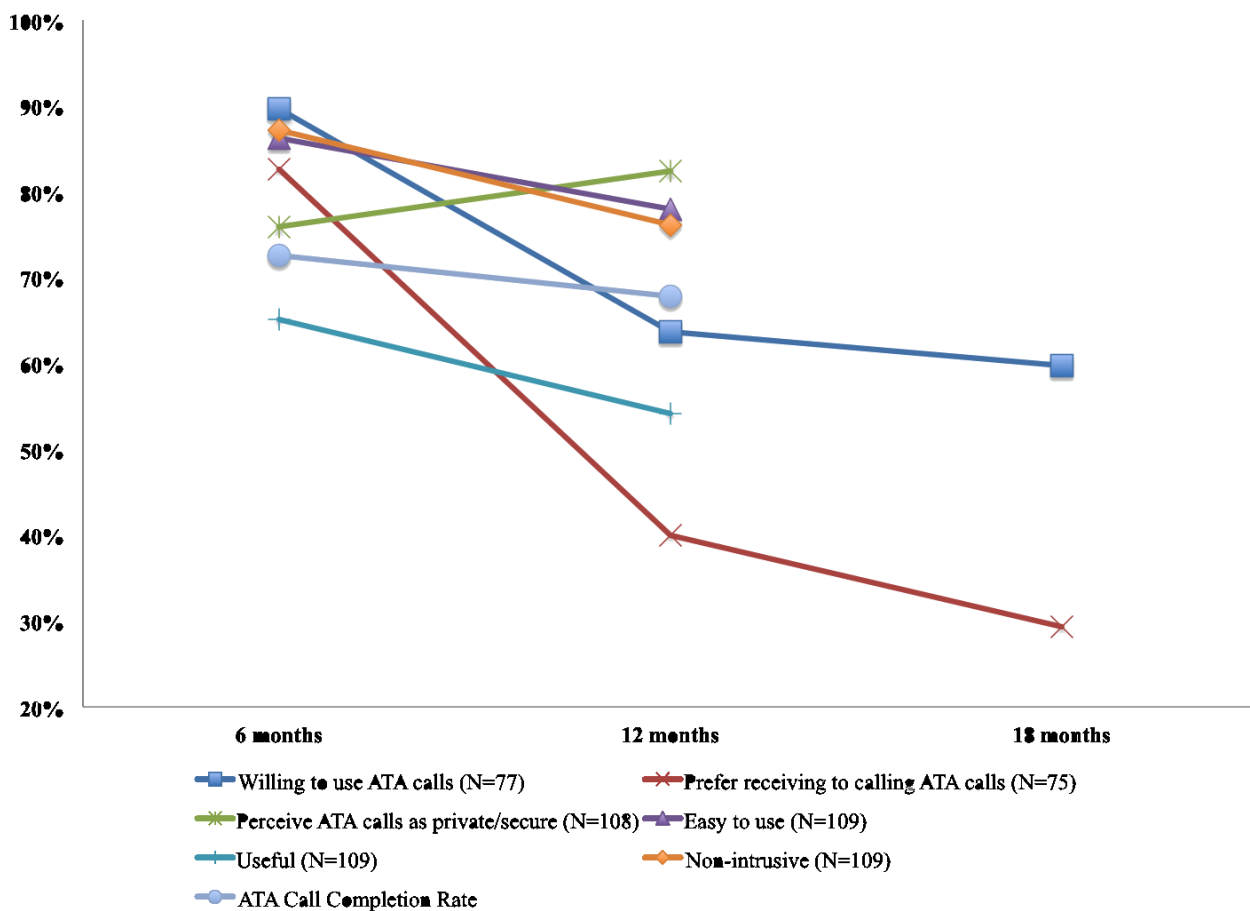
First Analysis: Patient Acceptance of ATA Calls Over Time

Figure 1 illustrates patient acceptance of ATA calls over time. In the first 6 months of the trial, 90% (69/77) of patients reported a high willingness to use ATA calls. At 12 and 18 months, however, the proportion of patients reporting a high willingness to use ATA calls decreased to 64% (49/77) and 60% (46/77), respectively. After 6 months in the trial, 83% (62/75) of patients agreed or strongly agreed that they would prefer to receive automated calls rather than calling the ATA system at their convenience. The proportion of patients reporting this decreased to 40% (30/75) and 29% (22/75) at 12 and 18 months, respectively. Throughout the trial, most patients agreed or strongly agreed that ATA calls felt private/secure (82/108 at 6 months, 89/108 at 12 months). At 6 months, 86.2% (94/109) of patients reported that ATA calls were usually or always easy to use. This number decreased to 78.0% (85/109) at 12 months.

The proportion of patients reporting that ATA calls were usually or always useful decreased from 65.1% (71/109) at 6 months to 54.1% (59/109) at 12 months. At the 18-month follow-up, 51.0% (64/125) of patients agreed or strongly agreed that the ATA calls were useful. At 6 months, most patients 87% (95/109) perceived that ATA calls were usually or always nonintrusive. More patients perceived the calls to be intrusive after 12 months in the trial as is evident from a decrease in the proportion of patients who reported otherwise 76% (83/109).

The ATA average call completion rate was 72.6% and 67.8% at 6 and 12 months, respectively—the difference between the two was not statistically significant ($P=.10$). In investigating the associations between the ATA call completion rate of months 0 to 12 (70.2%) and the various survey-based acceptance measures, only two measures were statistically significant: (1) perceived ease of use (Spearman correlation coefficient=0.25, $P=.008$) and (2) perceived nonintrusiveness (Spearman correlation coefficient=0.27, $P=.004$).

Figure 1. Patient acceptance of ATA calls over time.



Second Analysis: Factors Predicting Patient Acceptance of ATA Calls

We compared patients who reported, at 18 months, a high willingness to use ATA with patients reporting low willingness to use ATA calls to determine how the two groups differed in

terms of the various sociodemographic characteristics, health conditions, health care utilization, and ATA-related measures listed in Table 2. Table 3 provides results for characteristics where there was a statistically significant difference between the two groups. See Table A-3 in Appendix for full results.

Table 3. Characteristics of patients reporting high versus low willingness to use ATA calls at 18 months.

Characteristic	High willingness to use ATA calls at 18 months		Low willingness to use ATA calls at 18 months		<i>p</i> ^b
	N	Statistics ^a	N	Statistics ^a	
Toolbert diabetes self-care in the past 7 days (range 0-7) ^c	74	4.81 (0.95)	51	4.43 (1.05)	.03
Willingness to use ^c	74	4.17 (1.00)	51	3.75 (1.16)	.04
Perceived usefulness ^c	74	3.84 (0.82)	51	3.49 (0.97)	.03
Perceived nonintrusiveness ^c	74	4.42 (0.65)	51	4.09 (1.03)	.05
Perceived privacy/security ^c	74	4.42 (0.91)	51	3.81 (1.22)	.003
Long-term perceived usefulness	74	4.07 (0.91)	51	3.25 (0.91)	<.001

^aValues are numbers (column percentages) for categorical variables and mean (SD) for continuous variables.

^bTwo-sample *t* test

^cPatients' response at 6 or 12 months. If patients provided responses at 6 and 12 months, then the average of these was used.

When we compared patients who reported a high versus a low willingness to use ATA calls at 18 months, we found six factors to be significantly associated with patients' reported willingness to use ATA calls. Patients with a high willingness to use ATA calls at 18 months (1) had better diabetes self-care ($P=.03$) and (2) reported a higher willingness to use ATA calls while in the study ($P=.04$); they also reported (3) higher perceived usefulness ($P=.03$), (4) nonintrusiveness ($P=.05$), and (5) privacy/security ($P=.003$) while in the study. Moreover, patients who reported a high willingness to use ATA calls at 18 months also reported (6) higher long-term perceived usefulness ($P<.001$). We jointly entered the six factors into a logistic regression model with backward selection to identify predictive factors. The results revealed that two factors jointly predicted willingness to use ATA calls at 18 months: perceived privacy/security (odds ratio OR=1.59, $P=.017$, 95% CI [1.09, 2.33]) and long-term perceived usefulness (OR=2.77, $P<.001$, 95% CI [1.65, 4.63]).

Discussion

Principal Findings

The promises of connected health to efficiently improve access and quality of care [2], rest upon the assumption that patients will readily accept the technologies. Our study on safety-net patient acceptance of automated depression screening and monitoring using ATA calls has important findings suggesting that assumption may be questionable. In the first 6 months of the trial, most patients were accepting of ATA calls and perceived the calls to be private/secure, easy to use, useful, and nonintrusive. Over time, however, patients' acceptance and their positive perception of ATA call characteristics decreased—although call completion rates remained high and steady. One explanation may be that since ATA call results and prompts for follow-up were sent to DMP care teams during the

first 6 months of the trial and to PCPs thereafter, timely follow-up by the latter might have been challenging due to their busy practice loads. Thus, although patients continued to complete ATA calls in the second half of the trial, their PCPs may not have responded to their needs in a timely manner thereby leading them to doubt the value of ATA calls. Furthermore, patients' acceptance and their perception of ATA call characteristics may also reflect an improvement in their depressive symptoms over time. That is, patients with improved depressive symptoms—due, possibly, to the intervention itself—may no longer perceive the benefits of the ATA calls. We investigated this hypothesis and found that there was no statistically significant difference in the percentage of patients reporting high usefulness and high willingness to use ATA calls among those with improved symptoms, no change in symptoms, or worse symptoms. It may be, however, that our sample size was not large enough to detect these differences.

Another important finding in our study was the identification of two factors that significantly predicted patients' long-term acceptance of ATA calls: the perception that ATA calls are private/secure and the long-term perceived usefulness of ATA calls. These two factors could be potentially modified to improve patients' willingness to use ATA calls as part of their depression care.

Limitations

This study has limitations worth noting. First, we used two different samples for the analyses. For the sample used to determine patient acceptance of ATA calls over time, we included only those patients in the DCAT TC arm who responded to ATA-related measures at each of the corresponding measurement periods. For the sample used to identify factors that predict long-term patient acceptance of ATA calls, we included only those patients in the TC arm who answered the

question on willingness to use ATA calls at 18 months and at least once at 6 or 12 months. We chose to accommodate two sample sizes for our study in order to maximize the sample sizes for both analyses, although this may have introduced additional bias.

Second, although the two different samples for the analyses were not significantly different from each other, they were both somewhat different from the rest of TC patients who were excluded from the analyses because they did not answer any of the ATA-related questions. Samples used in the analyses reported a slightly higher willingness to use ATA calls at 6 and 12 months than TC patients excluded from the analyses. However, it is not likely that this limitation affected our findings because only a small percentage (about 10%) of patients excluded from the analyses refused to engage with ATA calls. Nearly 90% of them reported that they could not answer the ATA-related questions because they did not receive or did not remember receiving ATA calls, or they received calls but did not answer because they were unavailable.

Furthermore, the small sample size of 125 patients reporting on willingness to use ATA calls limits the robustness of our findings of factors predicting long-term patient acceptance of ATA calls. Future studies should validate the generalizability of our findings.

A final limitation is that in the analysis of factors predicting long-term acceptance, we defined acceptance as patients' self-reported willingness to use ATA calls at 18 months instead of using a more objective measure such as ATA call completion rate. This may seem to be a better indicator of patient acceptance, but since we were interested in learning about patients' *long-term* acceptance, we did not have the ATA call completion rate at 18 months (the intervention was only for 12 months). Moreover, in our qualitative study of DCAT TC patients with incomplete ATA calls, we discovered that patients were actually willing to take the ATA calls, but were unable to do so mainly because of nonintervention related reasons, including not being available, the ATA system having the wrong phone number, or experiencing connection issues [41]. For this reason, we assumed that if patients did not complete ATA calls, it was not due to a lack of acceptance. Therefore, given the DCAT study design and the practical reasons for patients not answering ATA calls, we chose to follow the Patient Technology Acceptance Model (PTAM) [39] and define acceptance as self-reported willingness (ie, intention) to use the technology.

Comparison With Prior Work

The finding that patients are generally accepting of ATA calls, albeit in the short term, is a promising start to our understanding of patients' perception of such technologies. Because automated depression screening and monitoring technology is emerging, little is known about patients' acceptance of it. Related studies of connected health technologies [42], including those focused on depression care [37,43-54], uncritically regard acceptance as patient satisfaction with care, which tells us little about why patients accept or reject the technology or how system design features affect patient acceptance. This study is significant in

the connected health literature for depression care in that it utilizes measures from the literature of user acceptance of new technologies [11,55,56]. These user acceptance measures allow us to derive new knowledge that helps not only to explain why the ATA system is acceptable or not to patients, but also to understand how we may improve patient acceptance through the design of the system.

Numerous studies on connected health applications have reported a drop in technology usage over time [57-67]. Unlike these studies, we found that patients' completion of ATA calls was high and constant throughout the trial. As mentioned above, the main reasons patients reported for incomplete ATA calls were not related to the intervention [41]. In fact, we found in an analysis not included in this paper that the survey-based measures of acceptance were not statistically significant predictors of ATA call completion rates. Nonetheless, as reported in the Results section, the ATA call completion rate was positively correlated with perceived ease of use and perceived nonintrusiveness. The significance of the former factor is in agreement with the PTAM. However, the finding that patients continued to complete ATA calls over time despite a general decrease in acceptance is surprising. Future research is needed to determine whether it was the special characteristics of the study population (ie, predominantly urban, low-income Hispanics/Latinos) or the technology design (ie, outbound calls to patients) that resulted in this finding.

The PTAM sheds light on factors that increase the likelihood that patients will be willing to use connected health technologies. Among a myriad of potential factors, the main ones predicting patient acceptance are perceived usefulness, perceived ease of use, subjective norm, and health care knowledge. Others have similarly reported that perceived usefulness and perceived ease of use are the main driving forces of patient technology acceptance [11,68,69]. Likewise, we found that long-term perceived usefulness of ATA calls significantly predicted patient acceptance of automated depression screening and monitoring. A new predictor of acceptance suggested in our analysis was patients' perception that calls were private/secure. Future patient technology acceptance research should consider this factor in the technology design and should validate the finding.

Conclusions

In the short term, safety-net ambulatory care patients with diabetes are generally accepting of ATA calls for depression screening and monitoring. How patient acceptance can be sustained over time is an important topic for future investigation. In order to increase the odds that patients will accept ATA calls over the long term, especially for sensitive mental health conditions, the system should gauge patient perception of its privacy/security. Moreover, it is critically important that the technology not only be aligned with patients' needs, but also be perceived as useful for them over the long term. Based on the items measuring long-term usefulness, future research should focus on designing and testing technologies that help patients be more aware of how they are feeling, remind them to take care of their health, and help them stay better connected with their health care providers.

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Conflicts of Interest

Jeffrey Guterman, reports a proprietary or commercial interest in the automated telephonic assessment system discussed in this article. For the remaining authors, none were declared.

Multimedia Appendix 1

DCAT TC Data.

[PDF File (Adobe PDF File), 395KB - [mental_v3i1e6_app1.pdf](#)]

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Abbreviations

ATA: automated telephonic assessment
BMI: body mass index
CMS: Centers for Medicare and Medicaid Services
DCAT: Diabetes-Depression Care-management Adoption Trial
DMP: disease management program
DMR: disease management registry
HIT: health information technology
ICD-9: International Classification of Diseases, 9th Revision
LACDHS: Los Angeles County Department of Health Services
PCP: primary care provider
PHQ: Patient Health Questionnaire
SC: supported care
SCL-20: Symptom Checklist, 20 items
SF-12: Short-form Health Survey, 12 items
TC: technology-facilitated care
UC: usual care

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Original Paper

Efficacy of Adolescent Suicide Prevention E-Learning Modules for Gatekeepers: A Randomized Controlled Trial

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Abstract

Background: Face-to-face gatekeeper training can be an effective strategy in the enhancement of gatekeepers' knowledge and self-efficacy in adolescent suicide prevention. However, barriers related to access (eg, time, resources) may hamper participation in face-to-face training sessions. The transition to a Web-based setting could address obstacles associated with face-to-face gatekeeper training. Although Web-based suicide prevention training targeting adolescents exists, so far no randomized controlled trials (RCTs) have been conducted to investigate their efficacy.

Objective: This RCT study investigated the efficacy of a Web-based adolescent suicide prevention program entitled *Mental Health Online*, which aimed to improve the knowledge and self-confidence of gatekeepers working with adolescents (12-20 years old). The program consisted of 8 short e-learning modules each capturing an important aspect of the process of early recognition, guidance, and referral of suicidal adolescents, alongside additional information on the topic of (adolescent) suicide prevention.

Methods: A total of 190 gatekeepers (ages 21 to 62 years) participated in this study and were randomized to either the experimental group or waitlist control group. The intervention was not masked. Participants from both groups completed 3 Web-based assessments (pretest, posttest, and 3-month follow-up). The outcome measures of this study were actual knowledge, and participants' ratings of perceived knowledge and perceived self-confidence using questionnaires developed specifically for this study.

Results: The actual knowledge, perceived knowledge, and perceived self-confidence of gatekeepers in the experimental group improved significantly compared to those in the waitlist control group at posttest, and the effects remained significant at 3-month follow-up. The overall effect sizes were 0.76, 1.20, and 1.02, respectively, across assessments.

Conclusions: The findings of this study indicate that Web-based suicide prevention e-learning modules can be an effective educational method to enhance knowledge and self-confidence of gatekeepers with regard to adolescent suicide prevention. Gatekeepers with limited time and resources can benefit from the accessibility, simplicity, and flexibility of Web-based training.

Trial Registration: Netherlands Trial Register NTR3625; <http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3625> (Archived by WebCite at <http://www.webcitation.org/6eHvyRh6M>)

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KEYWORDS

Adolescent; E-learning; Gatekeepers; Learning; Modules; Online Systems; Suicide; Prevention; Training; Web-based; Referral and Consultation

Introduction

According to the World Health Organization (WHO), approximately 1 million people die worldwide every year due to suicide [1]. Suicide is the second leading cause of death among 10- to 24-year-olds, and according to a WHO report, suicide rates are rising faster among adolescents compared to any other age category [1]. Moreover, for every adolescent suicide, there are at least 40 non-fatal suicide attempts [2]. Thus, the development and deployment of adolescent suicide prevention strategies are crucial.

Recently, it has become widely accepted that gatekeepers can play an essential role in suicide prevention; as a result, the training of gatekeepers has been identified as an important and promising prevention strategy [3-7]. Gatekeepers are professionals who, due to their profession, come in contact with people at-risk for suicide. Thus, the main purpose of training gatekeepers is to educate them in the necessary steps concerning recognition, guidance, and referral of these individuals [5,6,8]. For instance, primary health care providers, school staff, and police are all gatekeepers [3,7]. Several suicide prevention gatekeeper programs are available, which have been widely adopted (eg, Question, Persuade, Refer (QPR); Sources of Strength (SOS); Applied Suicide Intervention Skills Training (ASIST); Yellow Ribbon and safeTALK) [9]. QPR Gatekeeper Training [10] is one of the most well-known and used gatekeeper training programs in suicide prevention [11].

QPR Gatekeeper Training is based on the QPR model, which was developed and introduced in 1995 [10]. According to this model, three simple steps can be employed to prevent suicide attempts. First, gatekeepers must learn to recognize warning signs associated with suicide and learn how to ask questions about the presence of suicidal thoughts and feelings (Question). The earlier that warning signs are recognized and help is received by the at-risk individual, the better the outcome will be. Second, questioning those at-risk for suicide could lead to conversations during which the acceptance of referrals for help can be encouraged (Persuade). Lastly, referrals will lead to early intervention and treatment, which will lead to better outcomes (Refer) [10].

In recent years, several studies have investigated the efficacy of QPR Gatekeeper Training and the results are promising. These studies have targeted various types of gatekeepers, including Veterans Affairs staff, Veterans Health Administration staff, college residence advisers, university faculty staff, and social work students, and have shown that gatekeepers' actual or perceived knowledge and perceived self-efficacy with regard to suicide prevention improve after attending training [12-18]. Additionally, several research teams have studied the efficacy of QPR Gatekeeper Training in gatekeepers working with adolescents [11,19-21]. A randomized controlled trial (RCT) with an average 1-year follow-up period tested the impact of the training on school staff (health and social services staff,

administrators, teachers, and support staff) and showed enhancement of perceived knowledge, perceived efficacy, and preparedness of the trained gatekeepers to perform suicide prevention activities [19]. Another study using a nonequivalent control group design with a 3-month follow-up, demonstrated increased knowledge among trained teachers and counselors working in elementary, middle, and high schools [11]. Another nonequivalent control group design with a 3-month follow-up showed gains in knowledge and self-efficacy among trained school personnel at posttest [20]. Moreover, the self-efficacy gain was maintained at follow-up; however, this was not the case for knowledge. According to the authors, this could be explained by the limited subsample that completed the follow-up measures [20]. Finally, a study targeting faculty and staff who worked regularly with middle and high school students showed that the knowledge of participants increased after completing training [21].

The results of the discussed papers demonstrate that face-to-face gatekeeper training can be an effective strategy in the enhancement of professionals' knowledge and self-efficacy in adolescent suicide prevention. However, for several reasons, gatekeepers may be prevented from attending training sessions. The most critical barrier for gatekeepers is lack of time and resources to attend face-to-face training sessions. Another obstacle relates to the usually inflexible nature of face-to-face training: participants must take the entire training course, regardless of their prior knowledge and current needs. With the growth of Internet usage worldwide, new developments have occurred in the way people gather information; as a result, information providers are increasingly using this medium to transfer knowledge to their target groups [22]. In particular, the use of e-learning modules could be an effective technique to transfer adolescent suicide prevention knowledge to gatekeepers. "E-learning," also known as computer-based learning, online learning, distributed learning, or Web-based learning describes the use of computers to transfer knowledge to learners primarily through an intranet or the Internet [23]. This method has several advantages over traditional face-to-face training.

First, Web-based training is accessible from any location from which the gatekeeper has access to the Internet. Second, because information on the process of recognition, guidance, and referral of suicidal adolescents is presented in short separate modules, gatekeepers can customize their training. Lastly, this type of training can be composed and maintained with limited resources and as a result can be offered at a low price. Thus, gatekeepers could have easy, fast, and instant access to needed knowledge with regard to adolescent suicide prevention any time and from any location. Additionally, they can refresh their knowledge whenever needed. In 2012, a systematic review was carried out aiming to provide a first overview of existing e-learning modules on suicide prevention designed for gatekeepers, and their efficacy [24]. In that study, a Google search showed that worldwide e-learning modules were increasingly available on the topic. A literature search, however, yielded no published

papers on the same topic. The results of this review highlighted the need for research, especially RCTs, on the efficacy of educational suicide prevention e-learning modules for gatekeepers [24].

In 2011, VU University in Amsterdam started a program entitled Mental Health Online (MHO), with an aim to develop adolescent suicide prevention e-learning modules for gatekeepers and to test the efficacy of these modules [25]. A total of 8 e-learning modules were developed, each capturing an important aspect of the process of recognition, guidance, and referral of suicidal adolescents (12-20 years old). The content of the modules followed the QPR model, focusing on essential knowledge and frameworks that enhance early detection, assistance, and referral of adolescents at-risk for suicide. Although the QPR Institute has also made QPR Gatekeeper Training available on the Internet, we decided not to use that version because it focuses on “suicidal people” in general, while we aimed only to address adolescent suicidality in the e-learning modules of the MHO program. Further, Web-based QPR Gatekeeper Training takes approximately 1 hour to complete; in contrast, for this study, we chose to divide the process of recognition, guidance, and referral into short modules, so that participants could customize their training based on their previous knowledge and experience. Lastly, training licenses for Web-based QPR Training become available only after paying a fee. It was expected that payment requirements would affect the willingness of gatekeepers to participate in this study.

In this paper, the results of an RCT addressing the efficacy of the MHO program are presented. Efficacy of the program was determined by measuring change in (1) actual knowledge, (2) perceived knowledge, and (3) perceived self-confidence of gatekeepers after training compared to a waitlist control group. It was expected that gatekeepers’ actual knowledge, perceived knowledge, and perceived self-confidence with regard to adolescent suicide prevention would improve after attending the MHO program compared to those in the waitlist control group. It is important to point out that the MHO program was a stand-alone program and not part of a multi-prolonged approach. To our knowledge, this is the first time that the efficacy of a Web-based adolescent suicide prevention gatekeeper training program has been investigated in an RCT.

Methods

Protocol

The study protocol for *Mental Health Online* was approved by the Medical Ethics Committee of VU University Medical Centre Amsterdam (registration number 2009/328), and a detailed study protocol for this RCT can be found elsewhere [26]. The first

group of participants started the study in the second half of 2012, and the last group of participants finished the study in the second half of 2013.

Design

This study was a randomized trial with a *pretest, posttest, and 3-month follow-up design* with two arms: an experimental group and a waitlist control group. The intervention was not masked. The experimental group received the intervention during the study, and the waitlist control group received the intervention after completion of the study. Participants did not receive any type of compensation for participation in this study.

Participants

The participants of this study were Dutch-speaking gatekeepers who worked with adolescents. The inclusion criteria were the following: (1) gatekeepers 18 years of age and older, (2) who worked frequently with adolescents from 12 to 20 years of age, (3) whose profession involved responsibilities with regard to the (mental) health care of adolescents, and (4) who had access to the Internet. Although every individual who met the inclusion criteria was eligible to participate in this study, three main target groups were identified for recruitment: members of mental health care teams of schools, youth health care nurses, and (mental) health care employees.

Intervention: MHO Program

Overview

The intervention in this study consisted of 8 e-learning modules alongside additional information regarding adolescent suicide prevention. The base of the modules was a PowerPoint presentation containing features such as voice-over, case descriptions, and quizzes. Both the modules and the additional information were made accessible through the website [27] for participants of this study. Figure 1 depicts a screenshot of the website (overview of e-learning modules and additional information) and Figure 2 illustrates a screenshot of one of the e-learning modules. Each of the modules of the program addressed an important aspect of the process of recognition, guidance, and referral of suicidal adolescents (12-20 years old). With an aim to allow participants to customize their training based on their previous knowledge and needs, 8 separate modules were offered. Thus, the number and order of modules were individually determined by each participant. As it was expected that the number of modules each participant followed could influence scores on the three outcome measurements of this study, a user-track system was enabled on the website. With this system, it was possible to collect data regarding how many modules each participant had completed at each assessment point.

Figure 1. Overview of modules and additional information on the Mental Health Online website.

Mental Health Online Als het om suïcidaliteit onder jongeren gaat...

TOEGANG:
E-LEARNING MODULES
technische problemen
module 1
module 2
module 3
module 4
module 5
module 6
module 7
module 8
FILMS & DOCUMENTAIRES
LITERATUUR
FORUM
LINKS
LOGOUT

Overzicht Acht Suïcide E-learning Modules

De suïcide e-learning modules hebben tot doel het proces van (vroegtijdig) signaleren, bejegenen en doorverwijzen van (mogelijk) suïcidale jongeren te bevorderen. Handreikingen voor de bevordering van dit proces zijn verdeeld over acht e-learning modules.

Wij geven per module aan voor welke deelnemers de desbetreffende module relevant kan zijn, maar u bepaalt uiteindelijk zelf welke modules u wilt volgen.

Elke module wordt afgesloten met 8 toetsvragen samengesteld uit 4 algemene vragen en 4 specifieke casussen over de desbetreffende module.

Hieronder vindt u meer informatie over de modules.

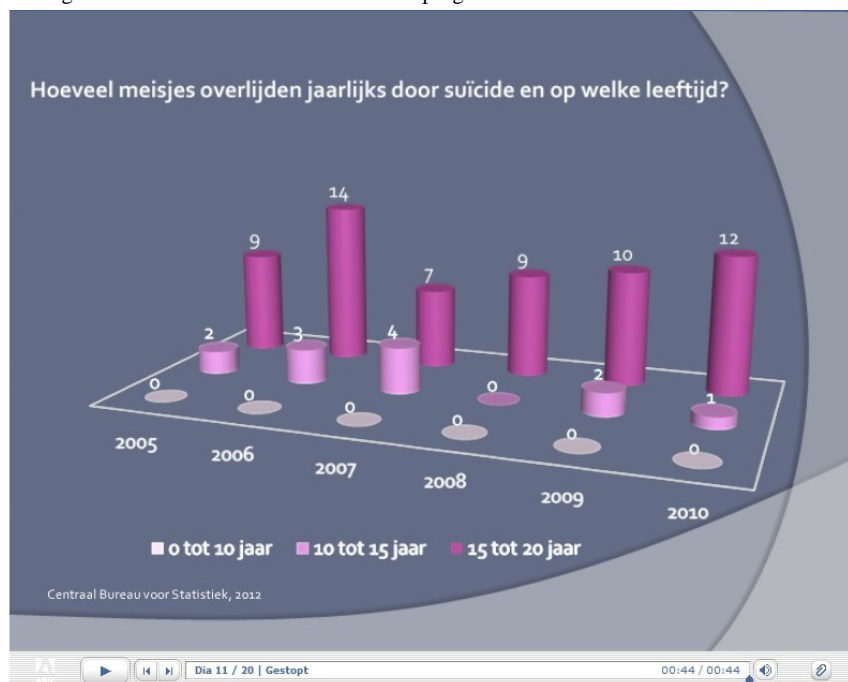
Bij technische problemen klik hier.

Module 1: Suïcidaliteit onder adolescenten

Leerdoelen:

1. Wat is suïcidaliteit?
2. Hoe vaak komt suïcidaliteit voor onder jongeren?

Figure 2. Layout of the e-learning modules of the Mental Health Online program.



E-Learning Modules

The first module was titled “Suicidality among adolescents” and gave a general introduction to the topic of adolescent suicidality, including statistics and figures. Risk factors associated with adolescent suicidality were discussed in the second module entitled “Risk factors.” The third module, “Ethnicity,” addressed the relationship between ethnicity and adolescent suicidality in the Netherlands. Warning signs associated with adolescent suicidality were presented in the fourth module entitled “Recognition of suicidality.” The fifth and sixth modules titled “Conversation with the suicidal

adolescent” and “Conversation with the parents” discussed needed tools and skills when engaging in conversation with suicidal adolescents or their parents. A seventh module titled “Suicide first aid” provided practical information about how first aid should be given once an adolescent attempts suicide. The eighth and final module titled “Care and aftercare” was specifically designed for schools and offers guidelines needed to arrange the process of care and aftercare after suicide (attempt) of a student. Each module took approximately 4 to 10 min to complete.

Additional Information

Since the aim was to create short modules, only essential information needed to capture the purpose of the module was included. As a result, additional information (literature, documentaries, and links to other informative websites) on (adolescent) suicidality were located in a separate section of the website for those needing more material. Furthermore, a Web-based discussion board was created where participants could interact with each other, and also ask questions of experts or present cases regarding adolescent suicidality.

Instruments

Overview

The MHO program was developed specifically for this study as there were no suitable instruments available. Three Web-based self-report questionnaires were developed to measure the outcomes of this study. The questionnaires were not modified from prior studies but were newly developed in collaboration with an expert in the field of suicide prevention in the Netherlands. The outcomes were (1) participants' answers to questions tapping their actual knowledge, and their ratings of (2) perceived knowledge, and (3) perceived self-confidence with regard to adolescent suicidality and suicide prevention. The 3 questionnaires were completed by the participants at the 3 assessment points: pretest (baseline assessment, T), posttest (second assessment, T₁) and follow-up (third assessment, T₂). In addition, at the beginning of the follow-up assessment, participants in the experimental group were asked 2 questions about implementation of their gained knowledge. Furthermore, during the baseline assessment demographic information was gathered. Lastly, participants in the experimental group were asked to complete an evaluation questionnaire during the posttest, which aimed to assess to what extent they were satisfied with different aspects of the program and which modifications they thought could improve the program. Results of the evaluation questionnaire (including insights regarding the construction of the e-learning modules) are not presented in this paper; however, they are discussed in a separate paper (personal communication by Ghoncheh, April 16, 2015).

Actual Knowledge Questionnaire

The Actual Knowledge Questionnaire consisted of 6 cases each providing several characteristics (name, age, and education) of a fictional adolescent displayed in a photograph. The purpose of the photograph was to help the user visualize the adolescent and his/her situation better. Each case was followed by 2 general questions (yes/no answer), and 8 specific questions (multiple choice, 1 correct answer) each pertaining to the content of one of the e-learning modules of the MHO program. The total number of questions each participant received depended on their answers to the 2 general questions. Scores per case could vary from 0 (wrong answers to all questions) to 10 (correct answers to all questions). Two cases were presented at each assessment point: a case about a native Dutch adolescent, and an adolescent originating from an ethnic minority group in the Netherlands. Since 3 items of this questionnaire were conditional and the items were not related to each other, psychometric characteristics for this questionnaire could not be tested.

Perceived Knowledge Questionnaire

The Perceived Knowledge Questionnaire consisted of 9 statements to be rated on a 3-point Likert scale (0 = disagree, 1 = partially agree, 2 = agree). The first item of the questionnaire was a general statement regarding knowledge about adolescent suicide prevention ("I have sufficient knowledge about the process of recognition, guidance, and referral of suicidal youth") [26], and the following 8 items each captured the essence of one of the e-learning modules of the MHO program. For instance, the fifth module addressed how to engage in a conversation with a suicidal adolescent and the corresponding statement was "I have sufficient knowledge to engage in a conversation with a suicidal adolescent" [26]. The scores could vary from 0 (disagreed with all statements) to 18 (agreed with all statements). During pretest, posttest, and follow-up the participants received the same questionnaire. Principal component analysis (PCA) revealed the presence of one component. The Cronbach alpha coefficient for the perceived knowledge questionnaire was .89 at pretest (experimental .89, waitlist control .90), .93 at posttest (experimental .88, waitlist control .87), and .92 at follow-up (experimental .82, waitlist control .88).

Perceived Self-Confidence Questionnaire

A 16-item questionnaire was developed, which consisted of statements regarding the necessary skills and attitudes when dealing with adolescent suicide prevention. The statements were rated on a 3-point Likert scale (0 = disagree, 1 = partially agree, 2 = agree) and were related to the 8 e-learning modules. "I can adequately provide first aid to a young person who has attempted suicide" and "I can make a distinction between my duties and those of a therapist" are 2 of the statements included in this questionnaire [26]. The scores could vary from 0 (disagreed with all statements) to 32 (agreed with all statements). The same questionnaire was used at each of the 3 assessment points. PCA revealed the presence of one component. The Cronbach alpha coefficient for the perceived self-confidence questionnaire was .93 at pretest (experimental .93, waitlist control .92), .95 at posttest (experimental .93, waitlist control .93) and .95 at follow-up (experimental .91, waitlist control .94).

Recruitment

Recruitment for this study was carried out in the second half of 2012 and lasted approximately 3 months. A broad and stepwise recruitment strategy was used. First, the domain name [27] was registered and information regarding the study was posted on the website. Second, almost all education partnerships in the Netherlands were contacted by email and asked to distribute the email to their mailing list. In addition, those interested were given the opportunity to invite the main researcher of this study for an on-site presentation. Third, several information websites that are followed by gatekeepers were asked to place a summary of the research and a link to MHO on their website. Fourth, the main researcher attended seminars and conferences also attended by potential participants and handed out flyers. Fifth, VU University Amsterdam released a press release about the study that was distributed through several newsletters, and led to 2 interviews with national newspapers. Lastly, Twitter and Facebook accounts were created for this study. Promotional

materials regarding the study and up-to-date information about the study were shared with followers on both accounts.

Procedure

As this was a Web-based study, every aspect took place on the Internet, including communication and data collection, which was done by the main researcher. All participants were required to register by sending an email and including their name, position, affiliation, and email address. The baseline assessment was sent to participants by email; after completion of this assessment, participants were randomized to either the experimental or control group. One week after completing the baseline assessment, participants assigned to the experimental group received a personal username and password, along with a guide to the website. The login information gave each participant access to the website for 14 days.

Four weeks after completing the baseline assessment, the link to the second assessment was sent to the participants by email. After finishing the second assessment, those in the experimental group regained access to the website until 1 week prior to receiving the third assessment. The link to the third and final assessment was sent to the participants 12 weeks after finishing the second assessment. After completing the third assessment, participants in the waitlist control group were given access to the website through an email containing a personal username and password. At the same time, those in the experimental group also received an email in which they were notified that they had regained access to the website, in case they wanted to refresh their knowledge or use the additional information.

Participation was monitored by the main researcher and participants received reminders or were contacted if necessary.

Data Analyses

All analyses were carried out on the intention-to-treat sample. Hierarchical linear modeling (HLM) was conducted in MLwiN version 2.28 to determine whether differences between the two groups existed in actual knowledge, perceived knowledge, and self-confidence after the experimental group received the intervention. MLwiN integrates data from participants missing one or more measurements, or 1 or more questionnaires into the analysis. A 2-level HLM was conducted for each outcome measure (perceived knowledge, perceived self-confidence, and actual knowledge) where the outcome measures (level 1) were nested within gatekeepers (level 2). In order to determine the

intervention effect, 2 separate models were tested for each of the 3 outcome measures. The first model explored the overall effect of the intervention across time correcting for the baseline assessment. The second model explored the effects of the intervention at posttest and follow-up by adding the interaction term ($group \times time$) to the previous model. Other analyses were conducted using IBM SPSS Statistics version 21.

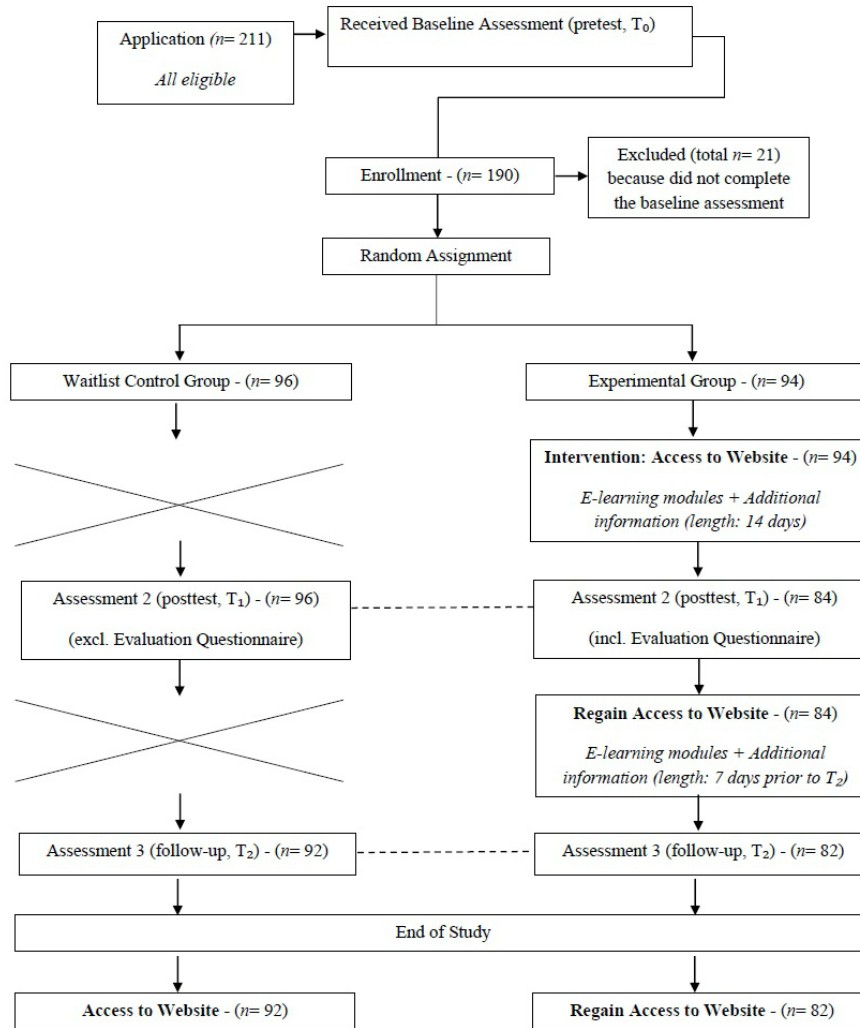
Results

Response Rates

A total of 211 gatekeepers registered for the study, of which 190 completed the baseline assessment and were enrolled. The enrolled participants were randomized to either the experimental group ($n=94$) or the waitlist control group ($n=96$). In the experimental group, 4 participants did not follow the e-learning modules and subsequently did not receive the second assessment. The remaining 90 participants received the second assessment and 84 completed the second assessment (response rate 89.4%, 84/94). All participants in the waitlist control group completed the second assessment (response rate 100%). The third assessment was completed by 82 participants in the experimental group (response rate 87.2%, 82/94) and 92 participants in the waitlist control group (response rate 95.8%, 92/96). Figure 3 illustrates the flow of participants through each stage of the study.

The 16 participants who dropped out of the study were contacted by the main researcher. The following reasons were given by the participants for not completing the study: lack of time ($n=7$), family circumstances ($n=2$), unable to open the questionnaire at work and lack of time to fill out the questionnaire at home ($n=2$), pregnancy leave ($n=1$), absence due to vacation ($n=1$), and objection regarding the nature of testing ($n=1$). The remaining 2 participants did not respond.

No differences were found between groups with regard to mean scores of participants who completed the study and those who dropped out: actual knowledge at pretest ($t_{188} = 1.271, P=.21$, two-tailed), actual knowledge at posttest ($t_{180} = 1.709, P=.09$, two-tailed), perceived knowledge at pretest ($t_{188} = -0.200, P=.84$), perceived knowledge at posttest ($t_{182} = 1.107, P=.27$, two-tailed), perceived self-confidence at pretest ($t_{188} = 0.269, P=.79$, two-tailed), and perceived self-confidence at posttest ($t_{181} = -0.168, P=.87$, two-tailed).

Figure 3. Flow of participants through each stage of the study.

Descriptive Analysis

Gatekeepers in this study were 21 to 62 years of age (mean 43.55, SD 10.96), the majority were female (81.6%, 155/190) and had a higher vocational (55.8%, 106/190) or university (38.4%, 73/190) degree. The majority (67.9%, 129/190) of the gatekeepers worked within a school setting (such as mentors, counselors, teachers, and social workers) while the rest worked in a (mental) health care related setting or institute (such as psychologists, behavioral scientists, youth health care nurses, and psychiatrists). The participants of this study had 0 to 30 years of experience in their current job (mean 8.28, SD 7.16). Moreover, 78.9% (150/190) of the participants reported knowing at least one adolescent who performed a nonfatal suicide attempt, and 39.5% (75/190) of gatekeepers reported knowing

at least one adolescent who died due to suicide. All participants were from the Netherlands, except one gatekeeper who lived in Belgium. No differences were found between the experimental group and waitlist control group in terms of demographics.

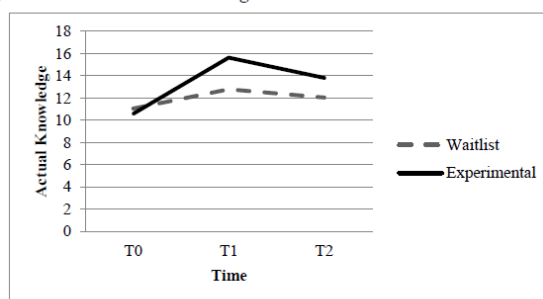
Table 1 shows the mean scores and standard deviations of both groups on actual knowledge, perceived knowledge, and perceived self-confidence at baseline, posttest, and follow-up. The groups' mean scores at the 3 assessment points are also illustrated in Figure 4. At baseline, no significant differences were found between the waitlist control group and experimental group for actual knowledge ($t_{188} = 1.106$, $P=.27$, two-tailed), perceived knowledge ($t_{188} = -1.042$, $P=.30$, two-tailed), and perceived self-confidence ($t_{188} = -1.301$, $P=.20$, two-tailed).

Table 1. Mean scores for actual knowledge, perceived knowledge, and perceived self-confidence over time.

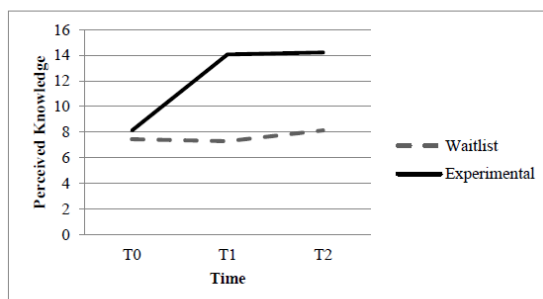
Questionnaire	Baseline (T)		Posttest (T ₁)		Follow-up (T ₂)	
	Waitlist Control (n=96) mean (SD)	Experimental (n=94) mean (SD)	Waitlist Control (n=96) mean (SD)	Experimental (n=88) mean (SD)	Waitlist Control (n=92) mean (SD)	Experimental (n=82) mean (SD)
AK ^a	11.05 (3.07)	10.59 (2.74)	12.79 (2.30)	15.63 (2.97)	12.05 (3.30)	13.82 (3.00)
PK ^b	7.45 (4.44)	8.13 (4.55)	7.30 (3.99)	14.07 (3.66)	8.14 (4.02)	14.22 (2.98)
PS ^c	16.78 (7.44)	18.21 (7.73)	16.08 (7.29)	25.94 (5.81)	17.52 (7.34)	25.93 (5.34)

^aAK: actual knowledge^bPK: perceived knowledge^cPS: perceived self-confidence**Figure 4.** Mean scores of the groups on the 3 questionnaires at T₀, T₁, and T₂.

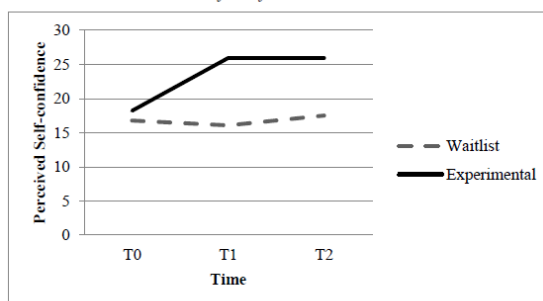
a) Mean Score Actual Knowledge



b) Mean Score Perceived Knowledge



c) Mean Score Perceived Self-confidence



Outcome Measures Across Time by Condition

As shown in Table 2, the overall effect of the intervention was highly significant across time and resulted in large overall effect sizes (ES) for actual knowledge (ES = 0.76), perceived knowledge (ES = 1.20), and perceived self-confidence (ES = 1.02). This indicates, first, that the MHO program had a large

positive effect on actual knowledge, perceived knowledge, and perceived self-confidence of the participants completing the program compared to those in the waitlist control group, and second, that the effects were sustainable as they remained significant at 3-month follow-up. Further analyses showed that the intervention effect was strongest at posttest compared to

follow-up for actual knowledge (ES = 0.94), perceived knowledge (ES = 1.30), and perceived self-confidence (ES = 1.12), and that the effects remained large for perceived knowledge (ES = 1.09), and perceived self-confidence (ES =

0.90) after 3 months. For actual knowledge, a medium effect size (ES = 0.57) was found at follow-up, indicating a decrease in the actual knowledge of the participants over 3 months.

Table 2. Training impact.

Variable	B	Overall Effect 95% CI	ES ^a	B	Effect at Posttest 95% CI	ES	B	Effect at Follow- up 95% CI	ES
Actual Knowledge	2.415	(1.76 - 3.07)	0.76	2.995	(2.19 - 3.80)	0.94	1.828	(1.00 - 2.65)	0.57
Perceived Knowledge	5.883	(5.12 - 6.65)	1.20	6.363	(5.52 - 7.21)	1.30	5.359	(4.92 - 6.22)	1.09
Perceived Self-Confidence	8.112	(6.82 - 9.41)	1.02	8.942	(7.49 - 10.39)	1.12	7.216	(5.74 - 8.69)	0.90

^aEffect size (ES) is the regression coefficient divided by the total standard deviation. All models were significant at $P < .001$.

Of the 84 participants in the experimental group who finished the second assessment, 71 (85%) completed all 8 e-learning modules of the MHO program. For this reason, further analyses exploring whether the number of e-learning modules a participant completed had an effect on actual knowledge, perceived knowledge, and perceived self-confidence were not conducted.

Application of Gained Knowledge

At 3-month follow-up, 45% (37/82) of gatekeepers from the experimental group reported that they had applied the knowledge gained over the past 3 months. According to the 36 respondents who elaborated on their answer, this application of knowledge was done in the following way: recognition of and/or engaging in conversation about suicidality (n=25), all the steps from recognition to referral (n=5), advising and sharing knowledge with other gatekeepers (n=3), awareness (n=2), and other (n=1).

Discussion

Principal Findings

This RCT investigated the efficacy of a Web-based adolescent suicide prevention gatekeeper training program (MHO), consisting of 8 e-learning modules and additional information. The results of this study show that the actual knowledge, perceived knowledge, and perceived self-confidence of gatekeepers who enrolled in the MHO program improved significantly compared to gatekeepers who did not have access to the program, and that the effects found immediately after the training remained significant at 3-month follow-up. Moreover, almost half of the participants that accessed the training program reported using the knowledge gained at least once during the 3-month follow-up.

Our findings are in accordance with previous studies that investigated the efficacy of QPR Gatekeeper Training delivered face-to-face to gatekeepers working with adolescents [11,19-21]. These studies also found gains in (perceived) knowledge and perceived self-confidence of gatekeepers attending the training. To our knowledge, Wyman and colleagues (2008) have conducted the only RCT assessing the impact of QPR Gatekeeper Training in gatekeepers working with adolescents. In their study, a large effect size was found for perceived knowledge (ES = 1.32) and perceived efficacy (ES = 1.22), and

a medium effect size (ES = 0.41) was found for QPR knowledge at 1-year follow-up [19]. Similar to the study of Wyman et al, we found a large effect size for training on perceived knowledge and perceived self-confidence, and a medium effect size for actual knowledge at (3-month) follow-up. Since we measured the participants three times, we were also able to estimate the effect sizes across time and immediately after finishing the training. For both of these analyses, we found large effect sizes for the three outcome measurements.

Although this study suggests that a Web-based training program has similar effects as face-to-face training with respect to training gatekeepers in adolescent suicide prevention, the current study did not compare Web-based training to face-to-face training, and to the best of our knowledge, other researchers have not yet compared the two formats. As a result, it remains unclear whether Web-based adolescent suicide prevention training for gatekeepers is actually as effective as face-to-face training. In-person interaction with the trainer and other participants and the opportunity to practice gained knowledge during role-play are probably the most important advantages of face-to-face training compared to distance learning. However, it remains questionable whether these elements actually contribute to additional increases in knowledge, self-confidence, and skills of gatekeepers, as the only way to implement and practice gained knowledge for the participant is to interact with a suicidal adolescent, which is similar for Web-based learning. As long as we cannot test the effects in real-life interactions between gatekeepers and suicidal adolescents, it remains unclear to what extent the outcome measurements really have increased as a result of training (Web-based or face-to-face). The fact that almost half of the participants in this study stated that they had implemented the knowledge gained during the 3-month follow-up suggests that it indeed led to increased self-confidence and implementation of the required steps, the latter of which could also indicate skill improvement.

Future research is needed to replicate the findings of this study and to determine which features enhance learning outcomes. As noted, we also asked participants to evaluate the MHO program, to understand better the program improvements that gatekeepers need. The results of the evaluation are discussed in a separate paper (personal communication by Ghoncheh, April 16, 2015). Furthermore, future research should also investigate to what extent Web-based learning can replace or

supplement existing traditional educational strategies in suicide prevention. Even if results of future research favor traditional methods compared to Web-based training, for example regarding acquired skills, the results of this study showed that Web-based training is effective in knowledge gain and self-confidence enhancement. Thus, based on the findings of this study, we recommend that evidence-based Web-based adolescent suicide prevention training programs should be offered as base training to gatekeepers. Due to the accessibility and flexibility of Web-based training, gatekeepers—as many as possible—will become familiar with the necessary steps in adolescent suicide prevention. This will likely result in detecting more adolescents in need and referring them to professionals who can assist them. Thereafter, those in need of more in-depth information and personal interaction or practice opportunities can attend face-to-face training. Subsequently, this could be beneficial to face-to-face training, as a more homogenous group of gatekeepers would attend, and custom content could be created for those looking for advanced material on adolescent suicide prevention.

The findings of this study have potential implications for education on prevention of other mental health issues. Although this study focused on adolescent suicide prevention, its results show that Web-based training is a promising tool for gatekeepers' education and that the findings are probably generalizable to other topics. Gatekeepers can be easily educated on various and highly important topics such as adult suicide, depression, and eating disorders, as well as child/adolescent behavioral, emotional, and developmental problems and disorders. For example, Dutch gatekeepers, especially those working in schools, may benefit from the advantages of Web-based training, primarily because the government has assigned them with prevention and intervention responsibilities concerning the (mental) health care of their students [28]. As such, adolescents at-risk can be detected early and referred for help.

This study has several strengths. It is innovative in being the first RCT investigating the efficacy of educational suicide

prevention e-learning modules for gatekeepers working with youth. Being an RCT, it yielded reliable findings obtained in a design with sufficient statistical power. However, the study findings should be interpreted in light of several limitations. A possible, yet inevitable, limitation of this study is that no standardized instruments were available to test the outcome measurements. Nevertheless, the perceived knowledge and perceived self-confidence questionnaires had high reliability across the three measurements and PCA revealed the presence of one component for both questionnaires. Unfortunately, psychometric characteristics of the actual knowledge questionnaire could not be tested as the item content was based on specific cases and several questions were conditional. Second, although 45% of the participants mentioned that they had put gained knowledge from the modules into practice during the 3-month follow-up, due to privacy reasons, it was not possible to monitor the gatekeepers who participated in this study or to obtain actual information on referrals they made. As a result, we could not measure changes in actual suicide prevention skills and performance. Future research should determine whether distance learning actually improves the behaviors of gatekeepers necessary for preventive activities and eventually leads to greater detection of suicidal adolescents, and correct referrals. Third, although we included a 3-month follow-up, maintenance of the intervention effects across a longer period was not ascertained.

Conclusion

Despite its limitations, this study is of value for gaining insight into the potential of e-education for professionals involved in the field of prevention of undesirable outcomes. It is the first study that tested the efficacy of adolescent suicide prevention e-learning modules targeting gatekeepers in an RCT. The findings are promising and provide evidence that the use of Web-based resources, such as e-learning modules, could be an effective strategy in the improvement of gatekeepers' actual knowledge, perceived knowledge, and perceived self-confidence in adolescent suicide prevention. Future research is needed to support the findings of this study.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Consort eHealth checklist.

[[PDF File \(Adobe PDF File\), 936KB - mental_v3i1e8_app1.pdf](#)]

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Abbreviations

AK: actual knowledge
ASIST: Applied Suicide Intervention Skills Training
ES: effect size
HML: hierarchical linear modeling
MHO: Mental Health Online
PK: perceived knowledge
PS: perceived self-confidence
QPR: Question, Persuade, Refer
RCT: randomized controlled trials
SOS: Sources of Strength
WHO: World Health Organization

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Original Paper

Therapeutic Alliance With a Fully Automated Mobile Phone and Web-Based Intervention: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: Studies of Internet-delivered psychotherapies suggest that clients report development of a therapeutic alliance in the Internet environment. Because a majority of the interventions studied to date have been therapist-assisted to some degree, it remains unclear whether a therapeutic alliance can develop within the context of an Internet-delivered self-guided intervention with no therapist support, and whether this has consequences for program outcomes.

Objective: This study reports findings of a secondary analysis of data from 90 participants with mild-to-moderate depression, anxiety, and/or stress who used a fully automated mobile phone and Web-based cognitive behavior therapy (CBT) intervention called “myCompass” in a recent randomized controlled trial (RCT).

Methods: Symptoms, functioning, and positive well-being were assessed at baseline and post-intervention using the Depression, Anxiety and Stress Scale (DASS), the Work and Social Adjustment Scale (WSAS), and the Mental Health Continuum-Short Form (MHC-SF). Therapeutic alliance was measured at post-intervention using the Agnew Relationship Measure (ARM), and this was supplemented with qualitative data obtained from 16 participant interviews. Extent of participant engagement with the program was also assessed.

Results: Mean ratings on the ARM subscales were above the neutral midpoints, and the interviewees provided rich detail of a meaningful and collaborative therapeutic relationship with the myCompass program. Whereas scores on the ARM subscales did not correlate with treatment outcomes, participants’ ratings of the quality of their emotional connection with the program correlated significantly and positively with program logins, frequency of self-monitoring, and number of treatment modules completed (r values between .32-.38, $P \leq .002$). The alliance (ARM) subscales measuring perceived empowerment ($r = .26$, $P = .02$) and perceived freedom to self-disclose ($r = .25$, $P = .04$) also correlated significantly in a positive direction with self-monitoring frequency.

Conclusions: Quantitative and qualitative findings from this analysis showed that a positive therapeutic alliance can develop in the Internet environment in the absence of therapist support, and that components of the alliance may have implications for program usage. Further investigation of alliance features in the Internet environment and the consequences of these for treatment outcomes and user engagement is warranted.

Trial Registration: Australian New Zealand Clinical Trials Registry Number (ACTRN): 12610000625077; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=335772&isReview=true> (Archived by WebCite at <http://www.webcitation.org/6efAc5xj4>).

KEYWORDS

therapeutic alliance; e-therapy; Internet interventions; depression; computerized cognitive behavior therapy

Introduction

Internet delivered psychotherapy for common mental health problems can assist with reducing the problem of unmet treatment need by overcoming barriers to access (including financial, temporal, and geographic constraints), and offering advantages of user-privacy and 24-hour availability [1]. In the case of depression and anxiety, interventions delivered via the Internet are popular with users [2], cost efficient, and clinically effective, with outcomes equivalent to face-to-face psychological therapies [3-5].

Much of the variance in outcomes of face-to-face psychotherapy has been attributed to the therapeutic alliance, defined as a non-specific treatment factor reflecting the extent of collaboration, purposeful action, and emotional connection between a client and therapist [6]. Considered the “quintessential integrative variable” of therapy [7] that enables patients to “accept, follow, and believe in treatment” [8], client-derived ratings of the therapeutic alliance have been associated with positive outcomes in face-to-face therapy irrespective of the type of psychological treatment, study design, and outcome measure used [8,9]. In some studies, therapeutic alliance accounts for approximately 50% of the effect size [10]. Positive associations have also been found between the therapeutic alliance and treatment engagement [11,12].

A tendency for humans to respond socially to computing technology in the same way as they respond to other humans has been well documented [13], and anthropomorphism (ie, the attribution of human qualities to inanimate objects) is widely recognized as integral to the successful design and use of information technologies [14,15], including in the therapeutic context [16,17]. Nevertheless, therapy provided in the Internet environment has been criticized for its limited capacity to facilitate a therapeutic relationship due to reduced responsiveness to nonverbal interpersonal cues, limited ability to provide reassurance and clarification of misunderstandings, potential for conflicts of interest, and difficulty providing timely corrective feedback [18-20]. By and large, however, the available evidence tends not to support these criticisms [21,22]. On the contrary, recent reviews show that client ratings of the therapeutic alliance in Internet-delivered interventions are generally equivalent to ratings in face-to-face therapy [21,22], suggesting that development of a therapeutic relationship during Internet-based psychotherapy is indeed possible. However, there is no consensus as to whether this has implications for treatment outcomes [21].

The majority of evidence relating to the therapeutic alliance in Internet-delivered interventions derives from studies of interventions that are therapist-assisted to some extent. The nature of the client-therapist interaction varies widely between existing programs, in terms of frequency (ie, number of interactions), nature (eg, provision of therapeutic support,

technical support, and/or feedback on therapeutic tasks), modality (ie, email versus SMS text message (short message service)), and timeliness (ie, synchronous versus asynchronous) [22-25]. Nevertheless, all programs have some degree of overt therapist input into a client’s treatment. In some studies, program users have even been provided with the name, photo identification, and biographical details of the assisting therapist [23]. This being the case, it is difficult to conclude whether existing findings of a positive therapeutic alliance in Internet-delivered psychotherapy reflect the quality of clients’ working relationships with the therapists involved or with the Internet programs themselves. Furthermore, it remains unclear as to whether alliance features can develop in the Internet environment in the absence of therapist assistance.

To the best of our knowledge, only one study has examined whether a therapeutic alliance can develop in a completely automated and self-guided Internet-delivered intervention without therapist input. Ormrod et al [26] used the Agnew Relationship Measure (ARM) [27] to examine the therapeutic alliance in a pilot study (N=16) of *Beating the Blues*, a Web-based cognitive behavior therapy (CBT) intervention for depression and anxiety. The ARM assesses 5 dimensions of the client-therapist relationship: bond, partnership, confidence, openness, and client initiative. On average, participants’ perception of the strength of their alliance with the program was positive, although ratings of the alliance were lower than those noted for face-to-face cognitive behavioral therapy (CBT). These pilot data are tentative, however, and require replication in a larger and more rigorously designed study.

In a recently completed randomized controlled trial (RCT), we reported significant symptom and functional outcome gains for people with mild-to-moderate depression, anxiety, and stress who used a fully automated mobile phone and Web intervention with no therapist input, known as “myCompass” [28] (ACTRN 12610000625077). This paper reports outcomes of a secondary objective of the RCT; namely to explore the role of the therapeutic alliance in this type of intervention. Specifically, we explored whether (1) participants reported a therapeutic alliance with the intervention; (2) participants’ ratings of the therapeutic alliance were associated with symptom and functional gains and improved positive well-being; and (3) ratings of therapeutic alliance features were associated with participants’ level of program engagement. Whereas previous studies of the therapeutic alliance have used predominantly quantitative methods, we also utilized interview methodology to further examine in qualitative detail the nature and form of participants’ reported alliance with the mobile phone and Web-based intervention.

Methods

Participants and Procedure

The myCompass RCT examined the effectiveness of a fully automated and self-guided psychological treatment that is delivered via the Internet to mobile and stationary technology devices for improving mental health symptom and functional outcomes. Participants in the RCT were 720 community volunteers with self-reported mild-to-moderate depression, anxiety, and/or stress symptoms who were recruited nationally in Australia between October 2011 and March 2012 via Internet, radio, and print media advertising. Following baseline assessment, participants were randomly allocated to the myCompass intervention, an attention control program, or a waitlist control condition, for 7 weeks. Subsequent assessments were conducted online on completion of the intervention phase (8 weeks) and at 20 weeks. The design and recruitment procedures for the myCompass RCT have previously been reported in greater detail [28].

Quantitative data for this secondary analysis was derived from participants randomly allocated to receive the myCompass intervention. This was supplemented by qualitative data provided by a purposively selected sample that completed the post-intervention questionnaire and agreed, via email, to participate in a semi-structured telephone interview with one of the authors (MAB). A sampling to saturation recruitment method was used in which data collection continued until no new themes emerged from the interviews [29].

The RCT was approved by the Human Research Ethics Committee of the University of New South Wales, Sydney, Australia (HREC 10019) and registered with the Australian and New Zealand Clinical Trials Registry (ACTRN 12610000625077). The CONSORT-EHEALTH checklist is provided as [Multimedia Appendix 1](#).

The myCompass Mobile Phone and Web Intervention

myCompass is a fully automated public health CBT-based intervention for the treatment of mild-to-moderate depression, anxiety, and stress [30]. The program is completely self-guided with no therapist input, and is accessible from any Internet-enabled mobile phone, tablet, or computer.

The myCompass program assesses users' self-reported symptoms on registration and then provides 24/7 access to a personalized intervention that includes real-time, self-monitoring of moods and behaviors (via mobile phone, tablet, or computer), and interactive, evidence-based psychotherapeutic modules (via tablet and computer). In addition, users can schedule SMS text message (short message service) or email reminders to facilitate self-monitoring, receive and print graphical feedback about their self-monitoring alongside contextual information on their phone or computer (to monitor change and assist identification of triggers), and elect to receive helpful facts, mental health care tips or motivational statements by text message or email. Registering to use the program is free, and users are not billed for the text messages they receive. A detailed description of the myCompass intervention is provided in Proudfoot et al [28].

Data Collection

Quantitative Measures

Participants in the RCT completed standardized and validated measures of mental health symptoms, work and social functioning, and positive psychological well-being at baseline, post-intervention, and follow-up, and the therapeutic alliance at post-intervention.

The Depression, Anxiety and Stress Scales (DASS) is widely used to measure the extent to which a person experienced symptoms of depression, anxiety, and stress over the previous week [31]. Total scores on the DASS range from 0 to 126 and subscale scores range from 0 to 42, with higher scores indicating greater symptom severity.

The Work and Social Adjustment Scale (WSAS) assesses the impact of mental health problems on daily functioning in 5 domains: work, social leisure activities, private leisure activities, home-management, and personal relationships [32]. Scores on the WSAS range from 0 to 40, with higher scores indicating poorer adjustment.

The Mental Health Continuum-Short Form (MHC-SF) measures positive mental health defined as the presence of positive feelings (emotional well-being), and positive functioning in individual life (psychological well-being) and community life (social well-being) [33]. Total scores and subscale scores on the MHC-SF range from 0 to 5, with higher scores indicating higher levels of positive mental health.

The Agnew Relationship Measure (ARM) uses 28 items to measure 5 elements of the client-therapist relationship: the affective element (bond), extent of mutual collaboration and engagement (partnership), perceived professional competence (confidence), perceived freedom to disclose personal concerns (openness), and empowerment (client initiative) [27]. Subscale scores range from 1 to 7, with higher scores indicating a stronger and more positive client-therapist alliance. In line with Ormrod et al [26], and to facilitate comparison of our data with theirs, ARM items were modified in the present study by replacing the word "therapist" with "program."

Participant engagement with the myCompass program was measured using the following 3 indices: (1) number of program interactions (ie, logins), (2) number of modules completed, and (3) frequency of self-monitoring [34].

Qualitative Measures

Participant interviews were semi-structured and asked about the non-specific or "common" treatment factors identified in previous studies as contributing to development, persistence, and quality of the therapeutic alliance in face-to-face psychotherapy (Table 1). The interview comprised 16 open-ended questions and commenced with the question "Can you tell me what you liked most about the myCompass program?" Interview questions were theory-based, derived from the ARM, and the Model of Common Factors (MCFs) [35,36] (Table 1). Consent for participation and tape recording was obtained before each interview.

Table 1. Components of the semi-structured interview and their theoretical bases.

Broad concept	Agnew Relationship Measure (ARM) [27]	Model of Common Factors (MCF) [35,36]	Sample question
Bond	Friendliness, acceptance, understanding, and support	Empathy, care, and genuineness	To what extent did you feel accepted by the program?
Partnership	Collaborative framework	Negotiation of goals, collaborative framework, and guidance	To what extent did you feel the program tried to influence you in ways that were helpful/not helpful?
Confidence	Respect for professional competence	Trust, development of a secure base, positive treatment expectancies	To what extent did you feel you could rely on the program for advice when you needed it?
Openness	Personal disclosure (client)	N/A	To what extent did you feel comfortable providing personal information to the program?
Client Initiative	Setting the agenda, client responsibility	N/A	To what extent did you feel the program allowed you to set your own goals?
Accessibility	N/A	Convenience and availability	To what extent did you feel the program was easy to use?
Reciprocity	N/A	Education and rationale giving, sensitivity, and flexibility	To what extent did you feel the program was flexible enough to meet your needs?

Analysis Strategy

Quantitative analyses were conducted using SPSS version 21, and used data derived from participants who returned a post-intervention questionnaire. Internal consistency of the modified ARM subscales was tested using Cronbach's alpha, and subscale means were examined to determine alliance strength. In line with previous studies of Internet-delivered therapies [22,23], residual gain scores were calculated to represent post-intervention treatment gains using the formula described by Steketee and Chambless [37] (the standardized subscale score at post-intervention minus the standardized subscale score at baseline, multiplied by the correlation between these scores). Residual gain scores thus represented treatment gains at post-intervention scores adjusted for baseline scores, and bivariate correlation analyses examined relations between these and scores on the ARM subscales. Since ARM data was collected at post-intervention only, it was not possible to perform the analyses on an intention-to-treat basis [24].

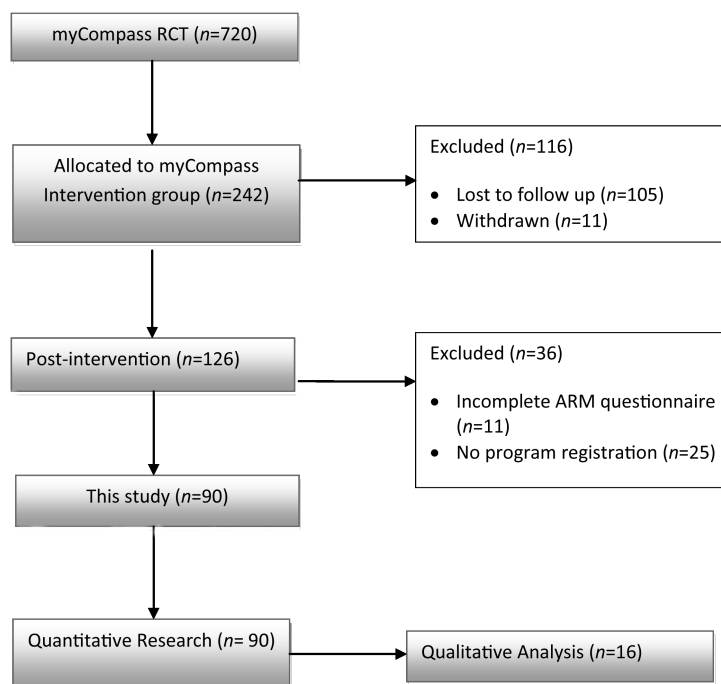
Interview transcripts were audio recorded, transcribed, and analyzed independently by 2 of the authors (MRB and MAB) using a word processing package (MS Word). Thematic analysis

of responses was used to identify the main themes and subcategories, while at the same time a thorough search was conducted for divergent views to enable a richer description of therapeutic alliance features [38]. A 95% level of agreement was reached for themes and subcategories, with differences resolved after discussion. A total of 8 principal themes were identified and agreed upon, and these have been used as organizing themes for the qualitative data.

Results

Sample

Of the 231 RCT participants allocated to the myCompass intervention, 126 (54.5%, 126/231) returned post-intervention questionnaires (Figure 1). On closer inspection, we found that 11 (8.7%, 11/126) had not completed the ARM subscales, and a further 25 (10.8%, 25/231) had not registered with and did not use myCompass. We excluded data from both of these groups, leaving a final sample for this secondary analysis of 90 participants that were predominantly female (72%, 65/90), and employed (78%, 70/90), with a mean age of 38 years (SD 10 years) (Figure 1).

Figure 1. Study flow diagram.

Quantitative Results

Strength of the Therapeutic Alliance

Cronbach's alpha coefficients for the ARM subscales ranged from .3 (client initiative) to .86 (confidence), and were slightly

higher than those reported in Ormrod et al [26] (Table 2). The descriptive statistics for the ARM total and subscale scores are also shown in Table 2. All means were higher than the neutral midpoints (ie, 4), suggesting a positive therapeutic alliance with the myCompass intervention.

Table 2. Descriptive statistics for study outcomes at baseline and post-intervention (N=90).

Outcome	Baseline, mean (SD)	Post-intervention, mean (SD)	Chronbach alpha (scale ^a , scale ^b)
DASS			
Depression	14.66 (9.68)	10.16 (7.92)	
Anxiety	7.84 (6.68)	5.85 (6.80)	
Stress	17.60 (7.63)	14.89 (7.51)	
Total	40.10 (19.20)	30.91 (18.47)	
WSAS			
Total	17.84 (8.93)	12.87 (7.99)	
MHC-SF			
Emotional	2.84 (1.04)	3.35 (0.85)	
Psychological	2.69 (1.02)	3.07 (1.04)	
Social	2.09 (1.00)	2.51 (1.18)	
ARM			
Bond	N/A	5.50 (1.03)	.82 (.82, .74)
Client initiative	N/A	4.40 (0.92)	.30 (.55, .26)
Partnership	N/A	4.71 (1.18)	.76 (.80, .59)
Confidence	N/A	5.11 (1.15)	.86 (.87, .68)
Openness	N/A	5.34 (1.17)	.74 (.77, .68)

^aScale reliabilities reported by Agnew-Davies and Stiles [27].

^bScale reliabilities reported by Ormrod et al [26].

Relations Between the Therapeutic Alliance and Study Outcomes

As in previous studies [27], we found that the bond, partnership, and confidence subscales of the ARM were highly

inter-correlated (Table 3). For this reason, and to reduce the number of predictor variables, a composite score representing the average response across these subscales was computed for each participant to represent the overall quality of their emotional connection with the myCompass program [27].

Table 3. Correlations between the ARM subscales.

ARM subscale	Client initiative		Partnership		Confidence		Openness	
	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value
Bond	.25	.01	.70	.00	.79	.00	.51	.00
Client initiative	N/A		.45	.00	.43	.00	.18	.08
Partnership	N/A		N/A		.72	.00	.27	.01
Confidence	N/A		N/A		N/A		.42	.00

Participant scores on the ARM subscales did not correlate with residual gain scores on the symptom, functioning, and positive well-being outcome measures (Table 4).

Table 4. Correlations between ARM subscales and residual outcome scores.

Outcome	Arm subscales						
	Composite score		Client initiative		Openness		<i>P</i> value
	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	
DASS symptom scales							
Depression	-.07	.52	.14	.18	.08	.47	
Anxiety	.00	.99	.07	.52	.01	.95	
Stress	.020	.85	.20	.06	.08	.43	
Total	-.03	.81	.17	.11	.07	.48	
WSAS							
Total	-.19	.09	.04	.71	-.16	.13	
MHC-SF well-being scales							
Emotional	.18	.09	-.12	.25	.20	.06	
Psychological	.19	.07	-.02	.82	-.15	.16	
Social	.18	.08	-.19	.07	.01	.90	

In contrast, participants' ratings of the quality of their emotional connection with the myCompass program correlated significantly and positively with all 3 indices of program engagement. Furthermore, the client initiative ($r=.26$, $P=.02$)

and openness ($r=.25$, $P=.04$) subscales were correlated significantly in a positive direction with self-monitoring frequency (Table 5).

Table 5. Correlations between ARM subscales and program engagement.

Engagement index (frequency)	ARM subscales					
	Composite score		Client initiative		Openness	
	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value	<i>r</i>	<i>P</i> value
Program logins	.33	.00	.19	.06	.26	.11
Modules undertaken	.38	.00	.14	.19	.12	.57
Self-monitoring	.32	.00	.26	.02	.25	.04

Qualitative Analysis

Interviews were conducted with 16 participants, 3 of whom

were male with a mean age 40.1 years (SD 8.4 years). Thematic analysis elicited 8 themes that described participants' relationship with the myCompass intervention ([Textbox 1](#)).

Textbox 1. Qualitative interview themes and subcategories.

Themes and subcategories
<ul style="list-style-type: none"> • Empathy and acceptance <ol style="list-style-type: none"> 1. Felt supported and understood 2. Did not feel judged 3. Able to be oneself
<ul style="list-style-type: none"> • Working in partnership <ol style="list-style-type: none"> 1. Collaboration 2. Motivated goal attainment (eg, prompts and reminders)
<ul style="list-style-type: none"> • Confidence and reassurance <ol style="list-style-type: none"> 1. Respect for program content 2. Positive regard for skills and techniques 3. Expectations about program effectiveness
<ul style="list-style-type: none"> • Openness <ol style="list-style-type: none"> 1. Personal disclosure (client) 2. Privacy and/or confidentiality encouraged honesty
<ul style="list-style-type: none"> • Client initiative <ol style="list-style-type: none"> 1. Able to set one's own agenda and/or goals 2. Flexibility to use the program in a structured and/or self-guided manner
<ul style="list-style-type: none"> • Availability <ol style="list-style-type: none"> 1. Convenience (eg, mobile phone, desktop) 2. 24/7 access
<ul style="list-style-type: none"> • Interactivity <ol style="list-style-type: none"> 1. Interactive exercises 2. Home tasks 3. Text message and/or email reminders and prompts
<ul style="list-style-type: none"> • Responsiveness <ol style="list-style-type: none"> 1. Program matched symptom needs 2. Personalized feedback 3. Graphical reporting of symptoms

Empathy and Acceptance

Interviewees commented that they felt accepted and supported by the myCompass program, and a majority felt that it offered a safe and non-judgmental context within which to deal with their difficulties.

The program was good, you could tell that it was made with an empathic voice, with no ulterior motives and that it was purely to help you. And you could tell that the authors had no judgment. [Female, 28 years]

One participant reported that she did not feel the program understood or accepted her.

It's just a computer...it doesn't need to understand me...If it was a therapist it would be different.
[Female, 27 years]

Working in Partnership

All interviewees felt that they collaborated flexibly with the myCompass program to set and work towards achieving their treatment goals. For a majority of users, the automated alerts

and reminders contributed to this partnership and were viewed as important motivators of goal achievement and prompts for staying on track.

When prompted, I responded to guidance to talk to a friend. I hadn't realized how low I was at that time
[Female, 48 years]

Confidence and Reassurance

Overwhelmingly, interviewees expressed confidence in and respect for program content, and experienced this as reassuring. Furthermore, a majority were optimistic that the quality of the skills taught and advice provided improved their capacity to manage future mental health problems. Several interviewees reported that they were at first skeptical about the usefulness of the program, but noted rising confidence with increased program use.

The more modules I did, the more confident I felt in the information. It was becoming more and more helpful, especially the home tasks [Female, 41 years]

One interviewee reported decreasing confidence in the program over time due to frustration caused by the compulsory home tasks.

Openness

Interviewees generally appreciated the privacy afforded to them by the program, and the opportunity to openly and honestly share their problem feelings and behaviors. Indeed, for some interviewees, the level of comfort they felt in interacting with the program was greater than they had experienced in the face-to-face context, including with friends and family.

It's very easy when you're feeling down to put on a brave face and tell everybody you're fine...but with the computer I was comfortable being honest...Instead of trying to pretend that everything was fine, I could actually say it wasn't...I felt more in control of things
[Female, 47 years]

Client Initiative

Some interviewees commented on the flexibility of the program in offering a structured (ie, making recommendations about symptom monitoring and modules), yet at the same time self-guided (ie, capacity for users to choose monitoring dimensions and modules) intervention. The capacity to choose how they used the program was generally viewed as empowering by the interviewees.

There's a little quiz that you do when you start, and I was a bit surprised at some of the areas that it recommended for me to look at. Then I thought I'll take a couple of those, and another one I was quite interested in as well, but ignore some of the ones that I thought weren't so relevant...I felt quite able to make decisions about which ones I was going to look at.
[Female, 42 years]

The linear structure of the program's modules was viewed negatively by a minority of interviewees who would have liked greater control over the speed with which they progressed through the interactive tasks.

Availability

A majority of interviewees accessed myCompass from both an Internet-enabled mobile phone and desktop computer; 3 interviewees chose not to access the program on their phone.

The availability of myCompass 24/7, and the option of using myCompass when and where needed from a mobile device were viewed as major program advantages by all interviewees. Nevertheless, some interviewees felt that myCompass was more easily used on desktop computers than mobile phones because of the larger screen size and more reliable Internet connectivity.

I liked the flexibility. And having it available on my mobile phone, just having the convenience there, meant that I could carry it around with me, I could update it on a needs basis, and it's something I could do at a time and location of my choosing rather than being stuck at a desk [Male, 37 years]

Interactivity

A majority of users commented on the usefulness of the interactive elements of the myCompass program, especially the in-task activities and the homework tasks. Several interviewees also appreciated being able to graph their self-monitoring data alongside contextual information.

myCompass helped me make changes...Noting my responses and reactions to certain situations and identifying those particular triggers that I wanted to monitor...There were things that I thought might be an issue for me, and it (the graphs) confirmed that they were [Female, 31 years]

One interviewee commented that the feedback graphs provided tangible evidence that she was underestimating the extent of her symptoms.

It (the graphs) identified that perhaps when I was convincing myself that I was fine, that perhaps really I wasn't. [Female, 47 years]

Some users reported that the feedback provided to them when they logged into the program about their self-monitoring and module progress put extra pressure on them.

Sometimes I would log in and there were lots of red marks. I felt pressured...like I'd missed my school work [Female, 39 years]

Responsiveness

Many users made comments about the capacity of the myCompass program to respond appropriately to their unique symptom needs, but views were mixed in this regard. On the one hand, there were users who felt the program recognized and appropriately responded to their personal symptom experience.

If I was having low days, it would...acknowledge that I'm having a low day and (that) it's ok to have a low day and have you considered speaking to somebody. Instead of just going, you know what, I can't help you
[Female, 41 years]

Conversely, some users commented that the program responded in ways that did not reflect an appreciation of their needs and left them feeling confused and misunderstood.

I tracked how I was feeling and then I'd get a message come up that says...perhaps you're really struggling at the moment and you need to talk to somebody. And I'd think that I didn't feel that I was that bad [Female, 46 years]

Discussion

Principal Findings

This secondary analysis of data from a large RCT explored the extent and nature of the therapeutic alliance in the fully automated, mobile phone and Web-based intervention, myCompass. Consistent with Ormrod et al [26] and other studies of Internet-delivered therapies [21,22], results of the quantitative analysis showed that participants reported development of a positive alliance with the myCompass intervention. A point of differentiation from most previous studies, however, is that these findings were obtained in the absence of any therapist involvement in delivery of the intervention. Insights gained from the qualitative interviews provided further evidence that non-specific alliance features were experienced in participants' interactions with the intervention, including empathy, collaboration, reassurance, and reciprocity. Whereas classic definitions of the therapeutic alliance require that a client and therapist are involved in the relationship [39], and therapists have previously questioned or down-played the existence of relationship process variables in computer-based therapies [19], our findings show that a significant and positive alliance can exist in the Internet environment in the absence of human support.

We also examined whether therapeutic alliance features were associated with treatment gains and program engagement. Consistent with previous studies of Internet-delivered interventions across a range of disorders [21,22,26], we found no support for a link between therapeutic alliance factors and symptom, functional, and positive well-being outcomes. These findings contrast with those for face-to-face psychotherapies [40], and lend further support for the idea that the quality of the alliance in the Internet environment may be less important than other factors for understanding treatment gains [21,26].

On the other hand, components of the therapeutic alliance did show significant and positive associations with participants' level of engagement with the myCompass intervention. Most notably, ratings of perceived emotional connection with the program correlated positively with program logins, frequency of self-monitoring, and the number of psychoeducational modules completed, suggesting that users may engage with an Internet intervention to the extent that they experience a collaborative partnership that is working well, just as in face-to-face therapy [11]. Engagement with program content is generally linked with increased treatment gains, yet rates of adherence with Internet-delivered therapies are characteristically low [34], and attrition rates are high [41]. A contribution of our study, therefore, is to suggest that incorporating program content and functions that target alliance processes directly may improve

client adherence and retention in the Internet context. Indeed, it has recently been proposed that the real value of a strong alliance may lie in its capacity to promote therapeutic engagement as opposed to contributing to clinical improvement [11].

Because the ARM and other popular measures of the therapeutic alliance (eg, the Working Alliance Inventory [42]) were originally developed for the face-to-face context, they are unlikely to tap clients' perceptions of common factors or relationship features that may be distinct to Internet psychotherapies. For example, flexibility in the nature of the therapeutic encounter (in terms of time, location, and duration of access) is generally considered a particular advantage of Internet treatment [1], as is the option of interacting via different communication pathways [43]. However, these relationship variables are not assessed in existing alliance measures, and they remain largely unexplored as contributors to psychotherapy outcomes in the Internet context [1]. Further work is needed to conceptualize, from a client's perspective, the common or non-specific processes that characterize relationships in the Internet environment, and to examine the implications of these for treatment outcomes and program engagement using appropriately developed and validated alliance measures.

Limitations

Some limitations must be considered in interpreting these findings. As we have discussed previously [28], dropout attrition in the intervention arm of the RCT was high, especially among employed participants. Given positive links between alliance strength and treatment engagement [11], and a typical pattern of high alliance ratings among trial participants [23], we cannot discount the possibility that dropout from the intervention group reflected a lack of perceived alliance with the myCompass intervention. Furthermore, the sample was predominantly female which is potentially problematic as gender differences appear to influence the therapeutic alliance [44]. The generality of our findings, therefore, is somewhat limited.

From a measurement point of view, we remain uncertain as to whether the psychometric adequacy of the ARM is affected when scale items are adapted along the lines reported here (ie, replacing the word "therapist" with "program"). Until reliability and validity of the modified ARM is demonstrated and/or alternative measures of the human-computer alliance are developed, our conclusions must be considered tentative. In addition, therapeutic alliance data were collected at only one time point (ie, at post-intervention). Previous researchers have discussed the importance of measuring therapeutic alliance variables at various stages of the therapeutic process [25], and there is evidence that therapeutic success in the face-to-face context is more likely for patients whose alliance increases in the early stages of treatment [45,46]. At the same time, relations between therapeutic alliance features and program engagement are potentially reciprocal, such that a strong alliance predicts increased program interactions and vice versa [11]. Repeated administration of the ARM over the course of the intervention would have allowed a stronger test of the contribution made by therapeutic alliance features to treatment outcomes, program engagement, and study dropout.

Conclusions

This study is among the first to provide quantitative and qualitative support for the existence of a positive therapeutic alliance with a fully automated, mobile phone and Web-based psychotherapy intervention involving no therapist assistance. Although it appears that a strong alliance contributes less proximally to therapy outcomes in a fully automated, Internet-delivered intervention compared with face-to-face psychotherapy, our data suggest that the ability to connect meaningfully and work collaboratively may be similarly

important for client engagement across both contexts. Client engagement is vital for therapeutic success, yet effective translation of non-specific alliance components of face-to-face therapies into the Internet environment is not easily achieved [10]. For the sake of expediency, and in the interest of optimizing therapeutic gains, future studies should isolate the critical relational components of encounters in the Internet environment that relate to treatment outcomes and client engagement. These can then be honed in the development of new and refinement of existing Internet-delivered interventions.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [47].

[[PDF File \(Adobe PDF File\), 947KB - mental_v3i1e10_app1.pdf](#)]

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Abbreviations

ARM: Agnew Relationship Measure
CBT: cognitive behavior therapy
DASS: Depression, Anxiety and Stress Scale
MHC-SF: Mental Health Continuum-Short Form
RCT: randomized controlled trial
WSAS: Work and Social Adjustment Scale

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Original Paper

Adjusting an Available Online Peer Support Platform in a Program to Supplement the Treatment of Perinatal Depression and Anxiety

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Abstract

Background: Perinatal depression and anxiety are common and debilitating conditions. Novel, cost effective services could improve the uptake and the impact of mental health resources among women who suffer from these conditions. E-mental health products are one example of such services. Many publically available e-mental health products exist, but these products lack validation and are not designed to be integrated into existing health care settings.

Objective: The objective of the study was to present a program to use 7 Cups of Tea (7Cups), an available technological platform that provides online peer (ie, listener) based emotional support, to supplement treatment for women experiencing perinatal depression or anxiety and to summarize patient's feedback on the resultant program.

Methods: This study consisted of two stages. First, five clinicians specializing in the treatment of perinatal mood disorders received an overview of 7Cups. They provided feedback on the 7Cups platform and ways it could complement the existing treatment efforts to inform further adjustments. In the second stage, nine women with perinatal depression or anxiety used the platform for a single session and provided feedback.

Results: In response to clinicians' feedback, guidelines for referring patients to use 7Cups as a supplement for treatment were created, and a training program for listeners was developed. Patients found the platform usable and useful and their attitudes toward the trained listeners were positive. Overall, patients noted a need for support outside the scheduled therapy time and believed that freely available online emotional support could help meet this need. Most patients were interested in receiving support from first time mothers and those who suffered in the past from perinatal mood disorders.

Conclusions: The study results highlight the use of 7Cups as a tool to introduce accessible and available support into existing treatment for women who suffer from perinatal mood disorders. Further research should focus on the benefits accrued from such a service. However, this article highlights how a publicly available eHealth product can be leveraged to create new services in a health care setting.

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KEYWORDS

online; peer; support; perinatal; postpartum; depression; anxiety

Introduction

Perinatal Depression and Anxiety

Depression and anxiety during pregnancy or within the first 12 months after delivery (perinatal depression and anxiety) are

common and debilitating conditions. More than 15% of women experience symptoms of depression and anxiety during this period [1-3]. Depression and anxiety have comparable impacts on quality of life [4] and are associated with high levels of lost work productivity and increased medical costs [5,6]. Untreated perinatal depression and anxiety carry several additional risks,

including obstetric complications, puerperal pathologies, and increased psychopathology in childhood or adolescents [7-9]. Overall, psychosocial treatments appear to be preferred to pharmacotherapy [10-12]. These treatments do not confer any exposure risks to the babies, for example, [13,14], and the availability of emotional and social support during perinatal period has a significant role in the prevention and recovery from perinatal mood disorders. Research has shown, for example, that low-income pregnant women with higher quality of social support tend to experience less postpartum depression [15], and that even brief interventions of postnatal support groups are effective in reducing the symptoms of postpartum depression [16]. Several barriers, however, to receiving such services present during the perinatal period including lack of time, stigma, and childcare [17]. Overcoming these barriers requires novel resources that expand potential models of delivery [18], which can offer a variety of services to meet each person's individual needs and preferences.

One new model of delivery is technology-based mental health services. Technology-based mental health services offer a host of features that can address several of these barriers and might be particularly useful among new and expectant mothers. First, technology-based interventions move the intervention outside of traditional clinics and into people's households. Services can be available 24/7, on demand, which might be useful for women whose demanding schedules often offer only brief pockets of availability throughout the day. They can be less stigmatizing and the use of peer support embedded with these interventions could help normalize the experience of perinatal depression and anxiety. Indeed, many women express interest in the use of Internet-based health care resources during the perinatal period [19]. Furthermore, Internet-based resources for perinatal depression and anxiety have demonstrated feasibility and efficacy [20-25]. For example, a pilot trial of an interactive guided Web-based intervention for mothers with postpartum depression found significant reductions in depressive symptoms with 77% reporting clinically important improvement on the Patient Health Questionnaire [20]. In a randomized controlled trial comparing computerized behavioral activation for postpartum depression to treatment as usual (limited access to the Internet website), medium to large effect sizes favored women who received the computerized treatment on scores of depression ($d=0.87$) and anxiety ($d=0.59$) [21]. In addition, a randomized control trial investigating therapist-assisted online therapy for postpartum depression found greater reductions in depressive symptoms from participants receiving the intervention compared to a waiting list condition [22]. Finally, a study investigating the feasibility of an Internet-facilitated intervention for disadvantaged mothers with elevated symptoms of depression found greater reduction in depressive symptoms for participants in the intervention group compared to waiting list condition [23].

Leveraging eHealth Products to Enhance Care

The promise of technology-based interventions in enhancing care has led to an expansion in the number of available e-mental health products in recent years. For example, a 2015 report identified over 165,000 health applications (apps) currently available on the leading consumer app marketplaces (Apple

iTunes and Google Play) [24]. This is over twice as many as were available two years prior, with mental health apps making up the largest portion of these apps [24]. Despite the large number of apps available, very few have empirical support [25,26], and many health apps lack basis in empirically supported principles [27,28].

In light of this, a significant gap exists between the interest and availability of e-mental health products and the current evidence supporting their benefit. As such, many researchers are developing new e-mental health products to be subjected to randomized controlled trials, however, very few of these products then become available for consumers or implemented within health care settings. For example, a recent review of mental health apps for depression identified 4 trials assessing 3 apps for depression [25], but none of these apps are available for consumer download.

It is worth noting, however, that just because an e-mental health product has not been subjected to a randomized controlled trial, does not mean it does not have some sound behavior change principles or that it is not beneficial. Given the consistently changing nature of software and the technological environment, it has been suggested that behavior change principles are the more important unit of analysis than the apps themselves [29]. As such, moving e-mental health products into practice requires research and information to guide decision making in this regard. Boudreaux et al [30] suggest several practical steps for health care professionals to evaluate and select publically available apps including piloting apps and eliciting feedback from target end users. Similarly, Chan et al [31] highlight three dimensions including usefulness, usability, and integration and infrastructure. Although these steps and guidelines do not establish the efficacy of the e-product, they provide useful information about how such products might be beneficial for end users and integrated into existing care settings.

Furthermore, given the number of available eHealth care products, rather than developing and evaluating completely new products, a more efficient use of resources might be to develop additional scaffolding to make products more in line with evidence-based practices and needs of particular health care settings. This approach could also ensure that the resultant product or program can stay relevant to the current technological environment, which is a major challenge in this field [32]. Research along these lines could also uncover information about principles present in these programs or products, which could still guide subsequent research and development.

The Current Study

This study presents a program to use 7 Cups of Tea (7Cups), an available technological platform that provides online peer-based emotional support, to supplement treatment for women experiencing perinatal depression or anxiety. 7Cups was chosen for this study because its solution enables to scalably train and engage interested individuals with those who seek their support [33], and also due to the high volume of available volunteers on the platform [34], which open new avenues for receiving peer-based emotional support in real world settings [35]. In this paper, we present the development process required to adapt the online emotional support platform for use as an

adjunct to treatment in an existing health care setting and gather patient's feedback on this program. We follow existing guidelines on key processes and factors to evaluate when considering existing eHealth products [30,31].

Methods

Adapting and Evaluating 7 Cups of Tea

The process of adapting and evaluating 7Cups was completed in two iterative stages. The first stage enlisted clinicians to identify program modifications necessary to use 7Cups to supplement existing treatment resources. This stage included providing these clinicians an overview of 7Cups, and discussing required safety practices and program modifications. In the second stage, patients with perinatal depression or anxiety used the platform for a single session and provided their evaluation of usefulness, usability, and impressions of the program.

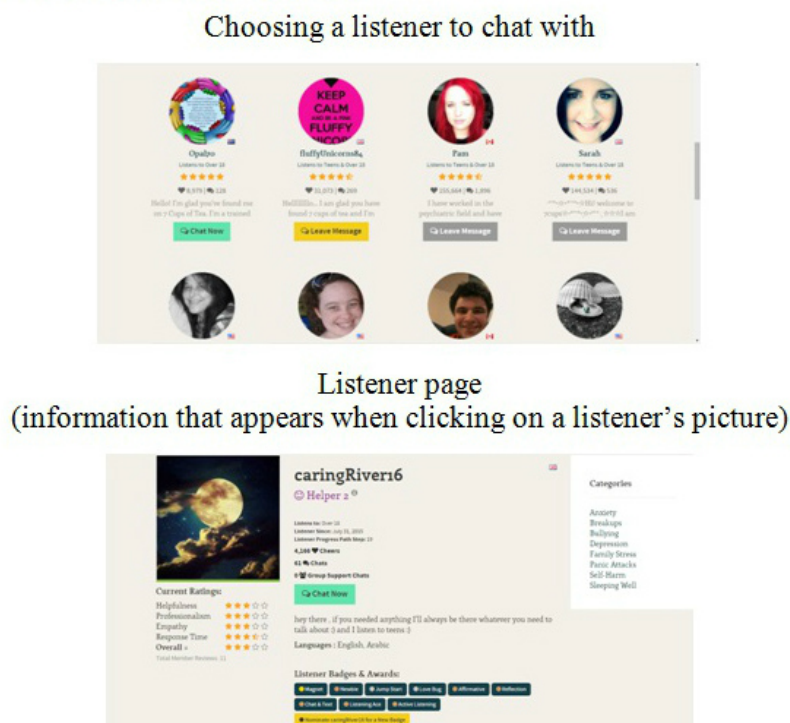
Stage I: Adjusting 7 Cups of Tea to Supplement the Treatment for Perinatal Mood Disorders

7 Cups of Tea Overview

7Cups provides free, 24/7, emotional support to users through a Web- or app-based messaging system [33]. Volunteers, referred to as "listeners", provide emotional support by receiving and answering chat requests from users. Before being able to respond to chat requests, listeners are required to complete a computerized training course on active listening, which includes video, text, and quiz components.

Upon logging into the platform, users can choose who they would like to chat with from a list of available listeners (Figure 1 shows this). Users and listeners are identified using anonymous user names. The platform provides some information about listeners including their country, age, group they will listen to, preferred topics for chats (eg, parenting), and experience on the platform (eg, number of chats conducted). Listener's average users' ratings in several domains (eg, helpfulness, professionalism) are displayed on a 5-point scale. A previous study on 7Cups found high levels of user satisfaction with the support provided by listeners [36].

Figure 1. Listeners' list and information page.

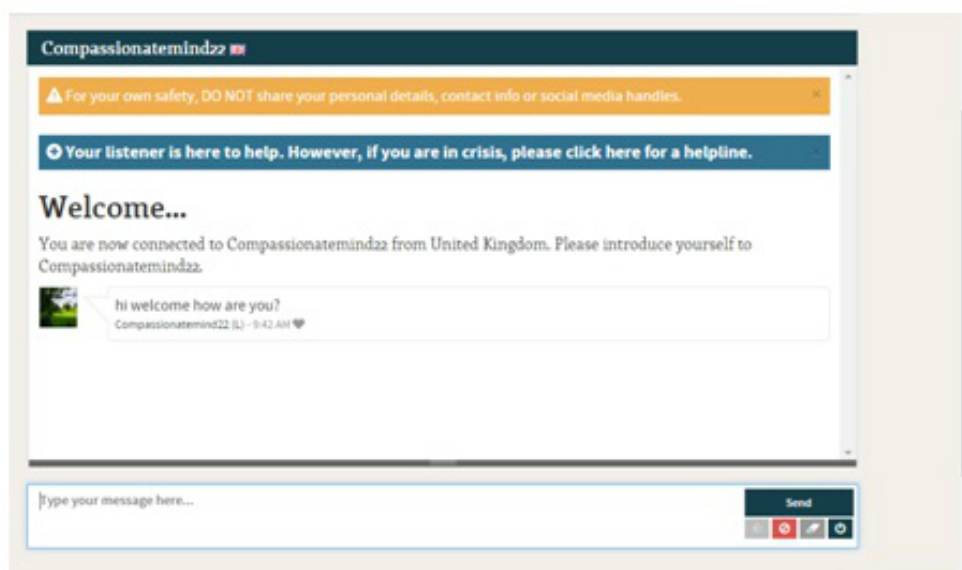


Safety Practices

Safety practices draw from recommendations for Internet-based intervention research and cover areas of system security, online safety, and clinical safety [37]. 7Cups online and system security was reviewed and approved by the IT (ie, information technology) risk management team of Feinstein Institute for Medical Research, part of NS-LIJ Health System. In terms of clinical safety, main concerns are confidentiality and ensuring users are not using 7Cups as a crisis management tool. In service

of confidentiality, both 7Cups users and listeners are anonymous. In order to ensure that 7Cups is being used appropriately, users must confirm that they are not in a crisis situation before beginning to chat. Banners on the chat window ask users to refrain from providing personal or identifying information, and provide information regarding help for crisis situations (Figure 2 shows this). Listeners are also directed to refer users to more intense programs or other resources in cases of need.

Figure 2. Beginning the chat on the 7 Cups of Tea (7Cups) platform.



Program Adjustments Based on Clinicians' Feedback

Feedback was elicited during a group discussion involving five clinicians specializing in the treatment of perinatal depression (2 psychiatrists, 3 psychotherapists) facilitated by the first author (AB). The aim of the discussion was to gather feedback regarding the ways 7Cups could complement treatment, and to understand clinicians concerns regarding the use of 7Cups as a supplement to existing treatment. Clinicians were instructed that this discussion was part of a larger program to refer patients to use 7Cups while undergoing treatment for perinatal mood disorders, and that their feedback could help influence this program.

At the beginning of the discussion, the group facilitator (AB) demonstrated the features of 7Cups, explained the training 7Cups listeners receive, and how people use the 7Cups program. During this demonstration clinicians could ask clarifying questions. Clinicians were then asked to discuss how 7Cups and this kind of support could complement the treatment they currently deliver, provide recommendations for additional training that would help listeners support people who suffer from perinatal mood disorders, and report any concerns regarding the use of online, peer-based, emotional support. During the discussion, the group facilitator took notes, asked for clarifications, encouraged members to expand on points raised by others, and finally read the points gathered by the group to examine participants' agreement. After presenting the main points, the facilitator asked participants if any additional comments or points needed to be considered.

Clinicians' Suggestions

In the group discussion, clinicians stated that online emotional support could be beneficial to individuals who suffer from perinatal mood disorders by making support accessible immediately during times of need. Additionally, although many patients may have social support, that support network might be already taxed by helping women cope with stressors associated with pregnancy and the birth of a child. As a result,

clinicians noted that in many cases, these patients do not have opportunities to share their feelings during the week and receive emotional support. As such, introducing 7Cups as an additional outlet for support could be beneficial. The group also noted that 7Cups provides this support online without requiring women to travel to the clinic to receive peer support. Time and travel are two barriers noted by the group and they saw value in overcoming these barriers.

The group suggested that listeners could be most helpful by: (1) providing active listening, (2) providing nonjudgmental support, and (3) pointing users to additional resources when relevant. The group also suggested that patients might desire to receive support from listeners who have personal experience with perinatal mood disorders.

The group emphasized the importance of educating patients who would use the platform to set appropriate expectations. This includes: (1) the difference between psychotherapy and emotional support, and how to appropriately utilize emotional support and (2) the inability of listeners to deal with crisis situations. Finally, the group also emphasized that listeners should be provided with basic information on perinatal depression and anxiety, as they are not trained experts in this area.

Based on clinicians' feedback, guidelines for referring patients to use 7Cups as a supplement for treatment of perinatal depression and anxiety were created, and a training program for listeners was developed.

Guidelines for Referring Patients to Use 7 Cups of Tea to Supplement Treatment

Clinicians' comments suggested guidelines to address potential safety concerns and to ensure that users have the proper education about how and when to use the platform. For the purposes of patient recruitment and referral, and in accordance with Internet-based intervention studies that relate to safety concerns [38,39] the following guidelines were created:

1. Patients with suicidal or homicidal intent will not be referred to use the online emotional support.
2. Patients with psychotic or manic symptoms will not be referred to use the online emotional support.
3. Patients who require hospitalization will not be referred to the online emotional support.
4. Patients using the platform will have to confirm while beginning to chat that they are currently not suicidal or homicidal (already embedded).
5. Patients will receive clear information (embedded in the platform and in program tutorial) that listeners cannot provide any support for emergency purpose. Helpline information will be provided on the platform for use in crisis situations.
6. Patients will receive clear information about the difference between the emotional support and treatment as psychotherapy, and about appropriate use cases.

Training of Listeners

A computerized training course was developed to provide listeners with relevant information for supporting women who cope with perinatal mood disorder. The specialized training made use of features present in the 7Cups training modules

consisting of text, video, and quiz components. A psychologist (AB), a psychiatrist (AT), and 7Cups staff including the community manager, collaborated to create this training (Figure 3 shows sample screenshots).

This training included five lessons: (1) “understanding perinatal mood disorder”, explaining the illness, symptoms, prevalence, and course; (2,3) “how to feel better”, providing basic wellness and self-care skills and accessible resources for those suffering from perinatal mood disorders (eg, postpartum support international); (4) common misperceptions regarding perinatal mood disorder (eg, perinatal depression happens always right after childbirth); and (5) guidelines for the supporter (eg, “Encourage the member to engage in self-care activities: Take a walk in the sun. Eat small meals”).

An invitation to complete this training course was sent to 7Cups listeners who had received the “verified listener” badge. A listener obtains this badge by completing a test chat with another listener and providing a positive and supportive experience. There were 64 listeners that signed up for the training in a one-week period (March 31 to April 6, 2015) and 46 completed it. These listeners were available to provide emotional support for women participating in stage II of this study.

Figure 3. Sample screenshots of listener's computerized training.

Understanding Perinatal Mood Disorder

Lesson 1

Need support? Connect to a Listener


Goal

To understand what pre/postnatal depression is and how it develops.

What is Perinatal Mood Disorder? (U.S. Department of Health and Human Services, pp. 3-9)

Depression or anxiety during or after pregnancy refers to a broad range of physical and emotional struggles that many women face and can range in severity from mild to severe. It can occur during pregnancy or within a year after the end of a pregnancy. Without help, symptoms may last a few weeks, months, or even years.

Postnatal depression. About 1 in 8 women suffers from postnatal (postpartum) depression. Symptoms can begin at birth or any time in the first year after giving birth. It is more severe than your basic "baby blues" that often occur during the first few days after delivery. "Baby blues" typically include crying, worrying, sadness, anxiety, mood swings, trouble concentrating, difficulty sleeping, and not feeling yourself. With time, patience, and the support of family and friends, symptoms linked with "baby blues" will usually disappear within a few days or within 1 to 2 weeks. If they don't, it may




Which of the following are symptoms commonly associated with pre/postnatal depression?

- Being irritable or cranky
- Trouble concentrating or remembering things
- Trouble making decisions
- All of the above

Next Step

Hear about one woman's postnatal depression journey and how she sought help by watching the following video:



As a Listener, How can you help?

Lesson 5

Need support? Connect to a Listener

1. Be warm. Give support in a non judgmental way (if you're here you already know that)
2. Make affirmations of caller's strengths.
3. Encourage the member to engage in self-care activities:
 - Take a walk in the sun.
 - Eat small meals.
 - Asking help from others. It's great to ask for help.
4. Remind the member that as long she's receiving treatment, things should turn out for the better.
5. Encourage the member to use 7Cups resource and talk with listeners whenever she needs. Remind her that 7Cups is there for her.

Remember!

Most relevant Wellness and self-care skills when it comes to this population:

- Getting at least 5h uninterrupted sleep, if possible, per night (which usually means getting family to help).
- Eating frequent small meals.

Stage II: Patient Feedback

Participants

In the second stage, nine patients with perinatal depression or anxiety disorders were recruited from the Adult Outpatient Department in The Zucker Hillside Hospital. Outpatient clinicians were provided inclusion and exclusion criteria and

indicated which of their patients would be eligible. Eligible patients required a diagnosis of perinatal depression or anxiety as indicated by their psychiatrist and recorded in their electronic medical record. Participants' ages ranged between 25 and 34 ($M = 28.9$, $SD = 2.6$), and most of them suffered from postnatal mood disorder (see [Table 1](#) for demographics and diagnostic information).

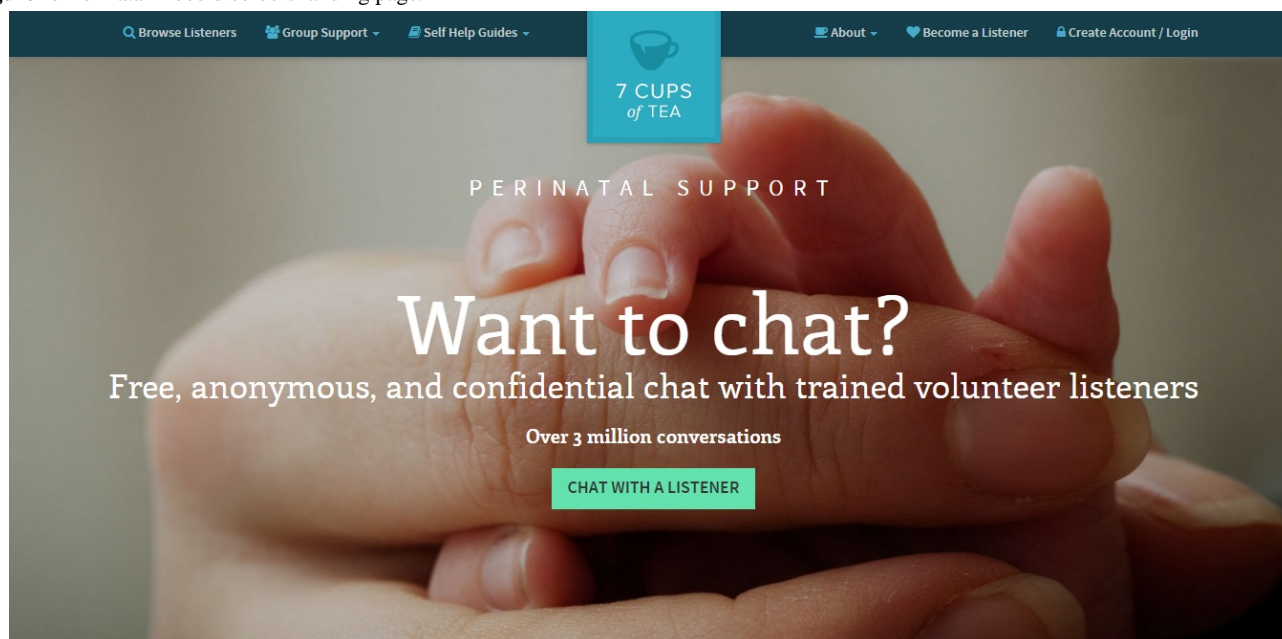
Table 1. Demographics and clinical diagnoses.

Participant	Age	Racial background	Clinical diagnosis			
			Antenatal	Postnatal	Depression	Anxiety
1	29	White		X		X
2	29	White		X		X
3	29	Multiracial	X		X	
4	25	Black/African American		X	X	
5	29	Unknown		X	X	
6	31	White		X	X	X
7	27	White		X		X
8	34	Unknown		X		X
9	27	Unknown	X			X

Procedure

Participants who met criteria were offered the opportunity to take part in this study by their clinician. Interested individuals provided their contact information and received a phone call from the first author (AB). On that call, the first author described the study's purpose and general procedure and obtained informed consent for study participation. Participants who consented to participate received an email with details regarding the study procedure. Participants were asked to examine 7Cups by conducting at least one chat on a day of their choosing between the hours of 7 and 10 p.m. A time window was required in order to ensure that listeners who completed the perinatal mood disorder training module would be available to chat. Clinical staff recommended 7-10 p.m. as a time that might be

ideal for listeners as well as users taking care of a new baby. Participants received an email with instructions how to use the platform including information, screenshots, and a detailed description of how to chat with listeners and were asked to contact the first author (AB) if they needed additional guidance. Participants accessed 7Cups through a specialized Web page (Figure 4 shows this), which limited the available listeners to those who completed the training program. Participants were asked to inform the first author when they had completed a chat session. At that time, they received a survey link via email asking them to report on their experience. Participants received a US \$25 Amazon gift card compensation for their participation. The Feinstein's Institutional Review Board approved study procedures.

Figure 4. Perinatal mood disorders landing page.

Measures

The survey consisted of Likert-type questions and free response open-ended questions. Five point Likert-scale measures addressed attitudes both toward the 7Cups platform and the

listeners providing support. There were 8 items that assessed usability, usefulness, and intention to use and recommend 7Cups and were adapted from established measures including the USE [40], Behavioral Intention to Use [35], and Word of Mouth Communication [41,42]. Attitudes toward the listeners were

measured using four items that were used in a previous study on 7Cups [36], adapted from measures of therapeutic alliance [43-45]. Minor modifications to existing questions were made to ensure they were relevant to 7Cups users (eg, “therapist” was replaced by “listeners”) and we consulted specialist health providers to confirm that modified questions were clear and understandable. Open-ended questions queried participants about additional aspects including general remarks regarding the program, in what ways (if any) using this support may complement treatment, preferences around use (ideal listener, times of use), and suggestions for improvements.

Data analysis included descriptive statistics of the multiple-choice questions, and an inductive thematic analysis of the answers to open-ended questions regarding general experience and complementing treatment. The latter was based on the six-phase method suggested by Braun and Clarke [46] which includes: familiarization with data, generation of initial

codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report.

Results

Satisfaction and Acceptance of the Online Emotional Support

Responses to the rating scales are presented in Table 2. All participants rated the emotional support program as usable and useful. Attitudes toward the listeners were extremely positive with 97% (35/36) of these responses being either agree or strongly agree. The highest ratings came on items related to the perceived helpfulness of the program including: “This kind of support can be helpful for me” (8/9 = strongly agree) and “I can see how in a certain amount of time after chatting with listeners, people can feel better” (8/9 = strongly agree). Finally, although all participants indicated that they would use and recommend 7Cups in relevant cases, only a minority indicated they would like to join 7Cups as listeners when they feel better.

Table 2. Participant usability, usefulness, intention to use and recommend, and attitudes toward the listeners’ ratings (n=9).

	Strongly disagree	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Strongly agree, n (%)
Usability					
I found the program accessible and easy to use.	0	0/9 (0)	0/9 (0)	5/9 (55)	4/9 (44)
Usefulness					
I liked to use this service.	0	0/9 (0)	0/9 (0)	4/9 (44)	5/9 (55)
This kind of support can be helpful for me.	0	0/9 (0)	0/9 (0)	1/9 (11)	8/9 (88)
Intention to use and recommend					
I would recommend this program to people who suffer from perinatal mood disorder.	0	0/9 (0)	0/9 (0)	2/9 (22)	7/9 (77)
I would recommend friends to use 7Cups.	0	0/9 (0)	0/9 (0)	7/9 (77)	2/9 (22)
I would recommend on using 7Cups to people who suffer from mental health difficulties.	0	0/9 (0)	0/9 (0)	5/9 (55)	4/9 (44)
I would probably use 7Cups in the future if needed.	0	0/9 (0)	0/9 (0)	5/9 (55)	4/9 (44)
When I will feel better, I would like to join 7Cups as a listener.	0	4/9(44)	3/9 (33)	1/9 (11)	1/9 (11)
Attitudes toward the listeners					
I felt the listeners cared about me as a person.	0	0/9 (0)	1/9 (11)	4/9 (44)	4/9 (44)
Listeners can do a good job in supporting people who suffer from perinatal depression/anxiety.	0	0/9 (0)	0/9 (0)	4/9 (44)	5/9 (55)
I believe these listeners can help people who suffer from mental health difficulties.	0	0/9 (0)	0/9 (0)	7/9 (77)	2/9 (22)
I can see how in a certain amount of time after chatting with listeners, people can feel better.	0	0/9 (0)	0/9 (0)	1/9 (11)	8/9 (88)

Thematic Analysis of Open-Ended Responses

Overall, most participants expressed a positive experience related to using the platform and indicated that easily available emotional support could complement treatment by enabling

them to receive just in time outlets for stress and emotions (see Table 3 for an overview of themes found in the analysis). Approximately half of participants suggested that this service could complement treatment by providing support when the clinicians are not available, and the same proportion of

participants indicated that this program might benefit them by providing an additional support person. Additionally, approximately half of participants noted a benefit of this program was it enables easy access to emotional support. A participant did comment negatively on feeling that it is difficult

to benefit when communicating on an online platform: (“It was fine, but I didn’t love it. Personally, I enjoy the bond forged by an in-person meeting. I liked the service in general, but do not feel that the chat that I had was beneficial to my overall anxiety”).

Table 3. Themes found in participants’ general remarks regarding the program and answers to the ways using this support may complement treatment.

Theme	n	Examples
Positive experience. A positive experience related to using the program.	8	“It was nice to discuss the experience I went through”. “Very helpful for me”.
Immediate outlet in a moment of need. Enabling to receive just in time outlet for stress and emotions.	8	“I think if one is in the throes of anxiety or a severe depression, it can be very helpful to talk things out in the moment”. “Immediate feedback and immediate response when you are dealing with high levels of depression or anxiety”.
Being there when the therapist is not available.	5	“Doctors and therapists are not always around, especially late at night. This is a great service for mom’s to be able to use during off hours”.
Providing additional support	4	“Another person validating my feelings are ok”. “It would reinforce the support”.
Accessible. Easy to access and use.	4	“It’s easy when you have a young child that you don’t need to leave the home or be on the phone”.
Nonjudgmental approach.	3	“I think it’s good for people to have someone to talk to that is not seeing them so they don’t feel judged at all. Therapists or loved ones are good, but there is still a certain level of feeling judged”.
Providing hope and comfort.	3	“It’s a nice feeling knowing there’s someone out there who will listen”.

Suggested Modifications

Participants desired increased availability from the listeners, noting that it would be helpful to have more listeners to choose from at any given time. A participant wanted to be able to designate a preferred listener so they would not have to repeatedly explain their story. Another participant requested email notifications when responses within the platform were replied to in order to eliminate the need to log in and check within the platform. Another participant requested for listeners’ ages to be displayed, as she chatted with a listener for some time before learning the listener was fourteen years old.

Preferred Listeners’ Identity

Participants were specifically asked preference for gender of the listener. There were six participants that indicated a preference for female listeners, whereas the other 3 had no preference between men or women. In the open-ended responses, 5 participants wrote that they prefer the listener will have personal experience with depression or anxiety (“Someone who has experienced the same kind of anxiety or depression that I have, so they can understand and be supportive”). A participant expressed preference for someone who has experience dealing with anxious people or first time mothers.

Preferred Times to Chat

Participants were asked to indicate all times in which they would prefer using 7Cups. There were six participants that identified the evening (6-10 p.m.) or nights (10 p.m. or later) as preferred times to chat with listeners. There were two participants who identified both days and nights as preferred times. A participant identified the day as the only preferred time to use this service.

A participant wrote, “I honestly wish this service was available 24/7. Being a parent is a 24/7 job”.

Discussion

Principal Findings

Following clinicians’ feedback and program adjustments, patients with perinatal depression and anxiety reviewed 7Cups and chatted with listeners. They found the platform easy to use, useful, and indicated they could see themselves using 7Cups and recommending it to other women who suffer from perinatal depression or anxiety. Patients also viewed the listeners quite positively.

These findings suggest that women who suffer from perinatal mood disorders recognize a need for help outside the scheduled therapy time and perceive online emotional support as a potential tool to meet this need. Although patients’ preferred time windows for chats lined up with the providers’ recommendations, it seems that participants wanted much more availability and perceived the listeners’ availability as one of the main program advantages. This finding converges with the Pugh et al study [47] showing that one of the main perceived advantages of a therapist assisted online program for women who suffer from postpartum depression revolves around the program flexibility and accessibility, due to the mothers’ need to manage themselves around the child care schedule.

It also seems that patients who suffer from perinatal depression or anxiety are interested in receiving support from people either “like them” (women, people with experience with depression, anxiety, first time mothers) or those who have experience with people like them. Accordingly, such platforms should find

appropriate ways to inform users regarding which volunteers have previously experienced these disorders, and attempt to recruit more women who had personal experience with perinatal depression or anxiety. Potential concerns include confidentiality and stigma on the part of the volunteer; however, overcoming these concerns could be a solvable problem in the design and implementation of future platforms.

It is worth noting that the majority of the study's participants did not see themselves volunteering in this kind of platform in the future. It could be useful, thus, to explore why women, who found this platform helpful, would be hesitant to volunteer for such a platform. It is plausible that these women feel overwhelmed by the demands of caring for a new baby and soliciting mothers with older children, who had experienced perinatal depression or anxiety disorder, would be a better target. Another possibility is that women might be more likely to volunteer after they had received extended support from this program and experienced a reduction in the mood and anxiety symptoms such that they would feel better able to support someone else through the process. It might also be worth exploring methods that allow people to receive and provide support at the same time, making the platform more scalable as additional users join, for example, [48]. Another solution to overcome the limitation in the number of volunteers would be for a single trained peer to offer support to a group of users. For example, studies have demonstrated that online group support can be beneficial for women experiencing postpartum depression [49], and depressive symptoms following breast cancer diagnosis [50]. With these considerations taken into account, one should note that in less than one week, 46 listeners were trained and then became available for this study. In fact, it is likely we could have trained more listeners, as the training is an automated and nonconsumable [51] resource. However, we choose not to do so given the small number of study participants, as we believed that recruiting listeners without providing them the opportunity to chat could contribute to dissatisfaction and burn out on the part of the listeners. Nevertheless, we cannot comment on how many listeners would be required to provide opportunities to chat around the clock. We limited our supply such that it would not outstrip demand, but given the large burden of perinatal depression and anxiety (and other similar mental health conditions), it could be possible that demand would be such that additional considerations would have to be made to recruit more listeners.

Participants would also appreciate a better display of listeners' characteristics and clear guidance on how to choose a listener based on these characteristics. A participant chatted with a very young listener, another participant was under the impression that she would have to repeatedly explain her story during each chat, and while some participants believed men could provide suitable support, others did not. Based on this feedback, it seems that different women might prefer different listeners. Choosing a listener is a critical step in using such a platform. Examining the listeners' characteristics and qualifications prior to the chat can provide appropriate expectations on whether that listener would be a good fit. It seems that platforms such as 7Cups could benefit from adding tutorials to educate users how to identify the most suitable listener for their needs, and from presenting

relevant information such as listeners' age in a more prominent manner.

It is worth noting that not all patients perceived this platform as beneficial. Indeed, 7Cups served only as a tool to provide emotional support. It might be helpful to also integrate more didactic information and resources to teach skills to cope with mood and anxiety. The clinicians' feedback called for increased knowledge of skills and resources for the listeners to recommend to users and this was included in the training program created. Digital tools such as mindfulness training exist [52,53] and could be impactful if provided to users.

Findings from this study should be considered in light of its limitations. First, feedback came from a few number of patients. However, given the formative stage of this research, significant problems and needs can be identified using only a few users. In the case of usability concerns, most problems can be uncovered using only five users [54]. Second, only a few listeners were trained to support the program with limited availability to provide support (only 7-10 p.m.). This made sense as this trial deployment recruited a few people to use the program and listeners available throughout the day would be used rarely and might become bored or unmotivated. A larger deployment with more users would necessitate more listeners, however, this could also expand availability throughout the day. Third, the program to support women with perinatal depression or anxiety was designed to supplement treatment, and thus, the results do not speak to whether this support is sufficient for women who suffer from these conditions, but do not receive formal mental health care. Finally, listeners in this project went through additional training and were required to have received the verified listener badge. Thus, not only had these listeners already indicated being a subset of listeners (through receiving the badge), but their willingness to complete the training may also differentiate them. The positive ratings in our study, including the "attitudes toward the listener", may not apply to chats completed with other listeners. Indeed, quality of peer supporters within this and other programs is a likely determinant of successful outcomes, which is one reason why the training program was included in our study.

Future Directions

The aim of the current paper was to present the development of a program to supplement treatment for perinatal mood disorder by leveraging an existing online platform and eliciting patients' opinions of this program. This study was motivated by a desire to implement such a program into a health care setting, introducing a novel form of support without placing added burden on health care providers. More research needs to address implementation into practice and evaluate efficacy and feasibility in real-world settings [55]. Leveraging the online emotional support provided by 7Cups listeners to complement ongoing treatment for perinatal depression or anxiety is a powerful example of such efforts.

Efforts are currently underway to expand the use of 7Cups for additional patients and to examine the utilization, satisfaction, and clinical outcomes of patients using this service. Based on the results of this study, modifications include training more listeners, recruiting listeners with personal experience of

perinatal mood disorders, providing group support tools, integrating relevant evidenced-based self help tools within the platform, and appropriately presenting relevant information about the listener.

Furthermore, similar investigations could evaluate the feasibility and impact on providing such a resource to women with perinatal depression and anxiety who are not receiving formal mental health care resources. Many women who suffer from these conditions are not able to receive formal resources for a variety of reasons (access, cost, time) and the resource examined in this study or similar tools could provide some benefit in these cases.

Conclusions

The results of this study highlight the promise of 7Cups as a tool to introduce accessible, freely available peer support into

existing treatment settings. Along with other studies that have demonstrated that peer support is an effective tool to prevent perinatal depression via phone [56] and is generally acceptable by women who suffer from postpartum depression [57,58], 7Cups could meet several of the needs of women seeking treatment for perinatal depression or anxiety. These findings are also congruent with the Griffiths et al study [59] showing that peer support delivered online is perceived to provide a useful support for those who suffer from depression. This study also demonstrates how adjustments made to a publically available off-the-shelf product could increase its usefulness for a given health care setting. Given the high development costs of technological resources and evolving technological landscape, studies that use existing tools rather than developing and evaluating completely new products might be more likely to influence current clinical practices.

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Conflicts of Interest

None declared.

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Abbreviations

apps: applications

7Cups: 7 Cups of Tea

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Original Paper

Using Smartphones to Monitor Bipolar Disorder Symptoms: A Pilot Study

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Abstract

Background: Relapse prevention in bipolar disorder can be improved by monitoring symptoms in patients' daily life. Smartphone apps are easy-to-use, low-cost tools that can be used to assess this information. To date, few studies have examined the usefulness of smartphone data for monitoring symptoms in bipolar disorder.

Objective: We present results from a pilot test of a smartphone-based monitoring system, Social Information Monitoring for Patients with Bipolar Affective Disorder (SIMBA), that tracked daily mood, physical activity, and social communication in 13 patients. The objective of this study was to investigate whether smartphone measurements predicted clinical symptom levels and clinical symptom change. The hypotheses that smartphone measurements are (1) negatively related to clinical depressive symptoms and (2) positively related to clinical manic symptoms were tested.

Methods: Clinical rating scales were administered to assess clinical depressive and manic symptoms. Patients used a smartphone with the monitoring app for up to 12 months. Random-coefficient multilevel models were computed to analyze the relationship between smartphone data and externally rated manic and depressive symptoms. Overall clinical symptom levels and clinical symptom changes were predicted by separating between-patient and within-patient effects. Using established clinical thresholds from the literature, marginal effect plots displayed clinical relevance of smartphone data.

Results: Overall symptom levels and change in clinical symptoms were related to smartphone measures. Higher overall levels of clinical depressive symptoms were predicted by lower self-reported mood measured by the smartphone ($\beta = -.56$, $P < .001$). An increase in clinical depressive symptoms was predicted by a decline in social communication (ie, outgoing text messages: $\beta = -.28$, $P < .001$) and a decline in physical activity as measured by the smartphone (ie, cell tower movements: $\beta = -.11$, $P = .03$). Higher overall levels of clinical manic symptoms were predicted by lower physical activity on the smartphone (ie, distance travelled: $\beta = -.37$, $P < .001$), and higher social communication ($\beta = .48$, $P = .03$). An increase in clinical manic symptoms was predicted by a decrease in physical activity on the smartphone ($\beta = -.17$, $P < .001$).

Conclusions: Clinical symptoms were related to some objective and subjective smartphone measurements, but not all smartphone measures predicted the occurrence of bipolar symptoms above clinical thresholds. Thus, smartphones have the potential to monitor bipolar disorder symptoms in patients' daily life. Further validation of monitoring tools in a larger sample is needed. Conclusions are limited by the low prevalence of manic and depressive symptoms in the study sample.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 05663421; <http://www.controlled-trials.com/ISRCTN05663421> (Archived by WebCite at <http://www.webcitation.org/6d9wsibJB>)

KEYWORDS

smartphone; sensor technology; bipolar disorder; monitoring; phase transitions; communication patterns; activity patterns

Introduction

Bipolar disorder is a serious and disabling psychiatric condition that encompasses a broad group of disorders. International lifetime prevalence estimates indicate that bipolar disorders are present in 1-5% of the general population [1]. It involves mood, behavioral, and cognitive disruptions during episodes of depression, mania, or hypomania. The recurrent and chronic nature of bipolar disorder results in a high burden of disease [2-4] and high societal costs [5]. The suicide rate of people diagnosed with bipolar disorder is the highest among all mental disorders [4,6]. Even during periods of remission, patients experience frequent subclinical mood symptoms that impair daily functioning and increase their risk for relapse [7,8].

The heterogeneity of symptoms and individual courses of disease in bipolar disorder make it difficult to predict the course of the disorder [9]. Compared to a patient with high blood pressure who needs to maintain blood pressure below a certain threshold, no analogous guidance is currently provided for patients suffering from bipolar disorder. As a consequence, patients often do not recognize their mood changes in a timely manner and lose their insight into illness [10], leading to adverse consequences [11]. In order to prevent relapses, timely information on upcoming phase transitions must be available to patients and doctors [12]. This information could allow providers to intervene shortly after symptoms appear.

Information from patients' daily life can help provide an earlier and more reliable prediction of impending phase transitions in bipolar disorder [13-16]. It has been suggested that smartphones may be easy-to-use, low-cost devices that can be used to measure this information in the patient's daily environment. Using both self-reported information collected by the device and making use of the smartphone sensor capabilities, researchers hope to gain insight in the user's well-being and behavior. Among mental health patients, too, there is great interest in monitoring symptoms with mobile apps [17]. It has been found that daily mood and the level of physical and social activity can be measured with smartphone sensors [18-22]. These measurements are assumed to represent central aspects of bipolar disorders [23,24].

Additional research is needed to establish the relationship between smartphone measurements and clinical symptoms in bipolar disorder. In particular, a more personalized approach to capture warning signs for impending phase transitions needs to consider both the patients' overall symptom levels and the dynamic symptom changes occurring over time. The advantage of this approach is that it is able to capture the interindividual variability and heterogeneity of bipolar disorder, where symptom

severity within one patient fluctuates over time [25]. While statistical methods exist to compute predictions for overall symptom levels and symptom change in smartphone data [26], previous studies did not separate between these central illness components.

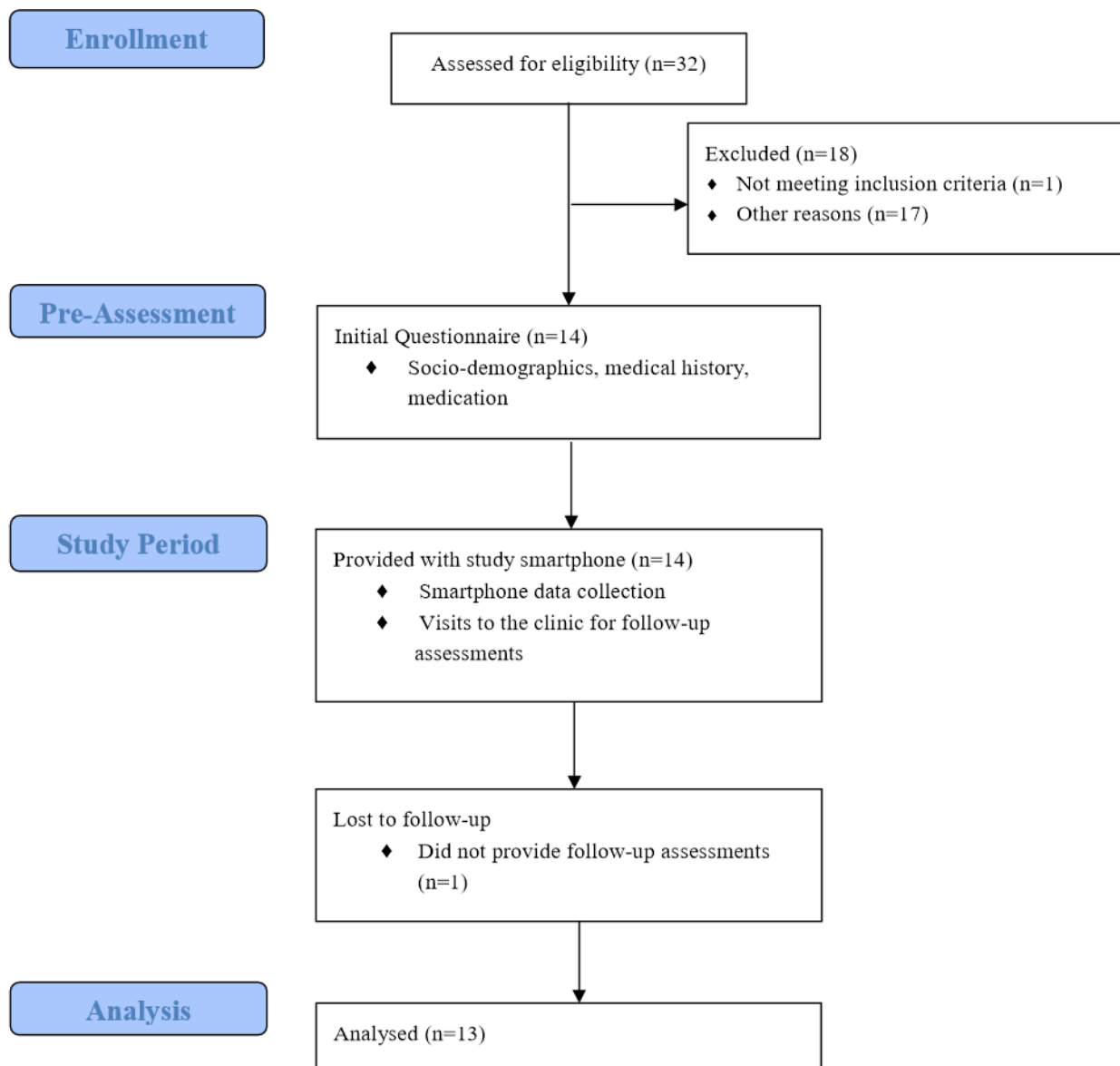
To address this research gap, a study was conducted to investigate whether smartphone data predict impending clinical symptoms in bipolar disorder. The aim of this study is twofold. First, we compare the relationship of daily self-reported mood, smartphone sensor data (ie, Global Positioning System [GPS], cell tower movements, accelerometer), and smartphone communication (ie, calls, short message service [SMS] log) with clinical symptoms. We hypothesize that for depressive symptoms, higher levels of self-reported mood, and higher levels of physical activity and social communication measured by the smartphone predict lower overall levels of depressive symptoms and temporal decreases in clinical depressive symptoms. For manic symptoms, we hypothesize that higher levels of self-reported mood and higher levels of physical activity and social communication measured by the smartphone predict both higher overall levels of clinical manic symptoms and temporal increases in manic symptoms. Second, to identify the clinical relevance of smartphone data we test the hypothesis that smartphone data predict the occurrence of overall symptoms levels above clinical thresholds.

Methods

Recruitment

Figure 1 presents the study flow chart. Participants were recruited from the outpatient department of a Psychiatric Clinic in Lower Saxony, Germany, between July 2013 and February 2014. Patients were contacted and assessed for eligibility in random order from the pool of outpatients. Inclusion criteria were diagnosis of bipolar I or bipolar II disorder according to the criteria in the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition (DSM-IV) [27], at least 18 years of age, sufficient knowledge of the German language, and basic competence in using mobile devices. Exclusion criteria were the need for inpatient treatment at the time of recruitment, suicidality, diagnosis of schizophrenia or an intellectual disability, and alcohol or drug abuse up to 6 month prior to the study. All participants provided written consent prior to participation and were loaned a smartphone for the 12-month study period. Participants were provided with an unlimited call, text, and data plan and were encouraged to use the study smartphone as their regular mobile device. The study was examined and approved by the Leuphana University Ethics Committee.

Figure 1. Study flow chart.



Measurements

Smartphone data were collected on a Sony Ericsson Xperia Neo V smartphone with Android 4.0.4. The device had the Social Information Monitoring for Patients with Bipolar Affective Disorder (SIMBA) app pre-installed. The app was developed by the authors and is based on two open source frameworks for the collection of both subjective self-report data [28] and objective sensor data [29], which are available at [30,31]. First, Open Data Kit developed at the University of Washington [28] collects subjective self-report data. Designed for socioeconomic and health surveys, Open Data Kit provides a platform to build questionnaires and to collect data on a smartphone. Its modular design allows for the implementation of questionnaires at fixed or random time points. Second, the Funf open sensing framework developed at the Massachusetts Institute of Technology (MIT) media lab [29] collects objective data using various smartphone sensors, for example, GPS, accelerometer, and screen state. It provides an extensible sensing and data

processing framework for smartphones. As using smartphone sensors can drain the device battery quickly, Funf is designed to prolong battery life. The source code for the software frameworks can be found in [Multimedia Appendix 1](#).

Three smartphone sensors were used to measure physical activity: GPS for the distance traveled per day, cell tower movement as an indicator of location changes, and accelerometer to measure the users' device activity. Both GPS and cell tower movements capture spatial movement and since the correlation between GPS and cell tower movements was low ($P=.06$), both measures were included. For the measurement of social communication, the number and duration of outgoing calls and the number of SMS sent per day were logged. The gathered data were cached in local storage and transferred to a secured server located at Leuphana University whenever an Internet connection was available.

Self-reported mood states were assessed once a day on the smartphone at random times with a 2-item questionnaire. When

the questionnaire was available, participants were notified via a beep and asked if the questionnaire should be answered now or if the participant wished to be notified later. Affect was assessed with the item, “On a scale of 1 (very good) to 10 (very bad), please describe your present mood,” and energy was assessed with the item, “On a scale of 1 (very energetic) to 10 (not at all), how energetic do you feel at the moment?” For the purposes of this analysis, both items were reverse-coded so that higher scores reflected better mood. Due to the high correlation between the 2 items ($P=.84$), a single mood index was constructed.

Clinical assessments were conducted repeatedly throughout the study and served as a reference point for the smartphone data. Appointments with the treating clinician, who was blinded to smartphone data, were scheduled at approximately 8-week intervals and included assessment of manic and depressive symptoms using clinical rating scales. Manic symptoms were assessed using the German Version [32] of the Young Mania Rating Scale (YMRS) [33]. The scale is administered by a clinician and rates major relevant manic symptoms (eg, elevated mood, motoric activity) on a scale from 0-64. Values less than 5 indicate complete remission [34]. Depressive symptoms were assessed with the German Version [35] of the Hamilton Depression Scale (HAMD) [36]. The scale is based on clinician assessment and scores 17 items within a reference period of 1 week. Values greater than 7 indicate at least a mild depressive syndrome [37].

Statistical Analysis

Smartphone data were aggregated to assessment periods before each clinical appointment by computing mean scores from the daily measurements resulting in an aggregated score for each assessment period. An assessment period is the number of days between two clinical appointments. Then, the effect of the aggregated smartphone data on the clinical symptoms was assessed for each assessment period. To accommodate the nested data structure, where observations are nested within patients, multilevel models were computed according to [38] in order to obtain robust and unbiased estimates of variance components. Random coefficient models were fitted, where assessment periods were nested within patients. Smartphone data were modeled to separate between-patient effects (ie, symptom level) and within-patient effects (ie, symptom change) [26].

We estimated three separate models for self-reported data, activity data, and social data, and one full model including all smartphone data. All models were adjusted for age, sex, and length of assessment period. The total length of assessment periods was used in order to compute more precise estimates, as opposed to restricting the analysis to the shorter time frame using the reference period of HAMD and YMRS before each clinical assessment. To compare the results of the models, standardized regression coefficients are reported [39]. To provide a graphical representation of the relationship between smartphone data and clinical symptoms, the results of the full model were used to compute marginal effects, which were plotted against symptoms. The analysis was performed using the “xtmixed” command in Stata 13, where the maximum likelihood estimation method was specified [40]. Significance levels are reported at the 95% level.

Results

Sample Characteristics

Of the 14 patients who were recruited, one dropped out before clinical follow-up assessment and was thus removed from the study. Table 1 presents the sample characteristics for the 13 patients who completed the study.

Description of Dataset

Table 2 shows the available data points for self-reported data, activity data, social data, and clinical data. The compliance rate for self-reported data was 55.7%. Activity data were complete on 78.2% of days, and social data were present on 56.1% of days.

Mean Levels of Smartphone and Clinical Data

Table 3 presents mean levels and range for smartphone-collected indicators and clinical data. The average level of self-reported mood was 6.7 (SD 1.7) with a maximum of 10, indicating that average mood levels of subjects were at the upper end of the end of the scale ranging from 1 (very bad mood) to 10 (very good mood). Clinical symptom ratings revealed mean manic symptoms levels assessed by YMRS of 2.7 (SD 3.6) and depressive symptoms assessed by HAMD of 5.1 (SD 5.3), indicating low prevalence of manic and depressive symptoms in the sample.

Table 1. Sample characteristics for 13 patients.

Characteristic	N	Value
Age in years, mean (SD)	13	47.2 (3.8)
Sex, %		
Male	8	61.5
Female	5	38.5
Education, %		
Lower secondary	9	69.2
Upper secondary	4	30.8
Qualification		
None	1	7.7
Vocational	10	76.9
University level	2	15.4
Employed, %		
Yes	4	30.8
No	9	69.2
Diagnosis, %		
Bipolar I	6	46.1
Bipolar II	7	53.9
Years since first diagnosis, mean (SD)	13	9.9 (3.1)
Manic episodes, mean (SD)	13	8.6 (1.6)
Depressive episodes, mean (SD)	13	12.3 (3.0)
Total hospitalizations, mean (SD)	13	6.9 (2.8)
Currently medicated, %		
Yes	11	84.2
No	2	15.4
Study duration in days, mean (SD)	13	365.1 (31.9)
Length of assessment period, mean (SD)	13	68.6 (23.6)

Table 2. Total available data points for self-reported data, activity data, social data, and clinical data collected by 13 patients.

	N	Mean (SD)	Min/Max	Rate, %
Self-reported	2456	188.9 (83.3)	24/291	55.7
Activity	3537	272.1 (74.9)	154/362	78.2
Social	2624	201.8 (109.3)	9/339	56.1
Clinical	75	5.8 (1.4)	3/8	NA

Table 3. Mean levels, interquartile range, and range for smartphone indicators and clinical variables for 13 patients.

Variable	Mean (SD)	Interquartile Range	Min/Max
Self-reported			
Mood	6.7 (1.7)	2.0	1/10
Activity			
Distance traveled, km	10.5 (41.5)	6.3	0/732
Cell tower changes	10.5 (17.0)	10.0	0/139
Device activity, % of day	7.3 (8.2)	9.2	0/75
Social			
Number outgoing calls	2.9 (3.6)	4.0	0/29
Duration outgoing calls, minutes	10.2 (19.6)	11.3	0/181
Outgoing SMS	1.7 (3.6)	2.0	0/54
Clinical			
YMRS	2.7 (3.6)	4.0	0/18
HAMD	5.1 (5.3)	9.0	0/18

Prediction of Clinical Symptoms

This section presents the results from the multivariate models with smartphone data as predictors for clinical symptoms. We begin with results from the between-patients analysis, representing the overall level of clinical symptoms as predicted by smartphone data. Next, we present results of the within-patient analysis, representing temporal changes in clinical symptoms as predicted by smartphone data.

Between-Patient Analysis

The combined model (Model 4) in Table 4 showed a significant negative relationship between mood level and clinical depressive symptoms (HAMD: $\beta = -.56$, $P < .001$) but not on manic symptoms. This suggests that patients who reported better daily mood on the smartphone were less clinically depressed. In the

activity data, distance traveled as measured by the GPS signal had a significant negative relationship with clinical manic symptoms (YMRS: $\beta = -.37$, $P < .001$), indicating that patients who were more physically active experienced fewer manic symptoms. Cell tower movements and device activity were not significantly related to any clinical symptoms. In the social data, the number of calls made on the smartphone were positively related to clinical manic symptoms (YMRS: $\beta = .48$, $P = .03$), suggesting that patients who made a higher frequency of calls experienced higher levels of manic symptoms. The duration of calls was not significantly related to symptoms. The number of outgoing SMS had a negative relationship with clinical depressive symptoms (HAMD: $\beta = -.17$, $P < .001$), indicating that patients who sent more SMS had less severe depressive symptoms.

Table 4. Between-patient relationship of self-reported data, activity data, and social smartphone data with bipolar disorder symptoms for 13 patients based on 75 clinical ratings^a.

	Beta (P)			
	Self-report Model 1 (N=74)	Activity Model 2 (N=62)	Social Model 3 (N=71)	Combined Model 4 (N=62)
Mood				
YMRS	-.09 (.45)			.05 (.79)
HAMD	-.42 (<.001)			-.56 (<.001)
Distance traveled, km				
YMRS		-.46 (.01)		-.37 (<.001)
HAMD		-.24 (.12)		-.12 (.34)
Cell tower movements				
YMRS		-.24 (.29)		-.14 (.12)
HAMD		.08 (.58)		-.04 (.82)
Device activity, %				
YMRS		.31 (.24)		.26 (.12)
HAMD		-.01 (.92)		-.06 (.80)
Number of calls				
YMRS			.19 (.38)	.48 (.03)
HAMD			.34 (.17)	.08 (.65)
Duration of calls, minutes				
YMRS			.17 (.45)	-.08 (.72)
HAMD			-.22 (.25)	.03 (.83)
Outgoing SMS				
YMRS			.03 (.72)	-.02 (.65)
HAMD			.04 (.84)	-.17 (<.001)

^aStandardized effects of random coefficient regression models with smartphone data as predictor of depressive symptom levels (YMRS) and manic symptom levels (HAMD).

Within-Patient Analysis

Table 5 displays the within-patient relationship between change in smartphone data and change in clinical symptoms. In the full model, change in self-reported mood on the smartphone was not related to clinical symptom changes. An increase in cell tower movement was negatively related to both manic symptoms (YMRS: $\beta = -.17$, $P < .001$) and depressive symptoms (HAMD:

$\beta = -.11$, $P = .03$), suggesting that when a patient's activity level as measured by the smartphone increased, both manic and depressive symptoms decreased. However, changes in distance traveled and device activity were not significantly related to symptom changes. In the social data, an increase in outgoing SMS was negatively related to a change in depressive symptoms (HAMD: $\beta = -.28$, $P < .001$), which suggests that when more SMS are sent, clinical depressive symptoms are lowered.

Table 5. Within-patient relationship of change in self-report, activity, and social smartphone data with change in bipolar disorder symptoms for 13 patients^a.

	Beta (P)			
	Self-report Model 1 (N=74)	Activity Model 2 (N=62)	Social Model 3 (N=71)	Combined Model 4 (N=62)
Mood				
YMRS	-.09 (.28)			.03 (.73)
HAMD	-.18 (.10)			-.09 (.26)
Distance traveled, km				
YMRS		.03 (.40)		.01 (.85)
HAMD		.07 (.23)		.03 (.66)
Cell tower movements				
YMRS		-.10 (.03)		-.17 (<.001)
HAMD		-.17 (<.001)		-.11 (.03)
Device activity, %				
YMRS		-.11 (.17)		-.07 (.26)
HAMD		-.15 (.09)		.02 (.87)
Number outgoing calls				
YMRS			.18 (.34)	.24 (.44)
HAMD			-.07 (.60)	-.07 (.73)
Duration outgoing calls, minutes				
YMRS			-.25 (.27)	-.34 (.24)
HAMD			-.07 (.63)	-.09 (.58)
Outgoing SMS				
YMRS			-.05 (.35)	.03 (.68)
HAMD			-.30 (<.001)	-.28 (<.001)

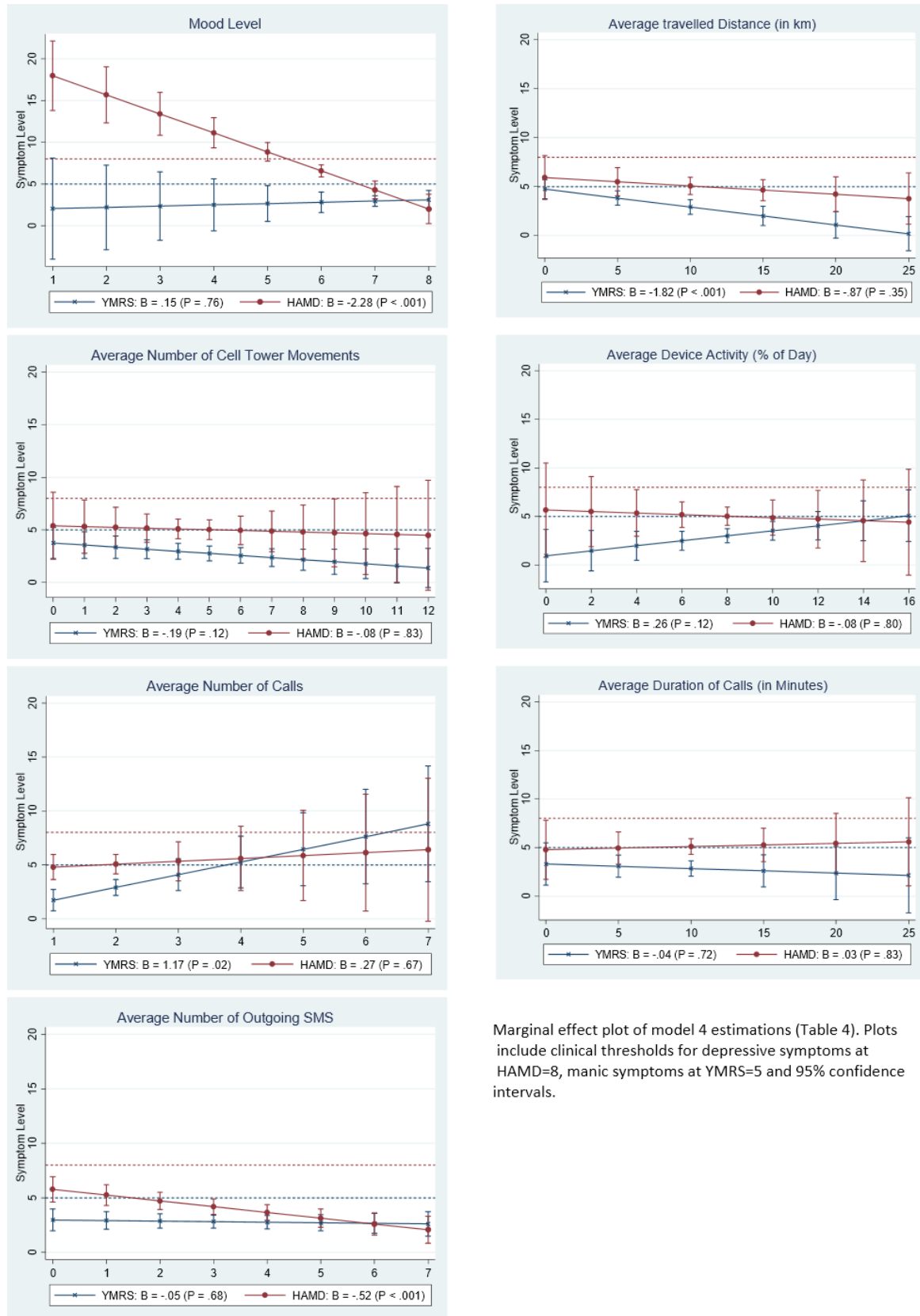
^aStandardized effects of random coefficient regression models with smartphone data as predictor of depressive symptom change (YMRS) and manic symptom change (HAMD).

Clinical Relevance of Smartphone Data

Figure 2 plots predicted symptoms levels including clinical thresholds, and Figure 3 plots predicted symptom change by

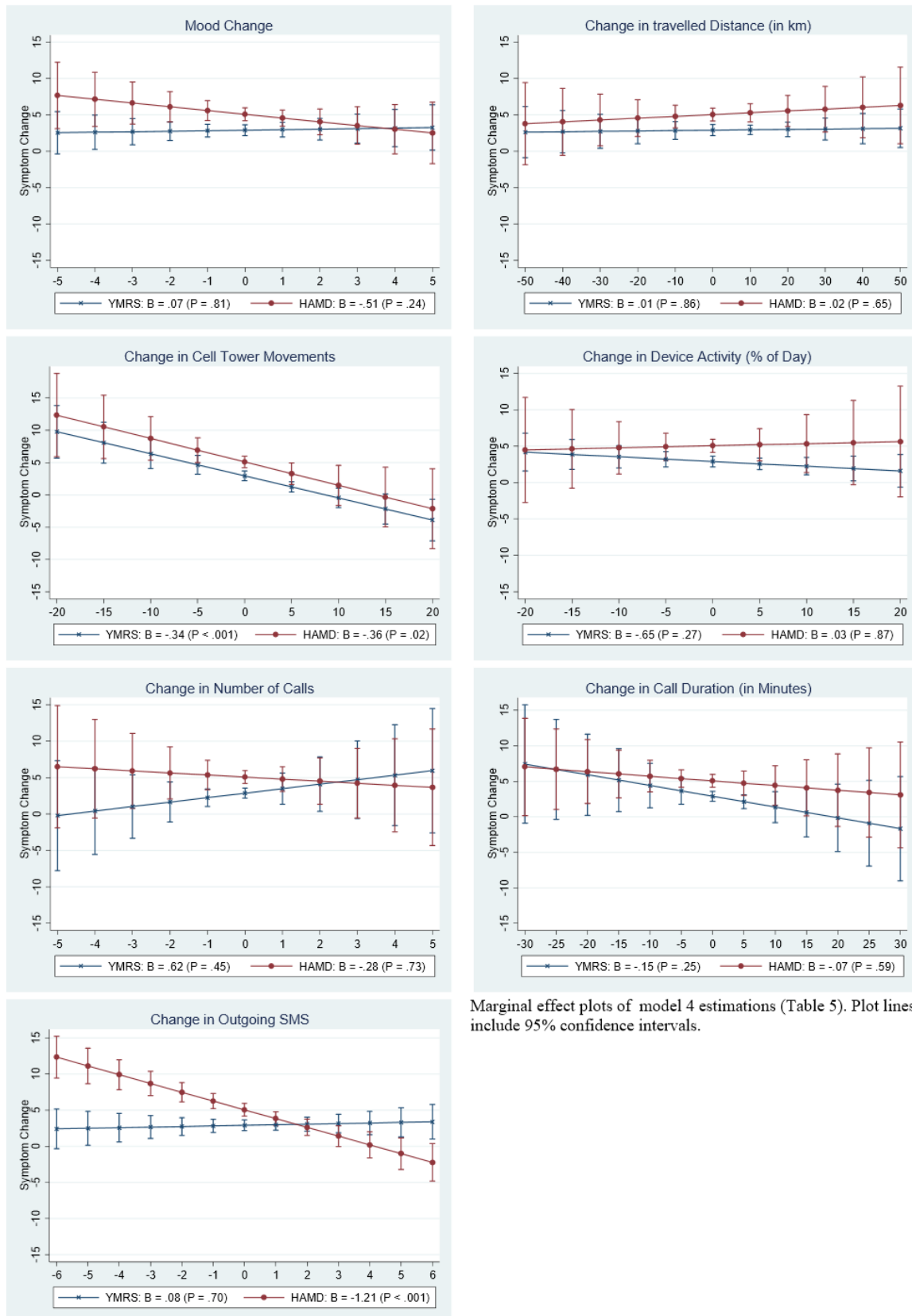
smartphone data. The plots are computed from the full models in Tables 4 and 5.

Figure 2. Between-patient analysis of smartphone data and symptom levels.



Marginal effect plot of model 4 estimations (Table 4). Plots include clinical thresholds for depressive symptoms at HAMD=8, manic symptoms at YMRS=5 and 95% confidence intervals.

Figure 3. Within-patient analysis of smartphone data and symptom change.



Marginal effect plots of model 4 estimations (Table 5). Plot lines include 95% confidence intervals.

Between-Patient Analysis

Figure 2 shows that depressive symptoms above the clinical threshold are predicted when the average mood level is lower than 6 points on the 10-point mood scale. While the average

number of calls had a positive effect on clinical manic symptoms (YMRS: $\beta = 1.17$, $P = .02$) and the average number of outgoing SMS had a negative relationship with clinical depressive symptoms (HAMD: $\beta = -.52$, $P < .001$), this did not predict the occurrence of symptoms above the clinical threshold.

Within-Patient Analysis

Figure 3 visualizes the relationship between change in smartphone data and change in clinical symptoms as computed in Table 5. The negative relationship of change in cell tower movements with both clinical manic symptoms (YMRS: $\beta = -.34$, $P < .001$) and clinical depressive symptom changes (HAMD: $\beta = -.36$, $P < .02$), indicated that when a patient's activity as measured by the smartphone was below average, clinical symptoms were elevated and vice versa. Figure 3 shows that when a patient made 20 cell tower movements fewer than average, the model predicts an YMRS score of approximately 10 points and an HAMD score of 12 points above the patient's average. Last, Figure 3 visualizes the negative relationship between change in outgoing SMS and change in depressive symptoms (HAMD: $\beta = -1.21$, $P < .001$), implying that when a patient sent more text messages than average, symptoms were lowered.

Discussion

Principal Results

In this pilot study, smartphone-based monitoring of mood, physical activity, and social communication was conducted in the daily life of bipolar disorder patients over the course of 12 months. The between-patient and within-patient variance of smartphone data was analyzed to present the relationship of smartphone data with both overall levels and changes in clinical symptoms. The results allow conclusions on the usefulness of smartphone measurements for the monitoring of bipolar disorder.

Higher overall levels of depressive symptoms were predicted by lower self-reported mood measured by the smartphone. An increase in depressive symptoms was predicted by a decline in social communication (ie, outgoing SMS) and a decline in physical activity (ie, cell tower movements). In contrast to our hypothesis, self-reported mood did not predict clinical manic symptoms. The overall level of manic symptoms was predicted by activity (ie, distance traveled) and social communication (ie, number of calls). In contrast to our hypothesis, an increase in clinical manic symptoms was predicted by lower physical activity (ie, cell tower movements). Other smartphone measurements (ie, device activity and the duration of calls) were related to neither symptom levels nor symptom changes.

In addition, the clinical relevance of the results was examined by investigating if smartphone measurements predicted symptom levels above clinical thresholds. This information may provide information on which smartphone measurements can be used to predict the occurrence of symptoms above clinical thresholds. Self-reported mood was found to predict depressive symptom levels above the clinical threshold but not manic symptoms. No other smartphone measurements predicted symptoms above clinical thresholds.

Comparison With Prior Work

Within the self-reported data, our data support the findings [14,20] that daily mood ratings are useful for monitoring depressive symptoms in patients who experience bipolar disorder. Similar to those studies, we could not support the

hypothesis that daily mood measured by the smartphone predicts clinical manic symptoms. This is probably the result of the low prevalence of patients with severe manic symptoms in our sample (see Table 3).

Physical activity was included in the analysis as it represents a warning sign for phase transitions in bipolar disorder and can potentially be measured objectively with smartphone sensors. Similar to the approach in Faurholt-Jepsen et al [20], we used GPS sensors to track the distance traveled, patient movements across cell towers as a second measurement of physical activity, and the smartphone accelerometers to assess patients' interaction with the device. In our analysis, some within-patient and between-patient effects showed significant relationships with clinical symptoms. However, we did not expect to find that physical activity was negatively related to manic symptoms, indicating that patients with higher overall levels of physical activity (ie, as measured by distance traveled) experienced fewer manic symptoms. We also did not expect to find that declining temporal activity (ie, as measured by cell tower movements) was associated with reduced manic symptoms. These findings run counter to the literature on the early warning signs of bipolar disorder [41,42], which assumes that increased activity is a prodrome of mania. These diverging results might be explained by the low prevalence of manic symptoms in our study sample. It can be speculated that for patients with subclinical manic symptoms, as in this study, increased activity signals better patient condition, but should not be mistaken with hyperactivity in patients with severe mania.

The social data measured by the smartphones capture patients' level of interaction with their social surroundings as an early-warning sign of bipolar disorder symptoms. Both between- and within-patient effects of social communication on clinical symptoms were found in the data, implying that overall levels and dynamic changes in communication are relevant for the prediction of bipolar disorder symptoms. The overall level of text messages sent and the number of calls placed indicated levels of depression and manic symptoms, respectively, while changes in text messages sent predicted changes in depressive symptoms. As a larger number of calls, but not the duration of calls, was associated with manic symptoms it is possible that patients with increased manic symptoms have a larger activity mirrored by more calls but not the ability to concentrate on lengthier calls. Overall, our research is in line with findings from other research that highlights the role of psychosocial variables in the illness course in bipolar disorder [43]. However, a comparable study [20] did not find significant correlations between social data and clinical symptoms.

A major feature of this analysis was that the collection of smartphone data and repeated clinical measures allowed us to separate two essential components of illness activity: overall symptom levels as observed by comparing the variance between patients, and dynamic changes that occur over the course of the illness as observed by comparing the variance within one patient over time. Although this approach introduces additional assumptions to the model and can make the interpretation of results more challenging, theoretical reasons speak for the separation of between- and within-patient variance. Evidence from modern follow-up studies shows that the course of illness

in bipolar disorder is characterized by high interindividual variability and heterogeneity [25]. Symptom severity within one patient fluctuates over time and often includes the expression of major, minor, and subclinical symptoms at different stages of illness [7]. Between-patient comparisons are insufficient to analyze how symptoms develop over time as they do not capture these within-person processes. The repeat sampling rate of the smartphone data in this study offers the advantage that the dynamic nature of psychopathology can be studied in real-time and in the real world.

Limitations

This study had several limitations. The small sample size of 13 patients may have lowered the statistical power of the study, leading to type II errors in the statistical conclusions. The number of participants did not allow the inclusion of additional level 2 predictors, which might explain between-patient differences (eg, type of bipolar diagnosis). Therefore, it is necessary to replicate the study in a larger sample to validate use of smartphone data for clinical applications.

The low prevalence of clinical depressive and manic symptoms (see Table 3) in our sample may have prevented us from detecting effects that would have been present in a sample of patients who experienced more severe symptoms. The generalization of the results to patients with more severe symptoms should be made carefully. Patients who are more severely ill may show different levels of acceptance in using smartphones for symptom monitoring. It is possible that the patients recruited for this study were particularly motivated to use smartphones.

Finally, compliance with filling out self-reporting data may have affected the results. However, we did not observe a decline in compliance with self-reported mood over time, indicating that missing values were missing at random. The compliance rate (55.7%; see Table 2) in our study is comparable to a study by Depp et al [44]. The conclusions of the social data could have been limited by the fact that we were unable to assess communication over social media (eg, WhatsApp, Facebook).

With communication habits moving towards social media apps, social media should be included in patient monitoring systems. We cannot exclude the possibility that patients shared the device with other people, although patients were instructed accordingly and no indication of such usage was found. Regarding the operating system, monitoring was restricted to Android smartphones and future studies should implement software for other operating systems (eg, iOS, Windows Phone) as well.

Ethical Considerations

Symptom monitoring in a patient's daily life involves the collection of sensitive health-related data including communication habits and movement patterns. Sensor-based data, such as GPS locations, need to be protected from unauthorized access. As such, concerns regarding data privacy and confidentiality issues need to be taken seriously in order to guarantee the safety of the collected personal data and to build patient trust. In this study, the encrypted and anonymized transmission of smartphone data to a protected server proved to be successful in ensuring patient data safety. From our experience, the full disclosure of the functionality of the monitoring app, as well as its potential clinical application, was also critical in fulfilling the ethical requirements.

Conclusions

Symptom monitoring is an important strategy to prevent relapses in patients with bipolar disorder. Smartphone apps are easy-to-use, low-cost tools that assist with symptom monitoring in daily life. In this pilot study, we tracked patient mood, levels of physical activity, and social communication over 12 months with an Android-based monitoring software (SIMBA). To our knowledge, this is the first study that successfully embedded a smartphone-based monitoring strategy in patients' daily life over such a long time frame. The study provides encouraging results concerning the feasibility, data analytic approaches, and clinical relevance of smartphone-based monitoring for bipolar disorder. With further clinical validation of smartphone data, it may be possible to provide smartphone-based monitoring tools for routine care, which may benefit patients and doctors.

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Authors' Contributions

TB analyzed the data, TB and SK wrote the manuscript, AM and CK contributed analysis tools, JM, WR, and GB obtained access to the dataset, and all authors contributed to the text and critically revised the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Source Code.

[ZIP File (Zip Archive), 5MB - [mental_v3i1e2_app1.zip](#)]

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Abbreviations

DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition

HAMD: Hamilton Depression Rating Scale

SIMBA: Social Information Monitoring for Patients with Bipolar Affective Disorder

YMRS: Young Mania Rating Scale

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Viewpoint

Mixing Online and Face-to-Face Therapy: How to Benefit From Blended Care in Mental Health Care

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Abstract

Blended care, a combination of online and face-to-face therapy, is increasingly being applied in mental health care to obtain optimal benefit from the advantages these two treatment modalities have. Promising results have been reported, but a variety in descriptions and ways of operationalizing blended care exists. Currently, what type of “blend” works for whom, and why, is unclear. Furthermore, a rationale for setting up blended care is often lacking. In this viewpoint paper, we describe postulates for blended care and provide an instrument (Fit for Blended Care) that aims to assist therapists and patients whether and how to set up blended care treatment. A review of the literature, two focus groups (n=5 and n=5), interviews with therapists (n=14), and interviews with clients (n=2) were conducted to develop postulates of eHealth and blended care and an instrument to assist therapists and clients in setting up optimal blended care. Important postulates for blended care are the notion that both treatment modalities should complement each other and that set up of blended treatment should be based on shared decision making between patient and therapist. The “Fit for Blended Care” instrument is presented which addresses the following relevant themes: possible barriers to receiving blended treatment such as the risk of crisis, issues in communication (at a distance), as well as possible facilitators such as social support. More research into the reasons why and for whom blended care works is needed. To benefit from blended care, face-to-face and online care should be combined in such way that the potentials of both treatment modalities are used optimally, depending on patient abilities, needs, and preferences. To facilitate the process of setting up a personalized blended treatment, the Fit for Blended Care instrument can be used. By applying this approach in research and practice, more insight into the working mechanisms and optimal (personal) “blends” of online and face-to-face therapy becomes within reach.

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KEYWORDS

blended care; Internet-delivered cognitive behavior therapy; mental health care; online; shared decision making

Introduction

The use of eHealth has shown promising results in various mental health treatments [1], especially when guidance from a care provider is included [2-4]. eHealth also provides opportunities for self-management and continuity of care. This combination of advantages of online and offline guidance and treatment render positive outcomes, making it a good alternative to regular face-to-face treatment [5].

In recent studies, this care provider guidance is mostly offered through email. Still, in order to offer patients the “best of both worlds,” the use of *blended* treatments, in which a combination of online (or mobile) components and face-to-face components is applied, is rising in clinical practice as well. Blended treatment or blended care is described in literature as “technology-supported care.” However, a clear definition of what blended care precisely withholds is currently unavailable, because blended care is operationalized in various ways. Studies have been performed on computer-assisted therapy as a partial

replacement of face-to-face sessions (sessions become shorter, not less frequent) [6]; unguided self-help modules combined with (scripted) face-to-face sessions to reflect on the progress of online treatment programs with a therapist [7]; and online modules as an addition to face-to-face depression treatment sessions [8]. Literature shows that blended care treatment can offer synchronous or asynchronous guidance, support via online guidance or self-help modules, and can apply personal or automated feedback and support, with promising effects [9]. Nevertheless, studies have shown that online and face-to-face treatments are often not integrated, but rather online components are used as an addition to regular therapy [3,10,11]. Moreover, often no rationale for applying specific blends of online and face-to-face treatment components is provided. These descriptions reflect the role of technology as supportive to traditional treatment, and do not acknowledge the potential equal contribution of both modalities of care.

To define blended mental health treatment and to decide which face-to-face components can be replaced by online modules is difficult. Up until now, only a fraction of all possible applications of blended treatment in mental health care has been explored and described. Previous research shows that there is a lack of knowledge on what exactly constitutes blended care, who can benefit from it, and how blended treatments should be set up [12]. This lack of research into the “ingredients” of proper blended care makes it hard to determine the effectiveness of this form of treatment and to advance implementation of blended care in practice. More specifically, questions like “what works for whom, and in what blend?” need to be answered. Therefore, the aim of this article is to describe postulates for blended care and to propose a strategy to implement blended care in a clinical setting based on predictors of successful online treatment that can be assessed previous to or during treatment.

Our viewpoint and postulates are based on previous research on the uptake of blended care and implementation of eHealth applications and e(mental) care in secondary care practice [12-14]. In a former study, we investigated barriers and facilitators to blended care [12]. First, we considered studies on types (operationalization) of blended care, and asked patients and therapists what their preferences for certain blended treatment configuration are, in a Delphi study [12]. These results showed that patients and therapists differ in their preference for division of online and face-to-face components. Besides, therapist did not have clear ideas on how online treatment can support face-to-face treatment; they asked for a guidance on how to blend online and offline care. This shows that adequate information and discussions between patient and therapist regarding the treatment operationalization are essential to enhance understanding and agreement on proper treatment. Further, therapists reported that the complexity of patients’ problems calls for a tailored blended treatment. What parts of treatment can best be offered online or face-to-face can differ between patients (based on ability, preference, severity, and type of problems) and should thus be considered for each patient individually. These findings indicate that blended treatment is no fixed formula, and should be approached as an opportunity to integrate treatment modalities to reach a proper, tailored

treatment plan. We describe the postulates for blended care that describe how blended care can fulfill this goal.

Postulates for Blended Care

To propose a definition of blended care, in which online and face-to-face components are used to their fullest potential to create an optimal combination, we defined the following postulates, based on our research in eHealth and blended care [12,13]:

1. The term “blended” refers to an integration of online and offline components in a treatment process. This means that online and offline components are interconnected in some way and not standalone treatment pathways [12].
2. Both the technology and face-to-face modalities contribute substantively and procedurally to the treatment process. This means that the use of online components contributes equally to the therapy as face-to-face components do [12].
3. In addition, online components should be carefully selected and adjusted to the treatment process and progress. This means that a standard 50:50 ratio of online and face-to-face care does not (always) suffice. Rather, weighing reasons and carefully deciding to apply one modality or the other are called for, while keeping a close look on the interrelatedness of both treatment modalities [12].
4. The integration of offline and online components should be based on the protocol for treatment, the capacities of technology to motivate and support patients to follow the treatment process, and the characteristics and capabilities of patients to receive and participate in online treatment [13]. This means that blended care is dynamic and flexible, as technology has the capacity to present the content in a nonlinear and dynamic way using text, images, interactive assignments, etc. Furthermore, it enables monitoring of online activities to intervene in an early stage when needed [13].
5. Therapists must consider the rationale for providing face-to-face and/or online modalities, following discussions with the patient to assure the fit between technology and the end users [13].

With these postulates in mind, a rationale for applying, developing, and researching blended mental health care is provided.

What Is Needed to Benefit From Blended Mental Health Treatment?

To translate these postulates into an instrument that summarizes relevant considerations in setting up blended treatment and guides therapists and clients through the process of jointly discussing and setting up blended treatment, we performed an additional literature search aimed at identifying predictors of blended treatment success. Only by knowing what variables play a role in desirable reach, use, and adherence of online therapy, the fit between a patient and a combination of online and face-to-face therapy can be created. A literature search on predictors of successful online treatment for depression showed that various variables play a part in the process of therapy use,

adherence, and success (for a complete overview, see [Multimedia Appendix 1](#)). First of all, people who have access to certain practical resources, are able to benefit from it. These resources include Internet access [15,16], a computer [15,16], and a place to work in safety and privacy [16]. In addition, having experience with computers and the Internet [16] and sufficient eHealth literacy [15,16] are necessary for online mental health treatment. Having enough time to integrate the treatment into (daily) life routine also facilitates online care [17,18]. Social resources are important for a successful treatment as well: support from a partner (or someone in the immediate vicinity of the patient) can improve discipline to use eHealth [16,17]. On a personal level, motivation and willingness to complete online therapy [17-20], trust in and credibility of the therapy [17,20-22], and need for support [17] during therapy all contribute to successful blended treatment. Independency, being disciplined, and being able to work in a structured way are also influential to treatment success [20]. Finally, personality traits have been reported to be associated with online treatment outcomes, as well as with locus of control, self-determination, and commitment and involvement in therapy [23-26]. Overall, these findings show that besides the practical necessities such as having a computer and Internet access, most predictors are facilitators rather than prerequisites for blended treatment, when treatment can be attuned to these particular characteristics.

To validate these facilitators for blended care, we invited health care professionals to discuss the rationale for the development of the instrument. We conducted a focus group in which 5 therapists (3 males) participated. These therapists are (mainly) experienced in treating patients with mood and anxiety disorders, personality disorders, and have (self-proclaimed) previous experience with eMental health treatment. In addition, we held individual interviews with 14 therapists (7 males), who had varying levels of experience in online or blended treatment. These clinical psychologists are (mainly) experienced in treating patients with mood and anxiety disorders, personality disorders, and developmental disorders. One of these therapists worked as a manager. These consultations with secondary health care therapists were essential to apply a practice-driven scope to the predictors we identified in literature. The focus of these iterative consultations was to assess how the predictors can be used in practice to help predict and anticipate blended treatment success. These discussions revealed that in practice, very few criteria make people fully unfit to benefit from blended mental health treatment: presence of practical barriers (no computer or Internet access, no place to work) and insufficient (cognitive) skills (intelligence quotient and Internet skills that do not match the program's minimal requirements). Rather, therapists claim that adjusting the treatment to a person's specific situation, needs, and abilities is an important predictor of treatment success. This is in line with what was found in our earlier study among both therapists and patients, that is, a discussion between patient and therapist is essential [12].

Therefore, to facilitate this dialogue on how to jointly decide on the configuration of the blended treatment, we created a shared decision-making instrument (Fit for Blended Care). This instrument addresses the topics regarding the needs, characteristics, and skills of an individual that need to be

discussed to enable therapists and patients to decide in which way blended therapy can best be applied. During the developmental process of the instrument, formative evaluations [13] were conducted with follow-up focus groups consisting of 5 therapists. One of these participants is male; all therapists are experienced in treating patients with substance-related disorders and in eMental health treatment. In addition, 2 clients (both treated for personality disorder; one of them is male) were interviewed. The interviews and focus groups were done to cocreate and assure a fit between the content of the instrument and actual practice. These consultations provided input on formulation on the questions, and also on how such content and system would preferably be applied by care providers in clinical practice. This led to the insight that strict formulation of topics (by providing checklist rules; "yes/no" answers) leaves too little room for interpretation of the specific situation of the patient. Issues with specific items (in what situation would crisis or suicidality actually be a risk for starting or receiving blended treatment) continued to surface in our discussions, stressing the need for therapists to make their own assessment of the risks and discussing these with the patient and documenting the outcome of the discussion. In conclusion, care providers preferred checklist topics to start a shared decision-making process with their patients on the use and distribution of online care components.

An Instrument for Implementation in Practice

To support therapists and patients in outlining a fitting blended treatment, we created an instrument to assist a guided dialogue between therapists and patients, which is needed to shape and set up the blended treatment in such way that it matches patient characteristics (including abilities, needs, and preferences), according to our postulates, prior experiences with blended care [12], and underlying eHealth approach [13]. The aim of the instrument is to provide input for a conversation that leads to shared decision making on blended treatment setup, and creates awareness among both patient and therapist regarding issues that are relevant to blended treatment success. Because of the (preferably) natural course of such shared decision making, no checklist rules are provided. Rather, the topics that need to be discussed or those that patient and therapist should be aware of are summarized. This way, the topics (concepts) can be operationalized by therapists to match their own working definitions.

The "Fit for Blended Care" instrument consists of four main parts: (1) *prerequisites*, which are items on (mostly practical) preconditions that need to be met to be able to start blended treatment (9 items); (2) *possible barriers*, which are items on issues that might hinder blended treatment (5 items); (3) *possible facilitators*, which are items on issues that can facilitate blended treatment, and should be considered when deciding to start a blended treatment (6 items). (4) *advice overview*, an (written) overview of the possible barriers and facilitators that prompts therapists and patients to discuss and decide on the composition of blended treatment. Every item (barriers and facilitators) is linked to a specific advice, which can be considered if the item proved to be relevant (based on the answers and discussion). The advice describes how to deal with facilitators and barriers to blended treatment. Furthermore, it provides suggestions for

additional agreements on what to do if a problem related to barriers presents itself. The therapist and patient discuss these outcomes prior to the start of treatment and use the discussion to make agreements on what type of blended care the patient receives. Some of the items can be answered in advance by the therapist or by the patient (eg, before or during intake) to

facilitate and speed up the process. Currently, the full content of the instrument (items and advice) is available in Dutch [27]. [Textbox 1](#) provides an overview of the instrument items in English. An additional rationale per item is included in [Multimedia Appendix 2](#).

Textbox 1. Fit for Blended Care instrument overview (in English).

<p>Therapist checks</p> <ol style="list-style-type: none"> 1.1. Are appropriate online modules available related to the main symptoms/diagnosis of the patient? 1.2. Is there absence of (current) crisis (eg, severe suicidality or psychotic symptoms)? 1.3. Is there absence of an acute medical care need (that may hinder the patient's ability to independently work on his/her treatment?) 1.4. Is the patient's intelligence quotient match sufficient for the blended treatment content? <p>Patient checks</p> <ol style="list-style-type: none"> 1.5. Does he/she have computer access? 1.6. Does he/she have Internet access? 1.7. Does he/she have a private, safe place to work? 1.8. Does he/she have sufficient Internet skills? <p>Patient and therapist discussions:</p> <ol style="list-style-type: none"> 1.9. Does the patient have sufficient writing (expression) skills? 2.1. The patient's motivation and trust 2.2. The patient's risk of crisis 2.3. Cognitive problems that may hinder treatment 2.4. Psychosocial problems that may hinder treatment 2.5. Other issues/comorbidity that may hinder treatment 3.1. Whether they have (or chances on having) a good therapeutic/working relation 3.2. Practical reasons for preferring blended care, e.g., saving on cost and time, comfort. 3.3. Possible other reasons for preferring blended care such as stigma or safety issues (shame of having to enter a clinic, discussing reason for taking time off work with employer, fears of going out into public to travel to a clinic) 3.4. The likeliness of being able to be open in online communication 3.5. Is the patient conscientious? 3.6. Does the patient have a social support network?

Implications for Research and Practice

Blended mental health care may have some important advantages over face-to-face therapy. The client is encouraged to continue his or her treatment between the sessions with the therapist in a structured way. Likewise, blended care has advantages over online therapy because it enables personal guidance (face-to-face) when needed, and possibly a better adherence to treatment. This may make blended care treatments more cost-effective than face-to-face therapies. Moreover, the possibility to work on their mental health between sessions encourages clients' trust in their own abilities to self-manage and adapt, which are defined as core aspects of health [28]. These skills are supported by and united with blended treatment programs. Within a context of a large number of people suffering from mental health problems and limited professional resources, blended mental health care may offer treatment modalities that are both effective and affordable. However, more research and

innovation is warranted to decide what blend is preferred by clients and therapists in certain situations.

Implications for Research

A rapidly growing number of meta-analyses demonstrate the efficacy of both face-to-face and online treatments for psychological disorders [29,30]. However, the implications of using technology to support online treatments have hardly been studied yet. It is recommended to compare blended care treatments with current state-of-the-art, face-to-face treatments, to study whether similar effects can be obtained at lower costs and with similar client satisfaction. In addition, attention should be paid to understand which form blended care is effective and why, not overlooking the special role technology design has in such studies.

At present, little is known about this. Therefore, we have created an instrument that supports decision making in the preferred format for blended treatment. The effects of using this

instrument and the underlying motivations and mechanisms on decision making should be studied.

Implications for Practice

Blended mental health care is increasingly being applied and therapists and patients are discovering the opportunities of adding technology to treatment. The use of information and communication technology inherently calls for personalization of care; it offers a multitude of possibilities for tailored, personal treatment. This process of adjusting the design and content of treatment to patient (and therapist) needs and preferences is facilitated by technology. However, not much is known about why certain “blends” of design and content are chosen and applied, and with what rationale. Based on experiences from practice (best practices), and the postulates and instrument we provide, a well-thought rationale for blended care can be applied. The use of the postulates can support a therapist’s or organization’s own approach to blended care, and likewise, the instrument may facilitate implementation and actual execution of blended treatment. It was created to support practice and

create awareness about topics relevant for (starting) blended treatment.

Conclusions

Blended care offers new possibilities in terms of personalized mental health care treatment. Technology can (at least partially) replace face-to-face contact. Blended care invites patients and therapists to think about personal needs and preferences, for an optimally personalized treatment that can enhance the self-management of patients and translation of treatment into daily life. However, to reach the full potential of blended care, more insight is needed into what suits whom and how technology features and treatment operationalization via technology can be optimized. These fundamental issues should be of primary concern, as barriers for implementation and adherence lie within technology and organization of health care, not in specific patients or patient profiles [13]. We invite scholars to discuss our findings and ideas and to explore the underlying mechanisms that explain why blended care is of added value, in what format and to whom.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Literature review outcomes overview.

[\[PDF File \(Adobe PDF File\), 398KB - mental_v3i1e9_app1.pdf \]](#)

Multimedia Appendix 2

Instrument.

[\[PDF File \(Adobe PDF File\), 225KB - mental_v3i1e9_app2.pdf \]](#)

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Viewpoint

Heuristic Evaluation of Ehealth Interventions: Establishing Standards That Relate to the Therapeutic Process Perspective

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Abstract

In recent years, the number of available eHealth interventions aimed at treating behavioral and mental health challenges has been growing. From the perspective of health care providers, there is a need for eHealth interventions to be evaluated prior to clinical trials and for the limited resources allocated to empirical research to be invested in the most promising products. Following a literature review, a gap was found in the availability of eHealth interventions evaluation principles related to the patient experience of the therapeutic process. This paper introduces principles and concepts for the evaluation of eHealth interventions developed as a first step in a process to outline general evaluation guidelines that relate to the clinical context from health care providers' perspective. Our approach was to conduct a review of literature that relates to the examination of eHealth interventions. We identified the literature that was most relevant to our study and used it to define guidelines that relate to the clinical context. We then compiled a list of heuristics we found to be useful for the evaluation of eHealth intervention products' suitability for empirical examination. Four heuristics were identified with respect to the therapeutic process: (1) the product's ease of use (ie, usability), (2) the eHealth intervention's compatibility with the clinical setting, (3) the presence of tools that make it easier for the user to engage in therapeutic activities, and (4) the provision of a feasible therapeutic pathway to growth. We then used this set of heuristics to conduct a detailed examination of MyFitnessPal. This line of work could help to set the bar higher for product developers and to inform health care providers about preferred eHealth intervention designs.

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KEYWORDS

eHealth; mHealth; digital health; mobile health; heuristics; evaluation; principles; therapeutic process

Introduction

In recent years, the number of available eHealth interventions aimed at treating behavioral and mental health challenges has been growing. Tens of thousands of health, wellness, and medical applications are now available for download from online stores [1], and it is clear that eHealth interventions will play a substantial role in shaping health care in the future [2].

Scholars have described the need to empirically evaluate the efficacy of eHealth interventions, to develop standards of

assessment [3], and to find new ways of evaluating eHealth interventions as they evolve [4]. From the perspective of health care providers, the state-of-the-art evaluation of eHealth interventions is expensive, time-consuming, and involves a rigorous process of validation, primarily in terms of clinical aspects, data security, and legal agreements. While it is clear that not all of the eHealth interventions that vendors propose to health care providers can be empirically examined, it is important to develop assessment methods for each new product [4]. In effect, eHealth interventions should be examined prior

to clinical trials so that the limited resources for empirical research can be invested in the most promising products.

In reviewing the literature, we found a gap in terms of the minimum standards that eHealth interventions targeting behavioral and mental health should meet with regard to patients needs in the therapeutic process prior to empirical examination. This paper discusses relevant principles and concepts for evaluating eHealth interventions from this perspective, and outlines an approach to screen and identify suitable products. In the following sections, we outline the literature most relevant to our study, focusing on models informing eHealth interventions design, eHealth interventions' heuristic evaluation and rating systems.

Learning from Models of eHealth Interventions

There are several models that have informed the development of eHealth interventions [5-9] and established the fundamental principles of the design process. These models provide eHealth interventions developers with ways to transform clinical understanding and theories into actionable product designs aimed at creating behavioral change.

Fogg's model [8] relates to the performance of a specific target behavior and focuses on the dynamic between the user's motivations, abilities, and triggers. According to Fogg, for a person to perform a target behavior, he or she must be sufficiently motivated, have the ability to perform the behavior, and be triggered to perform the behavior. When these factors occur at the same time and exceed a certain threshold, the target behavior will be performed by the user. Fogg provides an example of target behavior, namely having website users provide their email address in order to receive a newsletter. Users may see the request to type in their email (ie, trigger) and find it easy to type the email address (ie, ability). However, if they have no motivation to do so the target behavior will not occur. It seems that if users have much more motivation to receive this newsletter they might be willing to do much more than to just type their email address. While Fogg's model does not provide a framework for evaluating more complex target behaviors or treatment outcomes, it does provide a point of reference for evaluating a feature's ability to create a specific behavioral change.

Mohr et al's model [5] is a detailed behavioral intervention technology (BIT) design model. It provides a step-by-step conceptual and technological framework that ensures the product is designed to be both useful and usable, while keeping in mind the clinical aim. The model is able to provide clear definitions and establish a common language for all parties involved in eHealth intervention development. For example, the model defines 5 questions that developers should answer when designing BITs or eHealth interventions: (1) "why," the clinical aim; (2) "conceptual how," the behavior change strategies used; (3) "what," the technical elements of the intervention (eg, notifications); (4) "technical how," the characteristics of the various elements (eg, medium, personalization); and (5) "when," the time when the intervention should be delivered.

These models emphasize the importance of relating the product design to the clinical context—a factor that we find to be

particularly relevant in the mental and behavioral health domains. At the same time, these models view the product from the developer's perspective, which makes it difficult for a person external to the development process to evaluate the product without having to trace the developer's and designer's intentions. In light of this drawback, we suggest that health care providers can use a global approach for evaluating a product as a whole, while taking the clinical context into account.

Heuristic Evaluation of eHealth Interventions

In contrast to these eHealth intervention development frameworks, heuristic evaluation is a method that has been broadly researched and used for assessing eHealth and technology products, particularly in terms of identifying problems with user interface usability [10]. Heuristics are broad principles of product design that can be inspected by evaluators prior to empirical testing. Heuristic evaluations can be implemented widely and transferred easily to new organizational contexts [11]. The advantage of heuristic evaluation is that it enables the cost-efficient identification of design problems [12], which is valuable in situations where time or budgetary resources are limited [11].

Kientz and colleagues [13] developed a set of 10 heuristics intended to find design problems in persuasive technologies aimed at health behavior change. Kientz's heuristics relate not only to user interface usability (eg, "appropriate functionality," "usable design"), but also to some aspects of the design that engage the user in the therapeutic process such as "use of positive motivation strategies." Kientz et al compared the performance of these heuristics to that of Nielsen's heuristics [14] and demonstrated the effectiveness of their heuristics in uncovering the main design problems in the domain of persuasive health technologies. Kientz's heuristics reveal the need to take the user's emotional perspective into account when evaluating the product's ability to change user behavior.

App rating systems can also inform the heuristic evaluation of eHealth interventions, since the subscales reflect the scholarly understanding of relevant issues. PsyberGuide [15] is a system through which experts from the clinical and research field can rate mental health apps and software. The rating scale consists of subscales based on the extent of empirical research and support associated with the product. Another rating system was introduced by the Anxiety and Depression Association of America for rating anxiety-related apps [16,17]. The rating scale includes dimensions such as ease of use (ie, usability), personalization, and empirical evidence. Most recently, Stoyanov et al [18] developed the Mobile Apps Rating Scale (MARS) for health and well-being based on the quality rating criteria found in the research literature. MARS provides a detailed framework for rating apps according to their engagement, functionality, aesthetics, information quality, and subjective quality. Another notable initiative in this domain is JMIR mHealth peer-review tool for mobile apps. JMIR mHealth aims to build a database of peer-reviewed and evaluated apps and then to use this data to identify important domains within the evaluation of mobile health applications [19].

This stream of literature highlights the need to develop a greater understanding of the core components of eHealth interventions

and provides a framework for researchers to discuss and compare different products. While these efforts have been advancing the science rapidly, there has been little focus on establishing principles for product evaluation in terms of the clinical context and the patient's experience of the therapeutic process.

Issues related to the therapeutic process have often been overlooked in the evaluation process because they are thought to be inherent in eHealth intervention design models and application development. However, being able to evaluate eHealth interventions targeting behavioral and mental health in terms of the patient's needs within the therapeutic process could contribute to the establishment of standards that eHealth interventions would have to meet prior to empirical examination. Below, we review the core evaluation principles that we found to be helpful in understanding the potential of eHealth interventions with regard to the clinical context. The primary aim of this paper is to describe these general principles for evaluating eHealth interventions as a first step within a process that demands rigorous testing of these heuristics across a number of contexts, using multiple eHealth products.

Process for Defining Heuristics

The initial process for defining the most relevant heuristics was composed of several steps. First, the study authors defined an overarching framework for defining heuristics. Second, the authors reviewed covered literature, heuristics, and rating scales within the behavioral health domain. Within the overarching framework, they discussed whether an evaluation principle that corresponds with the patient's clinical context is missing and can contribute to the evaluation process of new technologies (see [Textbox 1](#) for a list of reviewed heuristics, principles, and authors' comments). Then a group of 4 scholars was gathered. The group consisted of 3 psychologists (including the study co-authors) with experience in user-centered design and evaluation and 1 psychiatrist with experience in managing both health care clinics and research projects on technology-assisted interventions in behavioral health. The group reviewed and discussed the gathered principles, made modifications, and combined similar principles until reaching consensus. Finally, the authors provided a detailed examination of the MyFitnessPal

app using the set of articulated heuristics. In the subsequent section, we outline our overarching framework articulated for defining heuristics.

Overarching Framework for Defining Heuristics

Evaluating the Potential Success of eHealth Interventions from the Therapeutic Perspective

This paper relates to the context of the patient's needs from a clinical point of view. While there is overlap between the literature in several areas (eg, usability), we have attempted to explain these overlapping concepts within the context of the therapeutic process. Accordingly, we have found it useful to treat the relation between the product's usability and its therapeutic potential as the relation between a measure's reliability and its validity [20], wherein usability is compared to reliability and therapeutic potential to validity. In effect, a product can be usable without exhibiting any therapeutic potential, but it cannot have therapeutic potential without being usable. On the same note, we relate to heuristics and principles reviewed within the study scope ([Textbox 1](#)) as a starting point for the process of evaluating the therapeutic potential, whereas a product that does not answer, for example, safety or quality of information concerns [21] cannot hold a strong therapeutic potential.

Examining the Product as a Whole

One of the desired outcomes of heuristic evaluation is to be able to examine products in a short amount of time, and in a way that is easy to communicate and transfer to others [11]. Therefore, it is important to examine the product as a whole, rather than breaking it down into smaller pieces. Indeed, understanding the gestalt of eHealth interventions is rarely discussed in the literature; prior research has tried to separate component parts according to their therapeutic mechanisms, instead of evaluating the phenomenological experience of using the product. Similarly, since many eHealth interventions attempt to address complex problems, such as depression, self-management of chronic illnesses, and addiction [5], we recognize that there must be room for creativity in product design. Such creativity can only be engaged, however, when the heuristics reflect broader principles for product evaluation.

Textbox 1. List of established Heuristics/Principles based on covered literature.

Comments regarding missing evaluation principles are provided in the section following the textbox. The same heuristic/principle may appear under more than 1 subject.

1. Usability/Ease of Use/Functionality

- Visibility of system status
- Match between system and the real world
- User control and freedom
- Consistency and standards
- Error prevention
- Recognition rather than recall
- Burden and effort reduction
- Flexibility and efficiency of use
- Aesthetic and minimalist design
- Help users recognize, diagnose, and recover from errors
- Help and documentation
- Not irritating or embarrassing (eg, the technology should not inaccurately record or misrepresent the user's behavior)
- Appropriate functionality
- Appropriate time and place of information, feedback, and assistance
- Easy to use

2. Aesthetics

- Aesthetically appealing design
- Appropriate design for the target audience

3. Safety

- User's privacy is appropriately protected
- Data is secured
- The content is based on evidence-based principles and provides reliable information

4. Content

- The content is clear, logical, and correct
- The content is based on evidence-based principles and provides reliable information (eg, based on behavioral activation, etc)
- The content provides the tools or methods to accomplish its purpose
- The extent of content covered is comprehensive but concise
- The content is tailored

5. Engagement

- Entertaining
- Interesting
- Customized/tailored
- Interactive
- Relevant to target audience

6. Persuasive Design

- Motivate
- Educate users about the connection between user actions and desired outcomes: While the connection between user actions and desired outcomes is stated, the relation between this connection and the adherence to the therapeutic process should also be explicitly stated when examining the product within the clinical context.

- Sufficient motivation and triggers to promote desired behaviors
7. Research Evidence (this information is not gained from direct examination of the product)
- Data from pilots, open studies, and randomized controlled trials
 - The credibility of the organization that administered the research
8. Owners' Credibility (this information is not gained from direct examination of the product)
- The app comes from a legitimate source
 - Product has an advisory board with clinical-thought leader input

The usability principle (“Usability/Ease of Use/Functionality” in [Textbox 1](#)) should relate to the evolving nature of the user’s expectation as technology evolves all the time. From the user perspective, is there a benchmark to understand their evolving expectations regarding product usability? This benchmark could support the reviewer in the understanding of the patient’s changing expectations. If the relation between the technology and the clinical context in which it is being used is not clearly stated, it may affect the user needs in terms of content covered, reasons to use it, and impact the product’s applicability to be perceived as engaging and persuasive (see “Content,” “Engagement,” and “Persuasive Design” in [Textbox 1](#)). While relating to the question of meeting the product’s clinical aim, using different heuristics to examine content, engagement, and persuasive design may miss the gestalt of the intervention. It can be related to, after examining all other heuristics, by asking whether the product provides a strong case for reaching the desired clinical aim (see “Content,” “Engagement,” and “Persuasive Design” in [Textbox 1](#)). The direct impact of products in promoting desired therapeutic activities by making it “easier” to conduct them (ie, lowering the investment required for conducting these activities) should be explicitly stated and evaluated (see “Persuasive Design” in [Textbox 1](#)).

Design That Nurtures Users’ Motivation

We assume that the user’s motivation to engage with the computer program and to comply with the intervention increases the chances of achieving behavioral change, especially when the product concentrates on behaviors the user finds difficult [8]. User motivation can also help in eHealth program adherence, even when the program is not tailored to meet the user’s needs. Therefore, all of the heuristics we list below consider how design can nurture the user’s motivation by relating the product’s ability to provide a suitable user experience to the user’s therapeutic needs, beliefs, desires, and intentions.

Definitions

Features: Tools and components of the eHealth interventions that are being used to deliver the intervention (eg, assessments and psychoeducation ingredients).

Product usability: The extent to which the product is easy for the average user to learn and to use.

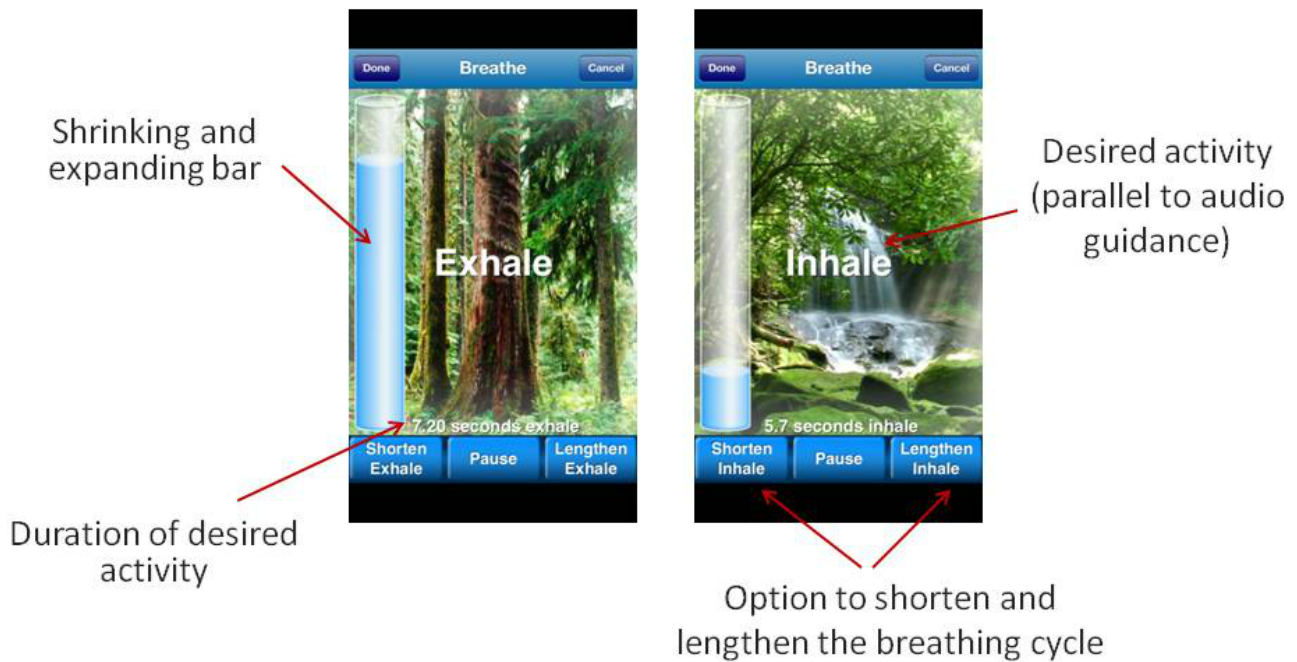
Heuristics

The Product Should Be as Easy to Use as Products in Similar Settings.

The product usability and ease of use have been described as a significant factor within the evaluation process in the covered literature [11,13,18]. Kientz and colleagues [13], for example, related appropriate functionality to the product, stating that: “The technology should function effectively in the user’s environment by being easy to use and integrate into one’s daily life and routine.” From the provider’s perspective, we focus on the user’s needs and expectations, which are based on available products in similar settings. We believe that users’ expectations are mostly general and not defined by the product’s domain (eg, entertainment, education, social media). In effect, products that are in general use set the user’s expectations of other similar products.

As an example, a tool providing breathing exercises (as part of a stress reduction feature) that consists of a text message explaining a breathing technique and asking users to do this exercise will probably result in poor cooperation. A breathing tool ([Figure 1](#)) that consists of (1) a bar that shrinks and expands, (2) an audio-recorded voice that directs the user throughout the exercise, and (3) the ability to adjust the time of the breathing cycle (ie, different people have different breathing cycles) will probably result in a higher level of user engagement.

Figure 1. Breathe2Relax screenshots.



The eHealth Intervention Should Respond to the User's Needs with Respect to the Specific Clinical Setting

While fundamental principles of eHealth interventions' design process explicitly relate to the clinical setting by addressing the clinical aim [5] and the user's current mental state [8], it seems that sets of heuristic evaluation and rating systems [13,15,18] do not explicitly relate to the user's needs as a derivative of the clinical setting. This gap can be filled by relating within the evaluation process to the implication of the clinical setting on the user's therapeutic needs.

Below, we introduce as examples basic principles derived from this perspective for a product meant to be used in 2 different clinical settings: without a clinician support (ie, standalone) or to complement the clinician's work (ie, as a supplement to therapy).

Standalone: As the user has to work through the therapeutic process alone without external guidance, it seems that he or she might benefit from:

1. A workflow that is tunneled, simple to understand, and includes tutorials, where applicable;
2. Ways to nurture and reinforce their inner motivation and to adapt over time to fluctuating and changing motivations;
3. The ability to receive relevant referral for external resources when needed.

A supplement to therapy: From the provider's perspective, a product can be easily integrated and used as a supplement to therapy when it meets the clinician's standards by providing tools, exercises, and psychoeducation in line with the clinician's practice. The clinician should also have the flexibility to assign different product features based on the patient's current state and be able to receive reports on the patient's engagement with the program.

The eHealth Intervention Should Make it Easier for Users to Engage in Therapeutic Activities by Providing Them with the Relevant Tools "In House"

EHealth interventions are part of a therapeutic intervention. As such, they often include recommendations to engage in activities for a therapeutic gain. Fogg [8] suggests that the lower the level of investment necessary for carrying out desired activities, the higher the chances for these activities to occur. This notion is congruent with studies in the behavioral health domain demonstrating that availability and accessibility of services promotes their utilization [22-27]. We thus suggest that eHealth interventions should also be evaluated by their ability to promote desired behaviors by providing tools that decrease the investment needed for these behaviors to occur.

Some examples from the mental and behavioral health domains are:

1. A suggestion to socially engage with other people might benefit from including features such as: (1) in-house engagement options (eg, a click button that makes it easier to send an email or make a call); (2) reminders to perform the desired activity, if applicable (eg, automatic pop-up reminders on the mobile screen); and/or (3) a list of modeled narratives to choose from and customize.
2. A cognitive behavioral treatment (CBT) app that promotes the documentation of unhealthy thoughts might benefit from providing the user with a documentation tool.

The eHealth Interventions Should Provide a Feasible Therapeutic Pathway to Growth

Relating to the product's clinical aim and how it is met is a crucial part of the eHealth product design process [5,6,8] and evaluation processes of eHealth interventions. Stoyanov et al [18] examine whether the mobile app has specific, measurable, and achievable goals, and whether the content is relevant to

meet the app's goals. Kientz and colleagues [13] provide a notable exception relating to the user motivation and experience in this process stating that: "users should understand why the actions they do promote positive behaviors and how their goals are being met."

From a clinician perspective, we suggest addressing these principles under one umbrella through the concept of a feasible therapeutic pathway to growth. Within the evaluation process, this concept is meant to capture whether the product features are built in a way that helps the product meet the eHealth intervention goal from the perspectives of both health care providers and patients:

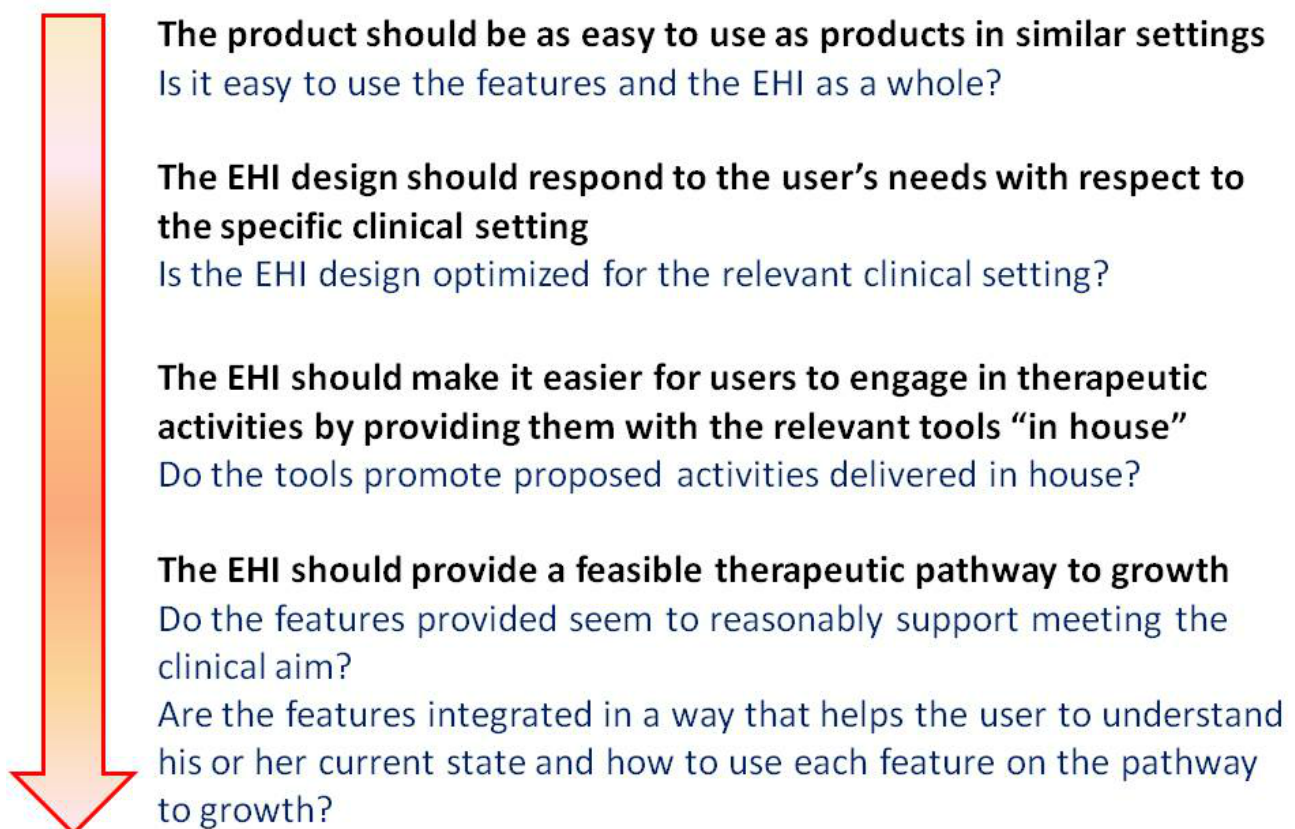
1. The eHealth intervention features should reasonably help the user meet the therapeutic goals. Scholars within the relevant domain should be able to roughly evaluate (based on experience and knowledge of evidence-based interventions) whether the product's features are sufficient enough to meet its goals.
2. In order to benefit users' adherence with the therapeutic process, the technology should engage users by providing

a connection between their actions and therapeutic goals. This might be accomplished if the features are integrated in a way that helps the user to understand his or her current state and how to use each feature on the pathway to growth.

Evaluation Process

The heuristics have been presented in the order we believe is most useful for examining eHealth interventions (Figure 2). The first question is whether the product "looks and feels" easy to use (ie, is usable) in comparison to widely used products. When examining the product's usability, the evaluator learns about the product and can consider the extent to which it corresponds with the clinical setting. These considerations allow the evaluator to then look closer at the features, assessing whether they are engaging and whether the necessary tools accompany the features "in house." One might argue that since the "feasible therapeutic pathway to growth" heuristic is more general than the preceding one, it should be examined earlier. However, we have found it more useful to examine the "feasible therapeutic pathway to growth" heuristic only after examining all of the product's features and becoming familiar with them.

Figure 2. Heuristic evaluation process.



MyFitnessPal as an Example

To further elaborate on each heuristic, we use the example of the MyFitnessPal (MFP) app previously examined by Mohr et al [5]. MFP is a mobile phone and computer application that is free to download; is available for iOS, Android, and Windows operating systems; and used by more than 40 million users [28]. The clinical goal of MFP is to promote weight loss by reducing caloric intake and increasing physical activity.

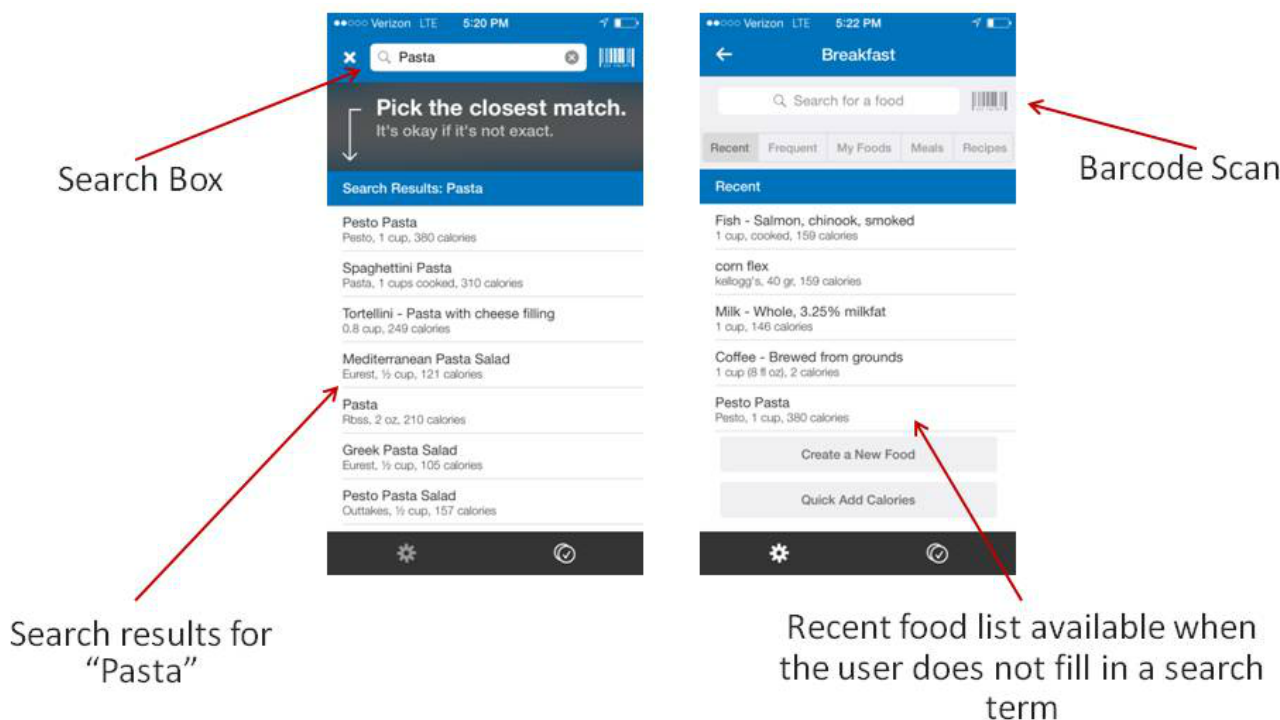
Since the aim of this paper is to provide guidance and clear definitions regarding the relevant heuristics, we address each heuristic in reviewing the app, a process we conducted in March 2015. For practical purposes, we focused on the app's ability to promote weight loss only in terms of reducing caloric intake.

The Product Should Be as Easy to Use as Products in Similar Settings

The user’s main investment in the MFP program is to provide information about food consumed each day. The average user of similar apps is used to utilizing search boxes to find the relevant food in the app’s database. Many search boxes in other programs also provide a word completion option, making it easier to find the relevant searched-for item. The MFP app uses several components that meet the average user’s expectations when it comes to adding the relevant food (Figure 3), including (1) a search box that enables the user to find products related to the search term (eg, the term “pasta” provides several

common pasta dish options), (2) an option to choose items from a “recent foods” list composed of previously reported foods, and (3) an option to use a word-completion function (this function is device-dependent; applicable for the iOS version of the app at the time of examination). Another available way to find the caloric and nutritional information for food consumed is scanning the product’s bar code into the app and clicking the relevant button on the mobile screen. While it would not be considered as a standard function by users of all ages, we believe the bar-code scanner meets the expectations of young and tech-savvy users. Based on these functions, it seems that the MFP app looks and feels easy to use (ie, usable) and offers features that meet the standards of the average user.

Figure 3. MyFitnessPal food-picking screenshots.



The eHealth Interventions Design Should Respond to the User’s Needs with Respect to the Specific Clinical Setting

While the MFP app is built to be used as a standalone product, probably by a subclinical population, we would like to consider its applicability as a supplement to treatment for the purposes of this study. While this app doesn’t seem to be designed to replace clinicians’ work with diagnosed patients, there are certain features in the app that make it helpful as a supplement to treatment that we would like to address. A certified dietitian can recommend that a patient use the app in order to easily track the patient’s caloric intake. In this case, the app would become a smart workbook, helping the patient to adhere to “the calories watch” and would enable the dietitian to easily view past caloric intake by examining the patient’s diary. While MFP can offer a path of communication between the patient and the dietitian through the “friend” feature (ie, the patient adds the dietitian as a friend in the app), it is not designed to meet this need. For this product to be optimized as a supplement to therapy, its design

should include ongoing automated reports and alerts sent to a designated dietitian and provide established communication pathways between the dietitian and the patient (including a feature that enables the dietitian to set goals and rewards tailored to the patient). These features also add an element of supportive accountability [29], which is especially important with higher-burden behaviors, such as food logging, and any reactive data entry by the end user.

The eHealth Intervention Should Make it Easier for Users to Engage in Therapeutic Activities by Providing Them with the Relevant Tools “In House”

Generally, the program design provides the relevant tools to carry out almost every activity it recommends and to minimize the investment needed from the user. MFP provides the user with the ability to easily find the nutritional value of each food and to receive summary reports. It enables the user to easily share accomplishments with friends using Facebook, phone contacts, or email. It provides live community forums and groups that users can join, which are managed within the

application. The program also provides healthy recipes with a designated space to save the recipes.

The eHealth Intervention Should Provide a Feasible Therapeutic Pathway to Growth

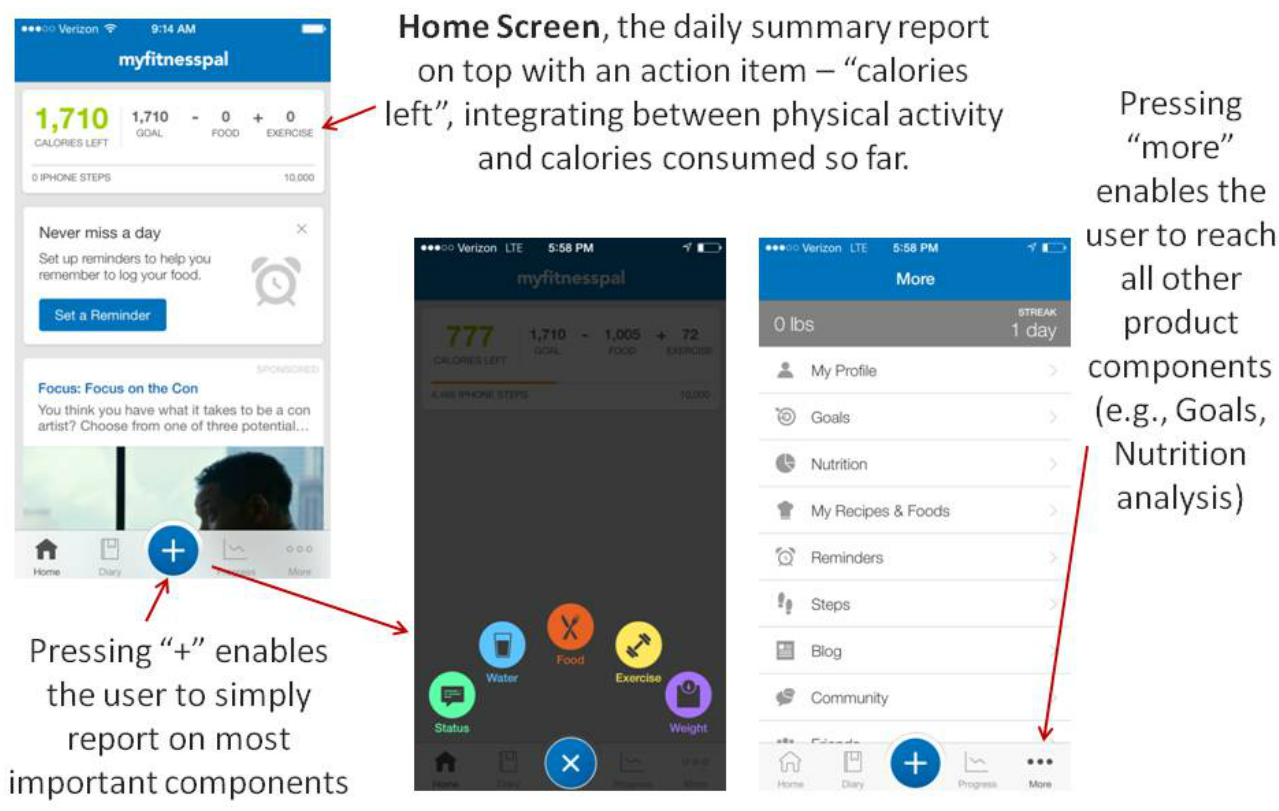
The app includes many relevant features to promote weight loss by reducing caloric intake. The main feature is the feedback the user receives, which provides a clear call for action by indicating how many calories the user can consume for the rest of the day. Other features include nutritional summaries, recipe collections, community (eg, blogs and newsfeeds sharing ideas and thoughts about healthy living), goal setting, and social engagement. In light of these features, it seems reasonable that the product enables users to watch their diet and adjust their caloric intake.

While the product provides most of its features as separate tools and does not offer comprehensive guidance as to how and when to use them, there are several elements that make it clear for the user. Certain features in the product seem to be more important and therefore receive a more prominent spot in the product’s

graphical user interface. The main features are the calorie consumption assessment and summary report presented on the main page (Figure 4). In addition, there are automatic reminders prompting the user to complete the assessment. Data components that need to be collected (eg, food, water) throughout the day are accessible by clicking the “+” button at the bottom of the screen, while pressing the “more” button reveals all other features.

This approach relies on several factors. First, the most important features are the calorie consumption assessments and the accompanying report. Second, since the informed user may do many different things to maintain or change a certain diet, the app does not offer only 1 way to use the tools provided; rather, it keeps all options open. Third, from the user’s perspective, the pathway to growth is very clear: it depends on the user’s ability to meet the set caloric intake goal (in relation to physical activity). The daily feedback reflects the user’s goal and pathway to growth by providing the amount of calories he or she can consume for the rest of the day.

Figure 4. Navigation between MyFitnessPal features.



Discussion

In this paper, we have described heuristic evaluation principles and how they correspond to the patient’s clinical context in order to outline an approach for identifying eHealth interventions that are suitable for empirical examination within the mental and behavioral health domains. We view this paper as a first step in a process aimed at establishing the minimum standards that eHealth interventions should meet prior to their empirical examination within care systems. While this list of

heuristics should be viewed as a starting point, it has several potential uses.

Principal Findings

When examining proposed eHealth interventions, these heuristics can promote better communication between vendors and care systems by turning the latter into educated consumers who can define a product’s requirements and focus on user’s needs from the health care providers’ perspective.

While our main aim was to describe general principles for evaluating eHealth interventions, we believe that by outlining

what is expected of these products in the mental and behavioral health domains, we have also provided the basis for developing rating scales. Rating systems developers can thus examine whether new scales that are formed based on the heuristics articulated in this paper provide additional information about the eHealth products compatibility to the clinical context.

Finally, these principles could provide common language for discussing the general potential for eHealth interventions to succeed within the clinical context. Therefore, they open the door for academic researchers to communicate about eHealth products and to assess whether certain interventions did not succeed because of their product design. For example, if an app aimed at treating depression as a standalone strategy does not provide satisfactory outcomes, it could be because such standalone technology is not effective for treating depression or it could be that the developed eHealth intervention did not meet the basic guidelines as set out in the heuristics. Being able to discuss these matters could contribute to gaining a better understanding of what works and achieving better outcomes in innovative research projects.

Limitations

There are several limitations of the present work that should be mentioned. First, the focus of this work was to describe principles of eHealth intervention evaluation as a viewpoint. As such, it did not include psychometric measures along with case studies in order to establish its reliability and validity. Future research should focus on being able to identify and evaluate promising eHealth interventions and on investigating

whether the clinical context perspective articulated in this paper contributes to making better evaluations. Second, the principles have been generalized in order to promote understanding and discussion among evaluators and product owners, and to ensure creativity in the design process. Therefore, while these heuristics might be used to locate major flaws in eHealth intervention products based on future research on that matter, it is important to note that they are not meant to be used to identify and compare nuanced differences between products. This kind of use case will be applicable only by developing rating scales that correspond to the articulated principles. Finally, we focused on the heuristics we found to be useful for evaluating products in terms of the therapeutic process. Future research should expand on the current literature and examine whether there are more heuristics that should be used in the evaluation process of eHealth interventions.

Conclusions

This paper presents heuristic principles for evaluating eHealth interventions targeting mental and behavioral health from the perspective of the therapeutic process. While it is difficult to evaluate the potential of technologies from this perspective, this line of work may assist in establishing guidelines for product evaluation that are unique to the behavioral and mental health domains. These guidelines could help to set the bar higher for product developers and to inform health care providers about preferred eHealth intervention designs. We hope that this work will encourage all relevant stakeholders to discuss this topic further.

Conflicts of Interest

None declared.

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Abbreviations

- BIT:** behavioral intervention technology
- CBT:** cognitive behavioral treatment
- EHI:** eHealth intervention
- MARS:** Mobile Apps Rating Scale
- MFP:** MyFitnessPal

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Review

Mental Health Smartphone Apps: Review and Evidence-Based Recommendations for Future Developments

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Abstract

Background: The number of mental health apps (MHapps) developed and now available to smartphone users has increased in recent years. MHapps and other technology-based solutions have the potential to play an important part in the future of mental health care; however, there is no single guide for the development of evidence-based MHapps. Many currently available MHapps lack features that would greatly improve their functionality, or include features that are not optimized. Furthermore, MHapp developers rarely conduct or publish trial-based experimental validation of their apps. Indeed, a previous systematic review revealed a complete lack of trial-based evidence for many of the hundreds of MHapps available.

Objective: To guide future MHapp development, a set of clear, practical, evidence-based recommendations is presented for MHapp developers to create better, more rigorous apps.

Methods: A literature review was conducted, scrutinizing research across diverse fields, including mental health interventions, preventative health, mobile health, and mobile app design.

Results: Sixteen recommendations were formulated. Evidence for each recommendation is discussed, and guidance on how these recommendations might be integrated into the overall design of an MHapp is offered. Each recommendation is rated on the basis of the strength of associated evidence. It is important to design an MHapp using a behavioral plan and interactive framework that encourages the user to engage with the app; thus, it may not be possible to incorporate all 16 recommendations into a single MHapp.

Conclusions: Randomized controlled trials are required to validate future MHapps and the principles upon which they are designed, and to further investigate the recommendations presented in this review. Effective MHapps are required to help prevent mental health problems and to ease the burden on health systems.

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KEYWORDS

mobile phones; mental health; smartphones; apps; mobile apps; depression; anxiety; cognitive behavior therapy; cognitive behavioral therapy; clinical psychology

Introduction

A smartphone is an advanced mobile phone that functions as a handheld computer capable of running software apps. Within the last decade, smartphones have been integrated into the personal, social, and occupational routines of a substantial proportion of the global population. Over half of the population in the United States owns a smartphone and 83% of these users do not leave their homes without it [1]. Average users check their phones as often as 150 times a day [2], which reflects how smartphone apps can generate, reward, and maintain strong habits involving their use [3,4]. Apps are also capable of implementing behavior change interventions [5], which may improve users' physical health [6], such as through promotion of physical exercise [7].

Over recent years, numerous mental health apps (MHapps) have been developed and made available to smartphone users. These apps aim to improve mental health and well-being, ranging from guiding mental illness recovery to encouraging beneficial habits that improve emotional health [8]. The demand for MHapps is strong, as evidenced by a recent public survey that found that 76% of 525 respondents would be interested in using their mobile phone for self-management and self-monitoring of mental health if the service were free [9].

MHapps and other technology-based solutions have the potential to play an important part in the future of mental health care [10], making mental health support more accessible and reducing barriers to help seeking [11]. Innovative solutions to self-management of mental health issues are particularly valuable, given that only a small fraction of people suffering from mood or anxiety problems seek professional help [12]. Even when people are aware of their problems and are open to seeking help, support is not always easily accessible, geographically, financially, or socially [13].

Smartphones are not constrained by geography and are usually used privately by one individual. This means that smartphone apps can be extremely flexible and attractive to users, empowered by the confidentiality of their engagement. Seeking help by downloading and using an MHapp is well suited to the needs of young adults and other users with a high need for autonomy [14]. Users also prefer self-help support materials if they are delivered via a familiar medium [15], such as a personal smartphone. Smartphone apps are almost always accessible to users, so they can be used in any context and in almost any environment [16]. Using these apps, users can remind themselves throughout the day of ongoing goals and motivations, and be rewarded when they achieve goals [17].

However, many MHapps have not capitalized on the strengths and capabilities of smartphones. Design principles that have led to the huge success of many physical health and social networking apps have not been utilized in the MHapp field. Furthermore, evidence-based guidelines that have been developed for other self-help mental health interventions have not been applied to many MHapps. For example, many available MHapps target specific disorders and label their users with a diagnosis. Much research has suggested that this labeling process can be harmful and stigmatizing [18].

There also appears to be a lack of appreciation for experimental validation among MHapp developers. Donker et al [8] revealed that there is a complete lack of experimental evidence for many of the hundreds of MHapps available. Their systematic review identified only 5 apps that had supporting evidence from randomized controlled trials (RCTs). A search of the Apple and Google app stores as of January 2014 reveals that none of these RCT-supported apps is currently available to consumers.

For a mental health intervention to be effective, there must be a process of rigorous experimental testing to guide development [19]. Appropriate theories of engagement and implementation should also be consulted when introducing an evidence-based intervention to the public [20]. However, such research is currently lacking. A series of recommended principles based on evidence and substantiated theories would be valuable in guiding the development of future MHapps and future RCTs. A review of the literature highlights the numerous ways by which the design, validation, and overall efficacy of MHapps could be improved.

Methods

This review aims to provide a set of clear, sound, and practical recommendations that MHapp developers can follow to create better, more rigorous apps. As such, this review covers work from a number of different research fields, including mental health interventions, preventative health, mobile health, and mobile app design. A review of currently available MHapps was also necessary to gain a clearer idea of where improvements can be made.

Databases such as PsycInfo, Scopus, and ProQuest were consulted for peer-reviewed sources. Search terms included (but were not restricted to) "mhealth," "anxiety," "depression," "help seeking," "self-help," "self-guided," "smartphones," and "gamification." Articles published between March 1975 and March 2015 were considered for inclusion. Meta-analyses and systematic reviews were sought for each relevant area of investigation. Several synoptic texts were also consulted to guide foundational understanding of theoretical concepts relating to mobile apps and product design [3,5]. Sources were excluded from the review if they did not relate directly to mental health or computerized health interventions. Because this was not a systematic review, and as such was not based on a single search of the literature, the specific number of articles found and excluded was not tracked. Furthermore, multiple searches were used to explore the concepts and formulate the recommendations presented. The lead author (DB) conducted these searches and formulated the basic recommendations. The secondary authors provided individual feedback on the review, suggested sources, and guided further searches that the lead author undertook.

Most research into mobile health has focused on validating single entrepreneurial apps, rather than pursuing rigorous RCTs to validate principles that can guide development of future apps [21]. Because of the infancy of the field, the recommendations presented in the results of this review have not been rigorously validated by RCTs in an MHapp setting. Instead, each recommendation should be treated as a guide for both

development of MHapps and future research. Each recommendation could well be the target of a future RCT.

Currently Available Apps

The recommendations explored in this review should be considered in the context of the existing range of MHapps available. The suggested recommendations are as follows: (1) cognitive behavioural therapy based; (2) address both anxiety and low mood; (3) designed for use by nonclinical populations; (4) automated tailoring; (5) reporting of thoughts, feelings, or behaviors; (6) recommend activities; (7) mental health information; (8) real-time engagement; (9) activities explicitly linked to specific reported mood problems; (10) encourage nontechnology-based activities; (11) gamification and intrinsic motivation to engage; (12) log of past app use; (13) reminders to engage; (14) simple and intuitive interface and interactions; (15) links to crisis support services; (16) experimental trials to establish efficacy. This is a recommended direction for future research. To demonstrate the necessity of such a future review or some form of accreditation system to ensure the quality of health care apps [22], the lead author conducted a brief overview of the range of currently available MHapps via a series of preliminary searches of the iTunes App Store. The search terms used included “anxiety,” “depression,” “low mood,” “mental health,” “therapy,” “relaxation,” and “self-help.” Inspection and use of the apps found in these searches revealed some major gaps in their capabilities when compared with the recommendations of this review. Table 1 compares a selection of these apps across the recommended features discussed in this review.

Results

The recommendations formulated by this review of the literature are summarized in the following section. Recommendations 1-7 have been chiefly extrapolated from the mental health literature, and Recommendations 8-14 have origins in research on user engagement and designing apps for behavior change. Recommendations 15 and 16 are recommendations specifically related to MHapps.

It may not be possible to build every single listed recommendation into a single app. Rather, this list has been compiled based on the available evidence to guide decisions when embarking on an MHapp development project. Many currently available MHapps lack features that would greatly improve their functionality, or include features that are not optimized. Thus, the purpose of this review is to collate a list of easily followed recommendations to be used by developers when creating future MHapps.

Some of these recommendations will be relevant to informing both the interface design and the marketing of MHapps. It is important to note that the marketing of an app is tied to the way

that users will interact with it [23], in the same way that pretherapy expectations can influence engagement motivation and hopefulness [24]. For example, if a user downloads an app because its description on the app store lists “relaxation,” the user will plan to use the app for relaxation purposes. When app design is mentioned in the recommendations, this is inclusive of an app’s marketing.

Recommendations

Cognitive Behavioral Therapy Based

Cognitive behavioral therapy (CBT) is a type of collaborative, individualized, psychological treatment that is recognized as the most supported approach to generate behavioral, cognitive, and emotional adaption to a wide range of common psychological problems [25]. The efficacy of CBT has been supported by a comprehensive review of 106 meta-analyses across different clinical groups [26]. Other meta-analyses have found strong support for CBT as an effective treatment for a huge range of psychological disorders, including depression [27,28], generalized anxiety disorder [29], social anxiety [30], health anxiety [31], panic disorder [32], posttraumatic stress disorder [33], obsessive-compulsive disorder [34], phobias, and anxiety disorders overall [35]. Meta-analytic evidence for CBT also extends to anger expression problems [36], insomnia [37], pathological gambling [38], hoarding disorder [39], irritable bowel syndrome [40], psychosis prevention [41], and occupational stress [42].

Although CBT’s most researched application is as a therapeutic technique delivered collaboratively by a trained clinician, its principles have also been used as the foundation of many self-help support measures. Using technology is a cost-effective way to enhance the efficiency of CBT treatment [43,44], and research has already demonstrated that CBT-based self-administered computerized interventions are successful for improving depression and anxiety symptomatology in adults. A meta-analysis of 49 RCTs revealed a significant medium effect size ($g=0.77$, 95% CI 0.59-0.95) for computerized CBT (CCBT) for depression and anxiety [45]. Another meta-analysis of 22 RCTs found an even greater effect size ($g=0.88$, 95% CI 0.76-0.99) [46]. Similar findings for CCBT’s efficacy have emerged from meta-analyses that have focused on anxiety [47], depression [48], and its use with young people [49]. CCBT interventions can be administered by a mobile device and still retain their therapeutic validity [50]. RCTs have established the efficacy of CBT-based interventions delivered via smartphone apps that reduce depression [50], chronic pain [51], and social anxiety disorder [52]. CBT-based features can also be appealing to users. In an analysis of features used on a smartphone app for smoking cessation, 8 of the top 10 used features were CBT based [53], such as progress tracking and journaling (see the “Reporting of Thoughts, Feelings, or Behaviors” section).

Table 1. Currently available iOS apps compared across recommended features.

App	Recommended feature ^a															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
AnxietyCoach	✓	✗	✗	✓ ^b	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✗	✗
Behavioral Experiments	✓	✓	✗	✗	✓	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗
Breathe	✗	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓ ^c	✓	✓	✗
DBT Diary Card and Skills Coach	✗	✗	✗	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓ ^c	✗	✗	✗
Depression Prevention	✗	✗	✗	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✓	✗	✗
Happify	✗	✓	✓	✓ ^b	✗	✓	✓	✗	✗	✗	✓	✓	✓	✗	✗	✗
HealthyHabits	✗	✓	✓	✗	✗	✓	✗	✗	✗	✓	✓	✓	✓	✗	✗	✗
HealthyMinds	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓ ^c	✓	✓	✗
HIAF	✗	✗	✓	✗	✓	✗	✓	✗	✗	✗	✗	✓	✓	✗	✓	✗
iCouch CBT	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗
iCounselor ^f	✓	✗	✗	✗	✓	✓	✗	✓	✓ ^d	✓	✗	✗	✗	✓	✗	✗
iMoodJournal	✗	✗	✓	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓	✗	✗
In Hand	✗	✓	✓	✗	✓	✓	✗	✓	✗	✗	✗	✗	✗	✓	✓	✗
MindShift	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗
MoodKit	✓	✓	✗	✗	✓	✓	✗	✓	✓	✓	✗	✓	✓ ^c	✗	✗	✗
Moodlytics	✗	✗	✓	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓ ^c	✗	✗	✗
Moody Me	✗	✗	✓	✗	✓	✗	✓ ^e	✗	✗	✗	✗	✓	✓ ^c	✓	✗	✗
Pacifica	✓	✗	✓	✗	✓	✓	✗	✓	✓	✓	✗	✓	✗	✓	✗	✗
Pocket CBT	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗
SAM	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✗	✗
Smiling Mind	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✓	✓	✗	✓	✓	✗
Stress & Anxiety Companion	✓	✗	✓	✗	✓	✓	✓	✓	✗	✗	✗	✓	✗	✓	✗	✗
SuperBetter	✗	✓	✓	✓ ^b	✗	✓	✗	✗	✓	✓	✓	✓	✓	✗	✗	✗
ThinkHappy	✗	✓	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗
What's Up?	✓	✓	✓	✗	✗	✓	✓	✓	✗	✓	✗	✗	✗	✓	✗	✗
WorkOut	✓	✓	✓	✗	✓	✓	✗	✗	✓	✓	✗		✓ ^c	✓	✗	✗
WorryTime	✓	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗	✗	✓	✓	✓	✗

^aSee the “Currently Available Apps” section for the 16 recommendations.

^bNot using automated processes.

^cDefault is for reminders to be off.

^dOnly because there are separate apps for separate problems, so each app recommends activities for that target problem.

^eAccessible via forums

^fIncludes separate iCounselor: Depression; iCounselor: Anger; and iCounselor: Anxiety apps.

Although primarily applied in clinical contexts, CBT is also fundamentally a prevention technique acting to prevent psychological problems from precipitating or maintaining clinical disorders [54-56]. This means that CBT-based MHapps have the potential to be effective for managing both clinical and subclinical psychological problems [57], provided that such apps avoid using CBT-based techniques that are used for very

specific clinical psychological problems, are marketed correctly, and employ well-designed interfaces.

To ensure that an MHapp is indeed CBT based, it is important to keep the core principles of CBT in mind. Mennin et al [58] summarize the unifying factors that underlie all CBT approaches into three change principles: context engagement, attention change, and cognitive change. Context engagement involves training clients in a way that promotes more adaptive associative

learning, which involves having them learn cues for threats and rewards that are more reasonable and lead to better functioning than existing cues. This includes CBT techniques that aim to recondition maladaptive associations, such as exposure and behavioral activation. The app SuperBetter [59] prescribes “power-ups” that may incorporate these techniques. Attention change is the ability to focus attention adaptively on relevant, nondistressing stimuli. This includes therapeutic processes such as attention training, acceptance or tolerance training, and mindfulness. These techniques are employed in Smiling Mind [60], and can be seen in the meditations displayed in Figure 1. Finally, cognitive change is the ability to change one’s perspective on an event, which then affects the emotional significance and meaning of that event [61]. This includes metacognitive awareness and cognitive distancing, which are promoted through therapeutic processes such as decentering or defusion and cognitive reframing or reappraisal. An example of this can be found in using the Thoughts tool in MoodKit [62], as seen in Figure 2. If these three change principles are being employed to some degree by an intervention, then it can claim to be based on CBT’s core principles.

To employ these change principles effectively, a therapist and client must develop a relationship that involves collaborative empiricism (CE) [63]. CE refers to shared work between client and practitioner to embed a hypothesis testing approach into interventions [64]. CE empowers clients to explore their behaviors and beliefs outside of therapy sessions using between-session (homework) interventions [65]. A meta-analysis of studies that compared therapy with and without homework found an effect size of $d=0.48$ in favor of using between-session activities [66]. In the context of CBT-based MHapps, CE may refer to how the app interacts with the user to complete therapeutic tasks, and whether it does it in a collaborative,

experimentation-based way. This would ideally involve encouraging users to develop their own hypotheses about what may happen as a result of using the app or participating in certain activities (see the “Recommend Activities” section). An app that embraces CE is Behavioral Experiments-CBT [67], which affords users the ability to predict the outcomes of any behavioral experiments they participate in. Behavioral experiments are CBT-based challenges that individuals perform to challenge their own beliefs about the negative outcomes of various situations [68]. This process of comparing predictions with actual outcomes can challenge unhelpful beliefs [69].

Self-determination theory (SDT) can aid in understanding CE’s benefits in CBT [64]. SDT emphasizes the effects of autonomy and mastery on intrinsic motivation [70]. Intrinsic motivation is the “prototypic manifestation of the human tendency toward learning and creativity” [71]. Autonomy feeds this motivation by affording individuals opportunities for self-direction and choice [72], and fostering self-efficacy [73]. Self-efficacy and a feeling of competency lead to a feeling of mastery, which is an intrinsic reward and motivator in itself [74]. CE and between-session activities promote autonomy and provide opportunities for development of competence in behavioral, emotional, or cognitive self-management. SDT can inform MHapps on how to best engage users in CBT-based interventions (ie, by intrinsically motivating them). Users will be more motivated to engage with apps and products that encourage autonomy, emphasize user choice, and allow opportunities for building mastery. For example, SuperBetter [59] employs SDT-based, game-based principles to intrinsically motivate users to engage with the app and experience the well-being-promoting effects of mastery (see the “Gamification and Intrinsic Motivation to Engage” section).

Figure 1. Screenshot of Smiling Mind displaying meditations.

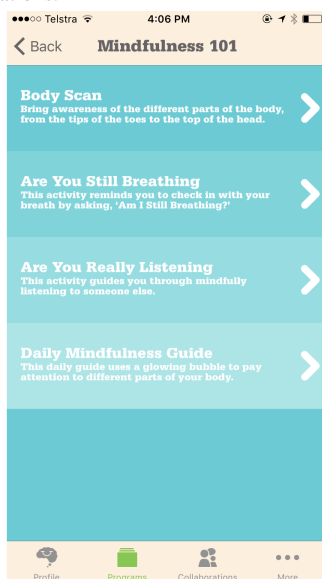
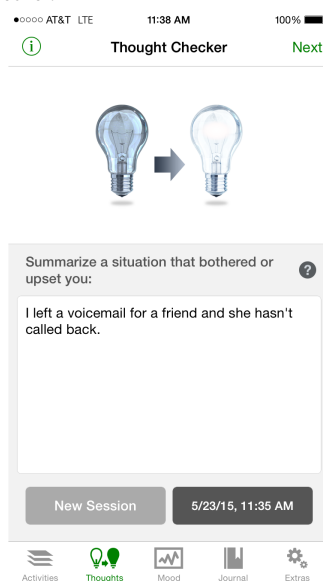


Figure 2. Screenshot of MoodKit displaying thought checker.

Address Both Anxiety and Low Mood

Emotional disorders (eg, anxiety and depression) are by far the most common psychological conditions in the community, with an estimated 20.9% of US citizens experiencing a major depressive episode and 33.7% suffering from an anxiety disorder at some point throughout their lives [75]. Emotional disorders are also the most treatable [76], but help seeking for sufferers is very low [77]. There is strong supportive evidence for CCBT as an effective therapy for reducing symptoms of the most common anxiety disorders and depression [45,46].

There is an extremely high comorbidity between anxiety and depression [78], with 85% of people diagnosed with depression problems also suffering significant anxiety and 90% of people diagnosed with anxiety disorders suffering significant depression [79]. In Australia, 25% of all general practice patients have comorbid depression and anxiety [80]; whereas in Great Britain, half of all mental illness cases are mixed anxiety and depression [81]. These two diagnoses share a few major underlying factors [82]. This raises two important considerations for MHapp self-help interventions. First, interventions designed for one disorder are likely to have some efficacy for other emotional disorders, and second, interventions that target shared underlying factors across emotional disorders will be more efficacious.

Transdiagnostic CBT (TCBT) is an effective therapeutic approach that targets the common underlying factors shared by different psychological disorders. A meta-analysis of RCTs found a large effect size (standardized mean difference = -0.79 , 95% CI -1.30 to -0.27) for TCBT across different anxiety disorders [83]. Furthermore, TCBT has been found to be successful in treating depression [25]. Barlow et al's [84] Unified Protocol (UP) is a recent TCBT treatment that focuses on monitoring and adjusting maladaptive cognitive, behavioral, and emotional reactions that underlie depression and anxiety disorders. The UP has yielded very promising results across various emotional disorders, reducing psychopathology [85] and improving psychological well-being [86]. It is important to note that TCBT protocols do not imply that all emotional disorders can be treated effectively with the exact same

techniques [87]. The basic structure for treating different clinical problems may be relatively uniform, but tailoring of interventions is still essential (see the "Automated Tailoring" section), and the structure of TCBT affords flexibility. For example, the UP consists of four core modules that are designed to (1) increase present-focused emotional awareness, (2) increase cognitive flexibility, (3) aid identification and prevention of patterns of emotion avoidance and maladaptive emotion-driven behaviors, and (4) promote emotion-focused exposure [88]. This enables a prescriptive approach, whereby certain modules can be focused on more than others, depending on the needs of the client or user [88]. An Internet-delivered TCBT intervention called the Wellbeing Program used a structure of 8 lessons, focusing on areas such as psychoeducation, thought-monitoring strategies, behavioral activation, and graded exposure [57]. A clinician guided users through the program and tailored the delivery of each lesson to the user's needs. An RCT supported the efficacy of this intervention across depression and anxiety disorders [57]. Although the Wellbeing Program was guided by a clinician and not via automated processes, many other self-guided CBT interventions use a transdiagnostic approach to maximize efficiency and adaptability [89], particularly in an automated Internet-delivered context [90].

Despite the success of TCBT, many MHapps are designed for the treatment of specific disorders. Some apps are marketed for anxiety and others for depression. Few apps acknowledge that the underlying CBT principles guiding self-help interventions for anxiety and mood problems are very similar; thus, broadening the target group of the app can be beneficial for all users. Combining treatments for both anxiety and depression into a single app would also reduce the commitment required for engagement. Users could consolidate their investment within a single app, instead of dividing their effort and time engaging with 2 separate apps (one for anxiety and the other for depression).

Designed for Use by Nonclinical Populations

Many apps have been designed for use with populations who have been diagnosed with a specific clinical disorder, from

depression (eg, Optimism [91]) and anxiety (eg, SAM [92]) to eating disorders (eg, Recovery Record [93]) and borderline personality disorder (eg, DBT [Dialectical Behavior Therapy] Diary Card and Skills Coach [94]). Some of these clinical diagnosis apps are known to be effective for interventions [8], but they do not capitalize on one of the major advantages of smartphones: high accessibility. Smartphones are interwoven into the routines of millions of people all over the world, the majority of whom have not been diagnosed with a clinical psychological disorder but do experience unpleasant psychological distress from time to time. Targeting a specific clinical population with an MHapp automatically excludes the majority of smartphone owners from using that app. By contrast, an MHapp built for a population interested in the *prevention* of emotional mental health problems increases the number of eligible and willing users. A meta-regression of 34 studies found that self-help interventions were significantly more effective when recruitment occurred in nonclinical settings (effect size $f^2=0.66$) than in clinical settings (effect size $f^2=0.22$) [48]. The field would therefore benefit from more MHapps with preventative applications that are widely marketable, rigorous, and effective.

An MHapp market saturated with clinical diagnosis apps also has the potential to be harmful for help seekers. Users who are experiencing low-level symptoms of a disorder may feel labeled by an app that assumes that they have a clinical diagnosis [95]. Self-stigma from this labeling can be harmful, lowering self-esteem and self-efficacy [96]. Initiatives that acknowledge the continuum of mental health and the importance of well-being promotion may reduce stigma and increase help seeking for mental health problems [97]. Programs such as Opening Minds [98] aim to reduce mental illness stigma by adopting a nonjudgmental, nondiagnostic, and nonclinical CBT-based stance to mental health problems. MHapps that focus on nonclinical mental health, psychological well-being, or coping abilities may therefore avoid the harmful effects of labeling mental illness [99].

CBT is built on the foundation that mental health is a continuum [89] and that supporting individuals in coping with nonclinical psychological distress can prevent symptoms from reaching clinical significance [100]. Furthermore, CBT-based support can help prevent relapse [101], expand an individual's coping skills repertoire [102], and assist individuals experiencing psychological distress to avoid developing a clinical disorder [103]. Building a CBT-based MHapp that acknowledges the continuum of mental health can be used by both clinical and nonclinical populations.

CBT treatment adopts a formulation-based approach rather than a diagnosis-based approach [54,104]; as such, a diagnosis is not necessary for support to be given. Formulation involves exploring the predisposing, precipitating, perpetuating, and protective factors connected to a psychological problem, and then building these factors into a causal model [105]. Conversely, diagnosis relies on detection of symptoms and fulfillment of criteria statistically linked to a particular disorder [106]. In many cases, a formal diagnostic label is not important for informing real-world treatment, and it does not specify the

causal factors contributing to an individual's unique psychological problems. Formulation is much more useful because it can inform exactly which precipitating and perpetuating factors are contributing to an individual's unique psychological problem, and which psychological techniques can produce optimal solutions [107]. Hofmann [108] proposed a cognitive behavioral approach for classifying clinical psychological problems that avoids diagnostic labeling, which is better at informing CBT-based support because it is based on formulation. MHapp developers are encouraged to explore formulation-based approaches to CBT to inform the development of CBT-based MHapps.

Designing MHapps for nonclinical support may mean adopting a preventative framework. There are generally three types of preventative intervention: universal (ie, delivered to everyone in the community), selective (ie, delivered to at-risk groups), and indicated (ie, delivered to individuals with preclinical symptoms) [109]. The flexibility of MHapps means that a single app could theoretically adapt to any of these three intervention models, providing a universal intervention as default, and tailoring to a selective or indicated approach if a user's responses suggest that they are at risk of a certain condition.

Some mobile interventions that have been validated and trialed experimentally were built for personal digital assistants (PDAs) and not for modern smartphones [7,110]. This severely limits their nonclinical use and introduces other barriers to routine engagement that are not experienced by smartphone apps. However, evidence and principles from PDA-based studies should be considered when designing smartphone apps.

Automated Tailoring

An advantage of eHealth interventions over other self-help interventions is their capacity for tailoring [90,111]. Tailoring in this context refers to the adjustment of technology-delivered self-help programs to suit the user's needs, characteristics, and comorbidities or case formulation [112]. Tailored CCBT interventions have been shown to be more efficacious than rigid self-help interventions across a range of depressive and anxiety disorders [112-115].

Formulation-based tailoring improves the functionality of an intervention and provides targeted solutions to a user's psychological problems. There is a large range of different self-help mental health interventions available, and selecting the right intervention can be a challenging and overwhelming process [15]. The complexity of choices can be simplified or reduced by building an app capable of automated tailoring, which combines elements of a large number of different interventions and deploys them strategically depending on the needs of individual users. A review of currently available MHapps reveals, however, that many apps aim to provide a service but do not service a need [116]. For example, many apps provide guided meditation, but do not guide users toward meditation when they are feeling anxious. With tailoring, the app can recommend users specific solutions to their specific problems.

Automated tailoring requires the collection of data to identify the needs of users and develop a functional analysis or case

formulation. This can be achieved in three main ways. First, self-report measures can be deployed to elicit in-depth responses about symptoms and characteristics. Second, data from a user's self-monitoring (see "Reporting of Thoughts, Feelings, and Behaviors" section) can be used to predict the types of interventions that are well suited to an individual user. Third, an app's behavioral usage data can be used to predict which features of that app a user is using most. If these second and third data sources are correctly utilized, tailoring can be carried out seamlessly, without any additional input from the user, which decreases users' required effort to use the app and thereby increases app functionality [3].

CBT includes a very wide range of evidence-based techniques that may be selectively employed by an MHapp depending on automated tailoring data. For example, if data sources suggest that the user is experiencing significant physiological arousal, rather than overwhelming worry or other anxiety-related problems, CBT techniques such as breathing relaxation may be recommended over others, based on the available evidence [117]. Ideally, these therapeutic techniques would be employed by the MHapp that actually performs the automated tailoring, but restrictions may mean that the MHapp must rely on referring users to other apps. This is not ideal, as it may disrupt the user's engagement with the MHapp. However, if necessary, any referrals should be based on a thorough review of the other existing apps and their supporting evidence [116].

Reporting of Thoughts, Feelings, or Behaviors

Clients who record their own thoughts, feelings, and behaviors as part of a CBT-based intervention are able to reflect on their reports and exercise self-monitoring [118]. Self-monitoring is a core feature of many evidence-based psychological therapeutic techniques, including CBT [119,120], mindfulness exercises [121], emotion-focused therapy [122], DBT [123], and acceptance and commitment therapy (ACT) [124]. Self-monitoring can be used to restructure maladaptive anxiety responses [125,126], challenge perpetuating factors of depression [127], and sufficiently treat a small but significant proportion of posttraumatic stress disorder sufferers [128,129].

Self-monitoring is particularly suitable for CBT-based interventions that aim to change behavior, with self-monitoring-only treatment conditions showing benefits for problem drinking [130] and sleep hygiene [131]. Furthermore, self-monitoring is a feature of successful weight loss interventions [132]. Encouraging MHapp users to report their thoughts, feelings, or behaviors in an objective way should therefore help promote accurate, beneficial self-monitoring.

Self-monitoring of mood can boost overall emotional self-awareness (ESA) [133], which can in turn lead to improvements in emotional self-regulation [134]. Emotional self-regulation is valuable for individuals in preventing distress from spiraling out of control and thereby culminating in clinical problems [135]. Poor emotional awareness is a common underlying factor for both anxiety and depression [136]. The ability to differentiate and understand personal emotions, an integral process in ESA, is positively related to adaptive regulation of emotions [137] and positive mental health outcomes [138]. Self-reflection and insight correlate positively

with levels of positive affect and the use of cognitive reappraisal, and negatively with levels of negative affect and the use of expressive suppression [139]. Explicit emotion labeling shares neurocognitive mechanisms with implicit emotion regulation ability, suggesting that increasing ESA through practicing labeling of personal emotions will lead to improvements in emotional regulation and adaptation [140].

Some self-monitoring interventions are limited by problems related to recall biases. Self-reflection at the end of a day or in a time and place removed from normal stressors can be inaccurate [141]. One of the benefits of MHapps is that smartphones are capable of ecological momentary assessment (EMA) and experience sampling methods (ESM), which involve measuring experiences and behavior in real time [142]. MHapp users can record self-monitoring data on their smartphones while they are participating in their usual daily routines, undergoing challenges, or directly experiencing stressors [143]. This can help reduce bias in self-monitoring [141], thereby improving the accuracy of users' reflections.

Increasing ESA should lead to greater help seeking, because factors preventing help seeking include low emotional competence [144] and low self-awareness [77]. Using technology for self-monitoring can increase help seeking, particularly if there is a capacity to contact health professionals built in to the service [145] (see the "Links to Crisis Support Services" section).

Self-monitoring via traditional means might also be less effective for very busy individuals who do not have the time to complete monitoring entries [118]. MHapps can reduce monitoring demands by automating some parts of the monitoring process, such as shifting the burden of some of the more administrative parts of self-monitoring (eg, entering dates and times, formatting monitoring entries) from the user to the smartphone [5]. Using smartphone apps also allows for more frequent and broader opportunities for recording reflections, such as while waiting or traveling on public transport.

Keeping all self-reports structured and objective can help users report quickly and in a format that facilitates data analysis by the MHapp. It may also reduce some of the barriers to self-monitoring: for instance, some depressed clients may find the demands of open-ended self-monitoring overwhelming, whereas perfectionistic or obsessive clients may spend too much time and effort on their monitoring [146]. MHapps with highly structured reporting in a simple interface (see "Simple and Intuitive Interface and Interactions" section) may be able to remedy this by limiting the amount of information necessary for logs, simplifying the monitoring process, reducing the demands on users, and increasing engagement in the app [5].

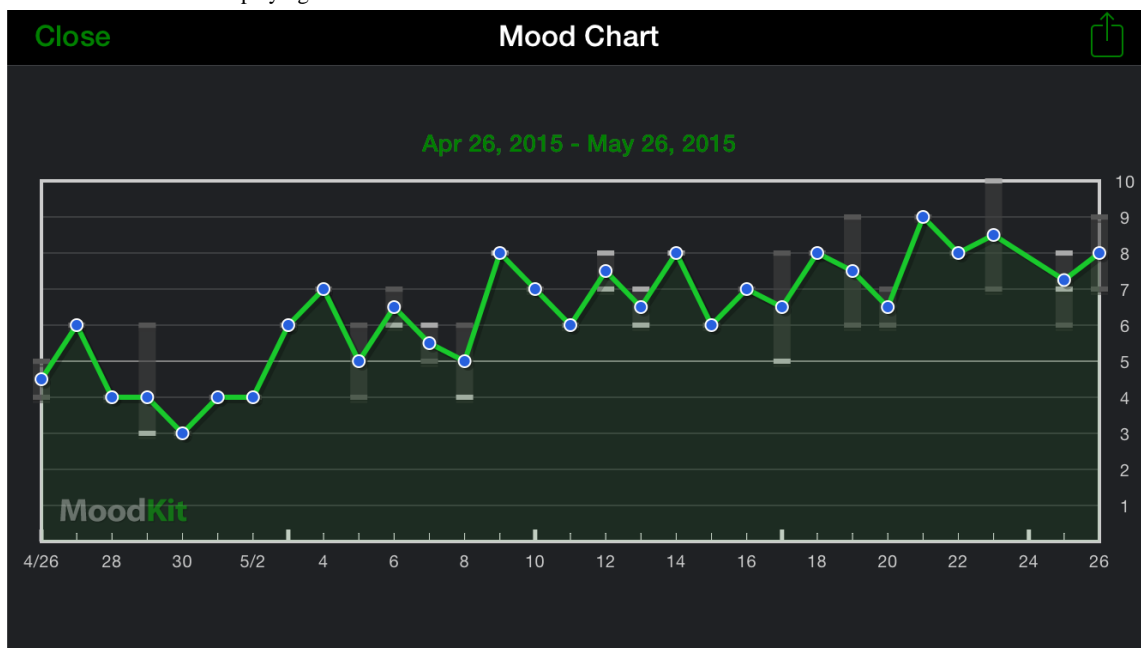
Several studies support the efficacy of using app-based interventions to increase ESA. Morris et al [147] developed an app that prompted users to report their moods several times a day. Users reported increases in their ESA, and upon reflection of their ratings, some were able to recognize patterns of dysfunction and interrupt these patterns through modification of routines. Kauer et al [133] used a mobile phone self-monitoring program to prompt users to report their emotional state several times throughout the day. Participants

who reported on their emotional state showed increased ESA and decreased depressive symptoms compared with controls. Both of these monitoring systems were, however, quite simple and offered little constructive feedback to users about their mood history. They were also trialed on small samples of individuals who had reported psychological distress. There is, therefore, a need to further investigate the impact of smartphone-based mood reporting on ESA and associated mental health outcomes, using an app that gives better feedback and is relevant to nonclinical users.

The reporting required for self-monitoring can also enable feedback and evaluation of therapeutic progress. In

psychological therapy, therapeutic outcomes can be enhanced by providing clients and clinicians with feedback concerning treatment progress [148,149]. These positive effects have been substantiated via a literature review [150] and a meta-analysis, which found a notable effect size ($d=0.10$, 95% CI 0.01-0.19) [151]. MHapps may be able to provide feedback by presenting a user's own reporting data back to them, but reframed in context with the user's treatment goal. For example, the mood feedback provided by MoodKit [62] can be displayed as a chart, as shown in Figure 3. This type of feedback-focused progress tracking relates also to gamification (see the "Gamification and Intrinsic Motivation to Engage" section) and keeping a log of past app engagement (see the "Log of Past App Use" section).

Figure 3. Screenshot of MoodKit displaying mood chart.



Recommend Activities

CBT aims to engage clients in a range of activities that are congruent with its core principles (ie, context engagement, attention change, and cognitive change) [58]. This represents a shift away from passive interventions toward ones that actively engage clients. CBT-based activities that can be recommended to MHapp users can be summarized into the following categories: (1) exercise and direct mood improvement, (2) behavioral activation, and (3) coping skills training.

Activities That Directly Enhance Mood Improvement

A range of activities might target mood directly. For example, it is well established that increasing physical activity and promoting exercise can reduce depressive symptoms [152-154] and anxiety [155], and improve psychological well-being [156,157]. A meta-analysis of 39 RCTs examined the effects of exercise on people diagnosed with a mental illness, and found large effect sizes for depressive symptoms (standardized mean difference=0.80, 95% CI 0.47-1.13) and schizophrenia symptoms (standardized mean difference=1.0, 95% CI 0.37-1.64), and a moderate effect size for quality of life (standardized mean difference=0.64, 95% CI 0.35-0.92) [158]. Effective smartphone apps that promote physical exercise have

already been developed [7], but lack an explicit link to mental health that mental-health-focused users may need to justify their use. Motivating MHapp users to engage in physical exercise can have a broad range of mental health benefits.

Another activity that has been directly linked to mood improvement is music listening. Music can be a powerful tool for evoking emotion [159]. Furthermore, relaxing music can challenge emotional recall biases [160] and decrease anxiety [161]. Over 68% of users listen to music on their smartphones [1], and many users use music to reach specific emotional goals [162,163]. An MHapp that includes music listening activities could help users with emotional regulation.

Behavioral Activation

Behavioral activation (BA) is a key CBT technique that involves encouraging individuals to engage in physiologically activating and psychologically rewarding activities [164]. A meta-analysis of 17 RCTs reported that BA for clinical depression outperformed control conditions (standardized mean difference=-0.70, 95% CI -1.00 to -0.39) and was as effective as CBT-as-usual (standardized mean difference=0.08, 95% CI -0.14 to 0.30) [165]. There is also evidence that BA can help relieve anxiety [166]. BA aims to (1) encourage the planning

of activities and the setting of goals so that clients move away from relying on mood-dependent behaviors; (2) break cycles of avoidance behavior; and (3) develop skills that focus attention on the present moment to enable engagement in activities and associated experiences of pleasure [167]. Motivating MHapp users to complete BA activities is therefore a simple and effective way to improve mental health and well-being outcomes.

Inactivity perpetuates itself via a vicious cycle of low mood: inactivity can lead to decreased opportunities to experience pleasure or gain a sense of mastery, which in turn leads to an increase in negative thinking. This leads to decreased mood, which again leads to greater inactivity, and so forth [168]. BA helps to break this cycle by scheduling activities and reducing escape and avoidance behaviors [167]. Selecting activities that involve mastery and promote positive feelings of self-worth is recommended [168], as such activities can boost motivation via factors related to SDT as well as self-efficacy [100]. Classifying activities as routine, pleasurable, or necessary can be useful, as each has different motivations and benefits to performing [169]. To maximize the likelihood that a recommended behavior will actually be performed by a smartphone user, the behavioral economics of the situation need to be considered [5].

Using a framework such as Fogg's [170] behavior model, which has been specifically designed with app users in mind, can help in the selection of short, tangible, and universal activities that will maximize user engagement. Fogg's behavior model states that three factors determine the likelihood of a target behavior occurring: behavior triggers, elements of motivation, and elements of simplicity. Most relevant to selecting BA activities are elements of simplicity, which affect a user's ability to easily perform the behavior, and include factors such as time, money, physical effort, mental effort, social deviance, and routine. Feedback and self-reflection (see the "Reporting of Thoughts, Feelings, or Behaviors" section) can be an important part of behavioral activation [169]. An app that promotes reflective learning by encouraging an activity and then prompting reflection on the experience immediately after can promote self-discovery [171].

Coping Skills Training

Coping skills training is the most direct way of improving self-efficacy [172,173]. Coping self-efficacy (CSE) is a type of self-efficacy reflecting an individual's perceived ability to effectively cope with adversity and distress [174]. Individuals with high CSE have confidence in their ability to cope with adversity [175] and engage in more active coping strategies [176]. Having greater CSE is associated with better mental health outcomes, including lower likelihoods of depression [177] and anxiety [174], lower overall psychological distress [178-180], and greater psychological thriving [181]. Furthermore, CSE can decrease the negative effect of stressful events on physical health [182]. The greater an individual's CSE, the less likely they will also be to avoid anxiety-provoking situations [174]. Avoidance plays a key role in the development of anxiety, depression, and many other psychological disorders [183], so interventions that boost CSE by encouraging participation in psychologically beneficial activities will both

reduce day-to-day distress and help prevent disorders from developing.

The development of coping skills is a central component in CBT-based practices, and such skills can help clients reduce distress that can trigger problematic maintenance cycles [54,100,104,184]. For example, a core exercise in the treatment of anxiety is the development of relaxation skills, and a meta-analysis of 27 RCTs found a medium to large effect size for relaxation training on anxiety ($d=0.57$, 95% CI 0.52-0.68) [117]. Relaxation training not only develops skills to reduce physiological arousal, but also builds self-efficacy and confidence in coping ability [185,186]. CBT for depression also involves exploration of activities that can reduce distress and improve self-efficacy [187,188]. Research in positive psychology stresses that development of a coping skills repertoire is not only beneficial for those vulnerable to anxiety or depression, but also important for individuals to function well emotionally and achieve their full potential [189]. Offering a range of different strategies and thereby allowing a client to choose which one fits them best can boost self-efficacy and perceived control [190,191]. Furthermore, according to SDT, this choice and control can feed intrinsic motivation toward self-improvement [70].

Unfortunately, there is currently a lack of technology-based interventions designed to develop CSE in relation to mental health. A comparison of 2 Web-based interventions for diabetes management, one involving coping skills training and the other focusing on education, showed that although both interventions had a positive effect on diabetes self-efficacy, only the coping skills (ie, active) intervention showed significant increases in primary control coping behaviors and decreases in perceived stress [192]. Other studies have found no advantage of coping skills training over educational interventions [193-195], but none has investigated the impact of the type of real-time engagement that smartphone apps offer. Many of the coping skills interventions investigated are limited to a series of educational sessions about potential coping strategies. By contrast, smartphone approaches to coping skills interventions could motivate participants to try a number of different coping strategies in real-time as they go about their lives and respond to stressors. This high level of engagement and interactivity could yield substantial improvements in CSE and psychological well-being.

Mental Health Information

Psychoeducation, an integral part of CBT, presents clients with mental health information in an attempt to teach them about the psychological processes underlying their distress and inform them of resources available to manage it [196]. A meta-analysis of 25 RCTs reported that the "Coping with Depression" psychoeducational intervention, developed by Lewinsohn et al [197], was effective at treating depression, albeit with a small effect size ($d=0.28$, 95% CI 0.18-0.38) [102]. Participants who completed the preventative version of the intervention were 38% less likely to develop clinical depression [102]. Psychoeducation can also improve mental health outcomes on a community-wide scale. A meta-analysis of 15 studies concluded that the Mental Health First Aid program, developed

by Kitchener and Jorm [198], improved participants' knowledge (Glass's $\Delta=0.56$, 95% CI 0.38-0.74), attitudes (Glass's $\Delta=0.28$, 95% CI 0.22-0.35), and supportive behaviors (Glass's $\Delta=0.25$, 95% CI 0.12-0.38) with regard to mental health [199].

MHapps are well positioned to deliver psychoeducation, as they can engage users with a range of multimedia and audiovisual tools to aid understanding of mental health concepts. A meta-analysis of 4 RCTs reported a small effect size ($d=0.20$, 95% CI 0.01-0.40) for passive psychoeducation including brief audiovisual sources and information presented via the Internet, demonstrating that even this minimal form of psychoeducation is effective at reducing depressive symptoms and psychological distress [200]. Another meta-analysis of 19 studies found a significant but small effect size of psychoeducation on stress (standardized mean difference=0.27, 95% CI 0.14-0.40); in a follow-up moderator analysis, this study showed that shorter interventions were significantly more effective than were longer interventions ($P<.05$, $B=-0.020$, 95% CI -0.024 to -0.016) [201]. Smartphones are well equipped to deliver this kind of brief, passive psychoeducation, and MHapps can offer links to websites for more in-depth information where required [202].

Psychoeducation topics that have greater relevance to the user's reported problems are of greater use to the user, so MHapps should tailor psychoeducation to individual users (see the "Automated Tailoring" section) [111]. For example, if a user reports feelings of anxiety, delivery of information about the physiological responses of anxiety and their relationship with thoughts and behaviors would be more appropriate than would delivery of information about the physiological symptoms of depression. Relevance and engagement may also be enhanced by adopting a collaboratively empirical approach [64], whereby users are encouraged to apply concepts learned through psychoeducation to their own circumstances through hypothesis testing. An app that engages users in a process of experimentation-based self-discovery may enhance psychoeducational outcomes.

Presenting mental health information and engaging individuals in psychoeducation can lead to boosts in mental health literacy (MHL) [203]. MHL has been defined as "knowledge and beliefs about mental disorders which aid their recognition, management or prevention" [204]. Greater MHL is associated with a reduction in stigmatizing beliefs about those with mental illness [205] and with greater and more appropriate help seeking [144,206,207]. Known factors preventing young people from seeking help for mental health issues include poor MHL, preference for self-reliance in problem management, and perceived stigma of mental illness [77].

Mental health information can also increase treatment credibility, thereby motivating users to engage with a given treatment [208], and can provide evidence-based justifications for performing recommended activities (see the "Recommend Activities" section). Notably, users have a tendency to perceive health information on the Internet as being credible [209], so this raises the ethical imperative of ensuring that all information is strictly evidence based. Providing links to sources of evidence may satisfy the needs of scientifically minded users and mental health experts. The wealth of mental health resources already

available online [210,211] could be utilized by MHapps. Improving MHL may simply be a case of providing easy access to these resources through the app.

Christensen et al [212] compared 2 Web-based interventions aimed at promoting mental health. BluePages, a psychoeducation site, and MoodGYM, a self-guided CBT site, both led to decreases in users' depression symptoms. MoodGYM reduced users' dysfunctional thinking, whereas BluePages failed to do this. However, BluePages improved users' knowledge of treatments for depression beyond what MoodGYM achieved. This evidence suggests that both psychoeducation and self-guided CBT interventions are needed to generate the most substantial and stable gains in mental health and well-being. A successful app-based intervention would combine elements of both psychoeducation and self-guided CBT.

Real-Time Engagement

The high engagement potential of smartphones means that users are able to seek help for psychological challenges in the moment they are experiencing them or soon after. MHapps that have not been designed to be used in real time will fail to capitalize on valuable opportunities to engage with users.

Many CBT-based therapy programs utilize in vivo exposure and between-session (homework) activities to help clients resolve maladaptive anxiety responses in ecologically valid settings [65,105]. The advantages of between-session interventions are wide ranging [66] and have already been covered in this paper under Recommendation 1 "Cognitive Behavioral Therapy Based." Some therapy programs have even utilized virtual reality to harness the power of real-time engagement [213,214]. These interventions acknowledge the benefits of engaging with clients in real-world contexts in real time.

The rationale behind real-time engagement includes basic behavioral principles of learning. It enhances the generalization of learned skills to new settings, and can encourage practice of behaviors to maintain therapeutic gains [215]. Real-time engagement opens up more opportunities for learning and applying coping strategies in ecologically valid contexts. Of the MHapps that aim to increase users' coping abilities, few utilize the real-time capabilities of smartphones [8,216]. Most deliver long-running interventions designed to increase users' overall resilience or optimism, such as SuperBetter [59]. The MHapps that do provide users with in vivo coping strategies, such as MindShift, are very clinically focused, which restricts their reach (see the "Designed for Nonclinical, Nondiagnostic Support" section). Engaging users to attempt coping strategies in real time improves the functionality of the MHapp and increases opportunities for learning.

Heron and Smyth [217] call health apps that use real-time engagement "ecological momentary interventions," and they present evidence for the efficacy of such apps in psychosocial applications. Depp et al [110] developed and trialed a mobile intervention called PRISM that used real-time data to prompt individuals with bipolar disorder to engage in self-management behaviors. The results from this study were promising, but this rather clinically focused intervention was built for PDAs rather

than for smartphones, and therefore was unlikely to be as unobtrusive in daily life as smartphone interventions.

Activities Explicitly Linked to Specific Reported Mood Problems

Linking recommended activities to specific psychological challenges helps trigger engagement with an intervention. Eyal [3] emphasizes the need for successful apps to have triggers that fulfill an immediate and obvious need, using the metaphor of vitamins and painkillers. Vitamin-like products do not satisfy immediate needs but are espoused as beneficial, whereas painkiller-like products give users immediate benefits. MHapps like SuperBetter [59] and Happify [218] require users to engage with the app regularly and encourage them to do so by reminding them of the benefits offered by the app. However, the activities recommended by these apps are not directly linked to any specific mood problems that users may be experiencing. Using specific problems as triggers can strengthen engagement [3] and can help in the learning of targeted coping strategies.

Utilizing habit formation can be a very effective way of guaranteeing repeated engagement with an app, which in the case of MHapps, should lead to mental health benefits. Habits are repeated behaviors that are triggered by cues [5]. To generate a habit that involves using an MHapp, a cue must be selected to associate with app use through the processes of conditioning [3]. Using mood problems as cues can drive real-time engagement (see the “Real-time Engagement” section). For example, an MHapp that is designed to be used when a user is feeling low or anxious is better suited to habit formation processes than is an MHapp that offers no cues for engagement and expects users to engage with it randomly throughout the day. Habit formation will also be driven if an MHapp is linked to activities that decrease psychological distress, increase self-efficacy, or reward users in some other way [5].

Encourage Nontechnology-Based Activities

When designing interventions for smartphones, it may be tempting to build the therapeutic activities into the app’s interface. However, this goes against the ethos of CBT-based practice, which emphasizes the important role of activities and interventions outside of contact with a practitioner, computer program, or self-help guide [120]. Encouraging users to engage in real-world activities, off the device they are using, respects that ethos and fosters the environmentally valid application of skills.

In this context, it is also of note that depression and lower psychological well-being are correlated with Internet use, especially among introverts with low levels of social support [219]. However, this role is moderated by the function of Internet use—for instance, Internet use for communication has been found to be related to lower levels of depression, whereas Internet use for noncommunication purposes has been found to be related to greater depression and social anxiety symptoms [220]. Internet use and Internet addiction have also been associated with social anxiety [221], and positive correlations

have been found between avoidance coping and Internet use [222,223]. This may also apply to Internet-enabled, noncommunication-based mobile phone apps that distract users’ attention away from psychological challenges. Avoidance coping has been shown to increase the likelihood of acute and chronic life stressors and depressive symptoms over long periods [224]. Providing users with nontechnology-based activities helps to balance MHapp-based technology use with positive behavior change strategies and limits use of avoidance coping strategies.

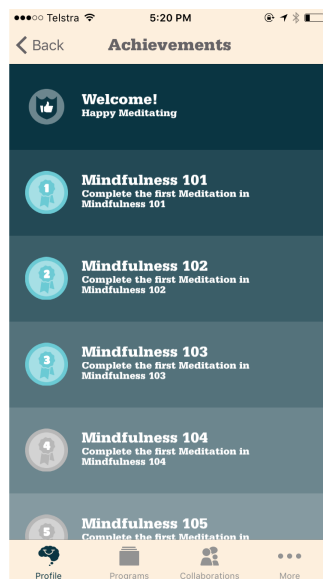
Technology can allow greater multimodal learning by combining text with spoken language, sounds, and graphics that are closer representations of learning in an applied setting [225]. For example, blended learning, which involves blending the use of technology with applied learning in the classroom [226,227], has been shown to deliver superior learning outcomes to traditional teaching methods [228,229]. It has been recommended that technology be used to enhance real-life experiences, not replace them [230,231]. MHapps may therefore harness the power of blended, multimodal methods to effectively enhance learning of real-world coping strategies.

Some available MHapps encourage users to engage in nontechnology-based activities. SuperBetter motivates users to engage in regular nontechnology-based resilience-building activities [232]. Preliminary results from an RCT suggest that SuperBetter is effective for reducing symptoms of depression [233]: specifically, SuperBetter users experienced a reduction in the equivalent of 5 symptoms of depression, and waitlist participants experienced a reduction in just 2.

Gamification and Intrinsic Motivation to Engage

The therapist plays an instrumental role in promoting clients’ motivation to engage in psychotherapy and undertake homework activities [65]. This means that self-help CBT may be of limited use if the user suffers from low motivation and volition, which is common among those with mood disorders [234]. Gamification is a novel solution that may help counteract problems with motivation and yield additional well-being outcomes.

To “gamify” something does not mean to turn it into a digital game. Gamification is instead the use of “game-based mechanics, aesthetics, and game thinking to engage people, motivate action, promote learning, and solve problems” [17]. Many apps have employed the principles of gamification to motivate users to pursue various goals, but such goals are likely to be most motivating if they originate from the users themselves [235]. Gamification can enhance a user’s motivation to pursue an existing goal, but it does not, in itself, create new goals for users. These goals may require the formation of new routines, and gamification excels at motivating people to repeat tasks until new habits are formed [3]. Some examples include Nike+ Running [236] and other fitness tracking apps that award points for reaching fitness goals, and Smiling Mind [60], which tallies minutes spent meditating and awards badges for specific meditation-related achievements, as seen in Figure 4.

Figure 4. Screenshot of Smiling Mind displaying achievements.

Games are abstracted, simplified versions of reality, so gamification can help users reduce reality's complexity into a more easily understood operating model [17]. This helps users to quickly learn cause-and-effect inferences, without complex extraneous factors detracting from their motivation to make change. Gamification is also based on the principle that making something goal oriented can increase the positive feelings associated with it and drive intrinsic motivation [232]. In this context, gamification is an applied expression of the concepts proposed by SDT [17] (see the "Cognitive Behavioral Therapy Based" section).

Gamification is a means of making intrinsic rewards more obvious and tangible. Alternate reality games (ARGs) link online or app-based events and achievements to real-world ones [237]. By tracking and quantifying the progress of real-world goals, users are able to reflect on their competency and experience mastery. Gamification also helps to break larger, more abstract goals down into smaller, more tangible and concrete tasks. For example, if a user's goal is to build resilience and recover from depression, the MHapp and ARG SuperBetter is able to break that goal down into daily tasks of activating 3 power-ups, battling 1 bad guy, and doing 3 quests [59]. Although many regular electronic games are attractive because they are escapist [238], ARGs are anti-escapist, motivating users to deal with real-world challenges and increasing the likelihood of them obtaining intrinsic rewards.

Individuals tend to choose more challenging activities when these activities are framed as games and imbued with intrinsic motivation [239,240], and making activities goal-directed further enhances enjoyment of their challenges [241]. When building points and award systems for gamified solutions, it is best to introduce users by awarding them some points or rewards on sign-up or early on. The endowed progress effect means that starting with some points rather than zero increases effort and motivation to engage [242].

Although fun is the primary reward in electronic games, self-efficacy is the primary reward in well-structured gamified solutions [235]. Gamification principles can amplify

achievements by offering immediate reflections of intrinsic rewards, thereby boosting self-efficacy. Badges, points, and other gamification rewards remind users that they have achieved something by quantifying their success and allowing users to reflect on their own growth [232]. Even apparent failure can be rewarding in a gamified environment, if the right animation or interaction—namely, one that maintains the user's feelings of competency—is used [17].

One study found that the reward- and motivation-related neurotransmitter dopamine was released during a simple, goal-directed game-based task, presenting neurological evidence for why game-based mechanics may yield positive well-being effects [243]. A meta-analysis of 10 RCTs found that electronic-game-based depression interventions had a moderate effect on depressive symptoms ($d=-0.47$, 95% CI -0.69 to -0.24) [244].

Apps allow constant improvement through updates and Web-delivered content [245], and this is very important for a successful gamified solution. Not only should the gamified structures be tweaked until users are being optimally engaged, but also novel and untried features should be introduced to motivate users to maintain their engagement with the app. Apps that sustain variability throughout use can maintain user interest with the promise of new and interesting content [3].

Log of Past App Use

Gamification relies on users having the ability to record and review their achievements. Thus, having a well-presented log of past app use can potentially raise intrinsic motivation and increase users' investment in the app. Logs of past use can also enable automated tailoring (see the "Automated Tailoring" section). If a log is being recorded for this purpose, then making it accessible to the user should not present coding difficulties.

Narratives in games can link discrete, seemingly unrelated tasks [232]. Narrative framework embedded into an app's use can motivate users to do small tasks to work toward an overall goal. Using a log that provides users with useful feedback about their successes and challenges can provide this narrative framework.

For example, many mental health boosting activities, such as exercise, relaxation, and cognitive reframing, appear to be unrelated. However, embedding them into a narrative that has an end goal related to boosting mental health can help users make sense of the tasks, thereby boosting users' motivation to achieve these goals.

Wilson's [246] story-editing technique can be applied to apps to enhance engagement [5]. According to Wilson's theory, reinterpretation of a self-narrative can affect future behavior. Past failings can be reinterpreted as learning opportunities, and other actions can be framed as preparations for a specific goal. Altering self-narrative in this way helps users see "themselves as someone for whom the action is a natural, normal extension of who they are" [5]. For example, fitness trackers and apps that count a user's steps, such as the Jawbone UP [247], show users that they have already been exercising, but may need to increase their level slightly to achieve their goals.

The addition of more storyline-based game principles, such as avatars with experience points, can further reinforce a sense of narrative [17]. Avatars are characters within a game that are representations of the user [248]. Bandura's [249] social cognitive theory states that the relatability and similarity of a model will increase the likelihood of a learned behavior being performed. Fox and Bailenson [250] substantiated this in a digital environment, with participants exercising more when they were shown an exercising avatar that resembled them than when the avatar did not resemble them. Furthermore, users who are given taller avatars act more confidently and aggressively than do those who are given shorter avatars, both virtually and face-to-face [251,252]. This indicates that the narrative elements used in a gamified solution can translate to behavioral changes in the real world. If users are capable of exercising autonomy and customizing their avatars so that these avatars better resemble users' ideal state, the likelihood of behavioral modification should be improved.

Importantly, users must also be aware of the cognitive or behavioral work they have completed. Investment through labor and work increases engagement and enjoyment [253]. Understood through SDT, this may be a reflection of a user's desire to build competency and mastery [254]. Therefore, users who can log the extent of their app use and receive feedback on how much they have done or invested are more likely to have greater, more enjoyable engagement with the app.

To maintain a log of app-based activity, users may have to create an account to synchronize their app progress with a server. This would allow users to use multiple devices and help them avoid losing their progress if their app were deleted or they changed devices. Many apps use a social networking site login, such as Facebook, for easy account creation, but this can trigger privacy-related anxieties in users [255], so it may be best to avoid this when creating an MHapp that collects potentially sensitive data. Other ethical and privacy concerns arise when recording app data to a server [256], so the integrity of storage sites should be thoroughly evaluated, especially with regard to obtaining users' informed permission to record and access their personal data [116].

Reminders to Engage

Some of the most successful guided self-help Web-based treatments for anxiety and depression use email or telephone reminders to maintain user engagement [10]. Reminders can increase adherence and reduce dropout from self-help CBT interventions [24]. Push notifications are alerts that can be sent via the Internet to apps on mobile devices [257]. MHapps that use push notifications are similar to Internet interventions that use short message service (SMS) reminders in that they prompt users throughout their day to engage in the intervention. Previous studies have demonstrated that interventions with SMS reminders can be effective for diabetes management [258], smoking cessation [259], and weight loss [260].

Although external triggers can be useful to remind users of an app, too many annoying or interruptive reminders can lead to disengagement. SDT stipulates that anything that quashes a sense of autonomy, such as a series of insistent reminders, can reduce intrinsic motivation to engage [71]. Eyal [3] distinguishes internal and external triggers of engagement, extolling the long-term benefits of the former over the latter. External triggers may help to initiate the engagement processes, but internal triggers are more reliable drivers of long-term habits. Eyal cites the example of social image-sharing app Instagram, which uses the internal trigger "I want to share this experience with others." However, if Instagram reminded users every day to post an image, it is likely that using it would soon be perceived as a chore with no intrinsic reward.

Although some reminders can restrict a sense of autonomy, others can encourage it. A recent meta-analysis of 42 studies found that phrases that emphasize an individual's right to refuse, such as "But you are free to accept or refuse," increase the likelihood of people agreeing to requests, with an overall effect size of $r=0.13$ [261]. External reminders should be framed within an SDT context to grant autonomy and respect intrinsic motivators. Chaiken's [262] heuristic-systematic processing theory can further inform the design of reminder communications. Framing reminders to satisfy the commitment and consistency, liking, authority, or scarcity heuristics can aid user engagement [263].

Simple and Intuitive Interface and Interactions

The simplicity of a program's interface and ease of navigation significantly influence user perceptions of quality in Web-based mental health interventions [264,265]. User satisfaction and perceptions of credibility directly influence engagement and therapeutic benefit [208]. Building an enjoyable app with good graphic design and a slick, intuitive, and satisfying interface is necessary for an effective intervention [5,266]. Simplicity also reduces the likelihood of technical difficulties that may dissuade users from engaging [267].

Fogg's behavior model (ie, the model of technology-based behavior change [268] discussed in the "Recommend Activities" section) emphasizes that simplicity reduces demands for initiating behavior outcomes, and increases the likelihood of a behavior occurring. A simpler interface decreases the ability required to engage with the app, and increases the likelihood of successful engagement [3].

No-action default (or “opt out”) options have enormous influence over the use of a product or service [269]. For example, countries that have presumed consent organ donation policies have 25-30% higher donation rates after all other factors that influence rates are accounted for [270]. It has been argued that making organ donation as the no-action default option for Australian citizens could significantly raise donation rates and save many lives [271]. No-action defaults both preserve autonomous decision-making and influence behavior toward goals [272], so MHapps are well positioned to capitalize on these effects to guide users toward beneficial outcomes. App settings should be customizable to allow for autonomous use and tailoring, but come with recommended default options preset. For example, the default option for reminders should be set to “on,” and at a frequency that is not overwhelming for the user (see the “Reminders to Engage and External Triggers” section).

The language used in the delivery of a mental health intervention, particularly a self-help intervention, can also have a major impact on engagement [273]. The language needs to be simple, concrete, confident, and hopeful for users to understand and engage with interventions. Language should also be inclusive of all sexual orientations and lifestyles [274] and be nonclinical, nonpsychopathological, and nondiagnostic to avoid stigma [57,99]. The literacy of intended users must be considered, just as it is for different newspapers [275]. The length of sentences and paragraphs is not only limited by the constraints of a smartphone screen, but also by the working memory of users. Making information meaningful to users can help its consolidation into memorable chunks, easing the demands on memory [276]. Using illustrations, such as faces, for emotions, can also improve the efficiency of understanding [277]. Decreasing load on memory is all the more important for users suffering from symptoms of depression or anxiety, which can restrict working memory function [278].

Although keeping information simple is necessary for initial understanding, enabling exploration of more in-depth information is important to satisfy some users [202]. Building a feature such as a “learn more” or “help” button into an MHapp can enable users to access more information about certain content or features. Furthermore, navigation around an app can be key to maintaining a sense of autonomy and competency. An app that limits a user’s freedom of navigation may be frustrating and not intrinsically rewarding to use. Features such as an ever-present button that navigates the user back to the home screen can remedy this.

Links to Crisis Support Services

Crisis support services are valuable resources for vulnerable individuals undergoing acute psychological distress [279]. Suicidal callers to crisis hotlines experience significant decreases in suicidality, hopelessness, and psychological pain [280]. Developing and utilizing these services has consequently become a key area for promoting public mental health care [281,282]. However, barriers to help seeking can prevent troubled individuals from utilizing these supports.

Building links to crisis support services into MHapps may overcome some of these barriers. Furthermore, an MHapp that

records a user’s mood (see the “Reporting of Thoughts, Feelings, or Behaviors” section) may be able to unobtrusively detect indicators of depressive episodes and prompt contact of the relevant supports. Negative attitudes toward seeking help can be a major barrier to engagement [77]. However, if an app presents support options in an attractive and easy-to-access way, accessing those supports is more likely to be perceived as acceptable and appealing [269]. Lack of awareness of service availability, or the nature of support offered, can also prevent help seeking [203], as can the belief that support is rarely available and will not help anyway [283]. An MHapp that enables access to information about how support services operate and how they can help could reduce these barriers. According to the Fogg’s behavior model [268], accessing crisis support services through technology should be made straightforward to reduce barriers to action and increase the likelihood of service contact being made.

Importantly, Internet supports are preferred to telephone helplines in some populations, including young people [284]. Organizations such as Lifeline have an online crisis support chat facility [285], so where these are available, links should be offered on mobile devices. There is also growing support for the effectiveness of online chat options [286], which may be better suited to how some individuals who use digital devices tend to communicate [287].

Experimental Trials to Establish Efficacy

A major shortcoming of currently available MHapps is the lack of RCT evidence for their efficacy. Although many apps use evidence-based frameworks, like CBT, only a handful have been experimentally trialed. Donker et al [8] conducted a systematic review of the literature, searching for evidence of effective MHapps; only 8 papers were identified as providing scientific support for MHapps, and in these papers, only 5 separate MHapps were described. Just 1 of these 5 was a self-contained app, with the other 4 requiring input from a mental health professional. Frustratingly for those who might benefit from these apps, none of them is currently available on the iOS or Android app stores.

This lack of controlled outcome research in the field is unexpected, given the ease of collecting data using mobile and Internet technologies [90]. Although validation of other psychological interventions requires time-consuming assessments, MHapps are capable of reliably, quickly, and automatically collecting a myriad of self-report and behavioral usage data [288].

When starting with a product vision for an app, target outcomes should be well defined in concrete, objective, and measurable terms [5]. These overarching goals guide development and enable a definition of success for the app. There are three main types of data that can be used to assess the target outcomes of MHapps: (1) assessment tools administered before and after a set period of app use, (2) EMA techniques to administer multiple brief self-report questionnaires throughout app use, and (3) app usage data. A thorough assessment of an MHapp should attempt to use all three data sources.

Assessment Tools Administered Before and After a Set Period of App Use

Wendel [5] stresses that, where possible, target outcomes for apps should avoid user “states of mind,” such as emotions and other internal, psychological variables, as these are problematic to measure. However, the main goal of MHapps is to alter the user’s state of mind. This means the tools used to measure the MHapp’s target outcomes should be selected carefully, keeping in mind the ease of administration via a smartphone, the ease of integration into an MHapp’s interface, the licensing of the assessment tool, and the validity and reliability of the measure.

Outcome measures for MHapps should contain a suitable assessment of emotional well-being and mental health. For example, the 9-item Patient Health Questionnaire (PHQ-9) [289] is a brief, self-administered, valid, and reliable measure with 88% specificity and 88% sensitivity for major depression. It is licensed to be used freely, and existing apps have successfully adapted it for a smartphone interface [290]. The 7-item Generalized Anxiety Disorder scale (GAD-7) [291] is a similar measure for anxiety, and using both the PHQ-9 and GAD-7 together can give a balanced assessment of emotional psychopathology [292]. To assess the languishing-flourishing dimension of mental health, the 14-Likert-item Warwick-Edinburgh Mental Well-Being Scale could be used, as it is a brief, reliable, and valid tool [293].

Secondary to mental health outcome measures are measures of the MHapp’s intervention targets. For example, a self-monitoring MHapp should aim to assess the degree to which insight and ESA are being enhanced by the self-monitoring intervention (see the “Reporting of Thoughts, Feelings, or Behaviors” section). To validate their MHapp, Kauer et al [133] used a short survey, delivered by phone, called the ESA Scale. This tool comprises 33 items, all rated on a scale from 0 (never) to 4 (a lot), and was adapted from the 20-item Self-Reflection and Insight Scale [294], the 10-item Ruminative Response Scale [295], and the 12-item Meta-Evaluation Scale [296]. MHapps that aim to boost CSE (see the “Recommend Activities” section) could use the Coping Self-Efficacy Scale [175], which is a short questionnaire that can be administered via a smartphone. MHapps that utilize elements of psychoeducation may require assessments of MHL (see the “Mental Health Information” section). There is no standardized assessment tool for MHL, but it is often measured using self-report questionnaires and vignettes [204], which can be adapted for smartphone-based assessment. However, vignettes tend to be long and cumbersome forms of assessment, and are not well-suited to the restrictions of smartphone screens and interfaces. A well-validated, standardized, brief assessment tool for MHL would benefit the development of many self-help interventions, including MHapps.

It is recommended that follow-up data are collected at several different time points throughout the MHapp intervention and after its use has been concluded. An RCT on the mindfulness meditation app Headspace [297] found that it led to increases in positive affect and decreases in depression, but had no effects for measures of negative affect, satisfaction with life, or flourishing. This failure to uncover effects may be attributable

to the limited time course of the research, as the intervention only lasted for 10 days and there was only one postintervention measurement [298].

Ecological Momentary Assessment

Using EMA, brief self-report questionnaires can be prompted at various periods throughout a user’s day [143], with the precise time of survey completion accurately recorded. EMA can reduce bias in self-report data [142] and enables study of ecologically valid contexts [141]. As described in the “Reporting of Thoughts, Feelings, or Behaviors” section, EMA can also be a valuable part of interventions.

It is important to adopt an EMA design that is most appropriate for the types of data being collected and for the MHapp being trialed. EMA questionnaires should be brief enough for smartphone users to feel capable of completing them without too much interruption to their day. The aim of EMA is to obtain an ecologically valid measurement, so limiting disruption maximizes validity [217]. The design of EMAs can be event-based or time-based, depending on whether responses are collected following a specific event, such as an app-based interaction, or triggered at a given time point [141]. The choice in design should also be well thought-out and justified. For example, if a time-based EMA collects measurements at the exact same time every day, it may not accurately capture changes in the user’s state experienced throughout the rest of the day. Event-based EMA should be used in an MHapp that recommends activities (see the “Recommend Activities” section) and requests a user to rate their mood before and after performance of the activity (see the “Reporting of Thoughts, Feelings, or Behaviors” section).

App Usage Data

Ongoing monitoring of client data is valuable to the validation of CBT-based interventions [142], and ongoing data collection should be a seamless and constant background process on smartphone apps. App usage data are often collected continuously by app developers to analyze user behavior and improve app functionality. The range of data capable of being collected in this way is very large, including measurements such as time spent using specific features of an app, number of times the app is used in day, and what times in the day features on the app are being used.

Data collected via EMA and other assessment tools may also provide insight into user variables that affect patterns of app usage. For example, it may be found that a specific feature is used most when users are highly distressed. This is an important information to consider, for both the development of psychological theories and the development of MHapps, as it may be appropriate to display a link to crisis services on the app’s interface when a specific feature is being used.

Program adherence is easily assessed with usage data, and app design can be concurrently altered to increase adherence [24]. Although there is no doubt that these data are already being used by developers to improve individual MHapps, there has seemingly been a lack of academic transparency to validate those MHapps and aid in the development of others.

Strength of Evidence for Recommendations

Each recommendation explored in this review is supported by a different rank of evidence. [Table 2](#) summarizes the 16 recommendations and ranks each according to evidence strength. The strongest level listed includes recommendations that are demonstrably effective, as shown by the numerous meta-analyses and RCTs of interventions previously cited in this review. However, more research in the form of RCTs is needed for such MHapps. The next rank of evidence pertains to recommendations that are probably effective according to available evidence but still require more research in the MHapp field. The rank under this includes recommendations that appear to be promising according to the evidence, but, again, must be researched in more depth to validate their stated principles in self-help interventions, including MHapps.

Discussion

MHapps offer exciting new opportunities to improve and manage the mental health of smartphone users. This review has generated 16 recommendations to be considered in the development of future MHapps. In summary, MHapps should aim to prevent emotional mental health problems by employing a wide array of CBT-based techniques that are tailored to an individual's needs and delivered via a simple, interactive design. Structures of gamification and habit formation should be used to maximize engagement in the app's interventions. The app itself should be experimentally validated, and user data should be utilized for its ongoing improvement.

It is highly recommended that MHapp developers familiarize themselves with the literature, both in the field of self-help CBT and in the field of app-based behavior change, before embarking on any MHapp projects. Respecting the value of both of these research fields should enable the reliable, engaging delivery of an evidence-based mental health intervention. This review may help developers get started with this familiarization process, but further reading is strongly advised. Furthermore, a multidisciplinary team consisting of experts in app usability engineering, programming, data collection and analysis, industry and health care sector applications, clinical psychological interventions, and any other relevant fields is strongly advisable.

The Mobile Application Rating Scale (MARS) is a recently developed measure enabling objective, multidimensional rating and comparison of mobile health apps [299]. Tools such as this will be essential for the future of MHapp development, and will enable clinicians and consumers to make more informed decisions about their choice of smartphone-based support.

There is a risk of researchers developing MHapps primarily for research needs rather than to meet the needs of end users. When an MHapp is released to the public, it is a self-contained product and must operate efficiently in the user's daily routine. For MHapp research to be ecologically valid, MHapp developers must create self-contained apps that still function outside of a research setting. Several RCTs have been conducted on MHapps that are not publically available [52]. This prevents researchers and intervention developers from analyzing and exploring existing evidence-based MHapps. It also blocks help seekers from finding evidence-based MHapps and benefiting from effective support.

Table 2. Recommendations for future mental health apps.

Evidence	Recommendation	Details
Demonstrably effective, but more research needed in MHapp field	1. Cognitive behavioral therapy based	Start with an evidence-based framework to maximize effectiveness
	2. Address both anxiety and low mood	Increases accessibility and addresses comorbidity between anxiety and depression. Also compatible with transdiagnostic theories of anxiety and depression
Probably effective, but more research needed in MHapp field	3. Designed for use by nonclinical populations	Avoiding diagnostic labels reduces stigma, increases accessibility, and enables preventative use
	4. Automated tailoring	Tailored interventions are more efficacious than is rigid self-help
	5. Reporting of thoughts, feelings, or behaviors	Self-monitoring and self-reflection to promote psychological growth and enable progress evaluation
	6. Recommend activities	Behavioral activation to boost self-efficacy and repertoire of coping skills
	7. Mental health information	Develop mental health literacy
Supported by theory and indirect evidence but focused research needed	8. Real-time engagement	Allows users to use in moments in which they are experiencing distress for optimum benefits of coping behaviors and relaxation techniques
	9. Activities explicitly linked to specific reported mood problems	Enhances understanding of cause-and-effect relationship between actions and emotions
	10. Encourage nontechnology-based activities	Helps to avoid potential problems with attention, increase opportunities for mindfulness, and limit time spent on devices
	11. Gamification and intrinsic motivation to engage	Encourage use of the app via rewards and internal triggers, and positive reinforcement and behavioral conditioning. Also links with flourishing
	12. Log of past app use	Encourage use of the app through personal investment. Internal triggers for repeated engagement
	13. Reminders to engage	External triggers for engagement
	14. Simple and intuitive interface and interactions	Reduce confusion and disengagement in users
	15. Links to crisis support services	Helps users who are in crisis to seek help
Necessary for validation of principles	16. Experimental trials to establish efficacy	It is important to establish the app's own efficacy before recommending it as an effective intervention

A behavioral plan is a “detailed ‘story’ of how the user progresses from being a neophyte to accomplishing the action while using the product” [5]. Any app should be designed from the foundation of a comprehensive behavioral plan [5]. This means that it may not be possible to incorporate all 16 recommendations listed herein into a single MHapp. To guide development of behavioral plans and interactive frameworks, it would be helpful to focus on specific foundations. Three of the recommendations listed can be used as foundations for intervention development, as they aim to target specific psychological constructs, such as ESA, MHL, and CSE. The “Reporting of Thoughts, Feelings, or Behaviors” section details mood reporting, self-monitoring, and improving ESA. MHapps that use this as a foundation could be referred to as “reflection-focused.” The “Recommend Activities” section relates to engaging users in activities to improve their CSE. MHapps that use this as a foundation could be referred to as “goal-focused.” The “Mental Health Information” section relates to mental health information, psychoeducation, and improving MHL. MHapps that use this as a foundation could be referred to as “education-focused.” More research is needed to investigate the different effects of reflection-focused, education-focused, and goal-focused MHapp designs on mental

health, and whether different users obtain different benefits from each design.

Each recommendation explored in this review could be the target of an RCT. RCTs that compare identical MHapps with or without specific features could provide evidence for or against these features in future MHapps. However, it is important to acknowledge the influence of the overall behavioral plan on the MHapp's effectiveness. Some features may work better in one MHapp's behavioral plan than in another's, and simply including more recommended features may not improve the overall intervention. Future MHapp and eHealth RCTs should aim to validate underlying theories and principles for intervention improvement [21].

The World Health Organization [300] predicts that depression will become the global leading cause of disease burden by 2030. There is an enormous worldwide need for better preventative mental health, and MHapps that target emotional well-being are set to provide exciting new opportunities in the field. The evidence-based recommendations discussed herein are important for all MHapp developers to acknowledge if better interventions are to be developed to meet this rising demand in the future.

Conflicts of Interest

None declared.

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Abbreviations

ACT: acceptance and commitment therapy
ARG: alternate reality game
BA: behavioral activation
CBT: cognitive behavioral therapy
CCBT: computerized cognitive behavioral therapy
CE: collaborative empiricism
CSE: coping self-efficacy
DBT: dialectical behavior therapy
EMA: ecological momentary assessment
ESA: emotional self-awareness
ESM: experience sampling method
GAD-7: 7-item Generalized Anxiety Disorder Scale
MARS: Mobile App Rating Scale
MHapp: mental health app
MHL: mental health literacy
PDA: personal digital assistant
PHQ-9: 9-item Patient Health Questionnaire
RCT: randomized controlled trial
SDT: self-determination theory
TCBT: transdiagnostic cognitive behavioral therapy
UP: unified protocol

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Original Paper

Reducing Depression Through an Online Intervention: Benefits From a User Perspective

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Abstract

Background: Internet interventions are increasingly being recognized as effective in the treatment and prevention of mental health conditions; however, the usefulness of such programs from the perspective of the participants is often not reported.

Objective: This study explores the experiences of participants of a 12-week randomized controlled trial of an automated self-help training program (e-couch), with and without an Internet support group, targeting depression.

Methods: The study comprised a community sample of 298 participants who completed an online survey both prior to and on completion of an intervention for preventing or reducing depressive symptoms.

Results: Overall, participants reported a high level of confidence in the ability of an online intervention to improve a person's understanding of depression. However, confidence that a website could help people learn skills for preventing depression was lower. Benefits reported by participants engaged in the intervention included increased knowledge regarding depression and its treatment, reduced depressive symptoms, increased work productivity, and improved ability to cope with everyday stress. A minority of participants reported concerns or problems resulting from participation in the interventions.

Conclusions: The findings provide consumer support for the effectiveness of this online intervention.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 65657330; <http://www.isrctn.com/ISRCTN65657330> (Archived by WebCite at <http://www.webcitation.org/6cwH8xwF0>)

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KEYWORDS

Internet interventions; depression

Introduction

Growing numbers of people are turning to the Internet as a preferred method for obtaining health-related information, or as an option for accessing therapeutic interventions [1]. In the area of mental health, Internet-based interventions for depression have undergone significant development [2]. Importantly, as use and service options have expanded, research has demonstrated the efficacy of online programs in reducing depressive symptoms [3-10], improving depression literacy [11,12], and decreasing stigma [11-13]. However, while

increased interest in online participation appears indicative of the acceptance of Internet-based interventions, the benefits of these programs from the perspective of the participants is often not reported.

Consumer satisfaction is integral in assessing the quality of any health service delivery. While the effectiveness of interventions in reducing symptoms is critical, the experience and satisfaction of participants has important implications for treatment outcomes, continuation of treatment (adherence), and re-connection with a service at a latter point of need [14,15]. Consumer satisfaction reports are increasingly being used to

assess the quality of mental health services [14,16-19]. Some research has also investigated the relationship between consumer satisfaction and objective mental health outcome measures [20]. However, to date, consumer feedback has primarily been utilized in the development and evaluation of community-based mental health services [21].

Some researchers have investigated consumer satisfaction with e-mental health programs. Proudfoot and colleagues [22] investigated community attitudes and the acceptability of mobile phones for self-monitoring of symptom severity and obtaining self-help for depression, anxiety, and stress, and obtained positive feedback. High levels of general satisfaction with Internet-based treatment has also been reported in the context of randomized controlled trials (RCTs) conducted for various mental health conditions [23-25]. One study [25] investigating an Internet based intervention for depression found that, on average, participants reported feeling very confident that the "treatment would be successful at teaching them techniques for managing their symptoms"; and a high level of confidence in "recommending the treatment to a friend with depression" (p21). However, largely this is an area within e-mental health services research that has not undergone detailed investigation.

Evaluations of the WellBeing trial [26,27] found that exposure to a 12-week automated training program comprising psycho-education and cognitive behavioral and interpersonal therapy (e-couch) used both alone and in combination with an Internet support group (ISG) produced significant reductions in depressive symptoms at 6- and 12-month follow-ups [27]. In addition, the automated training program was associated with immediate improvements in self-esteem and empowerment relative to control participants, and when combined with the ISG, 6-month improvements in perceived quality of life [28]. However, the subjective experience of the intervention participants in the WellBeing trial was not reported.

The aims of the present study are to (1) explore the level of consumer confidence in online e-mental health programs both prior to and following participation in the trial; (2) investigate the benefits and changes in behavior reported by participants following participation in the trial; and (3) identify any problems encountered by participants. Further, given that publicly available online mental health (depression) interventions are most likely to be accessed by individuals self-identifying as being depressed, comparisons were made between those reporting that they currently suffer from depression (at baseline) with those that did not.

Methods

This study was approved by The Australian National University Human Research Ethics Committee (Protocol 2007/2259) and the WellBeing trial described in this paper was registered with the Controlled Clinical Trials registry (ISRCTN65657330). The current paper contains only a brief description of the methodology specific to the present study as the complete WellBeing trial protocol has been published previously [26,27].

Participants

The study comprised 298 adults aged 18 to 65 years recruited to the WellBeing trial between August 2008 and May 2009. Participants were recruited through a screening survey posted to 70,000 adults randomly selected from the electoral rolls of 8 Australian electoral divisions (4 rural and 4 metropolitan). Participants were informed that the trial was designed to investigate "the usefulness of self-help Internet programs for improving emotional well-being and preventing or reducing the symptoms of depression" [26]. To be eligible for the trial participants required a Kessler Psychological Distress (K10) score greater than 22, and access to the Internet. Respondents were excluded if they were currently (1) receiving treatment from a mental health professional or participating in a mutual support group; (2) participating in another research project at the lead investigator's (KG) research center; and (3) reported current or past experience with or diagnosis of psychosis, schizophrenia, or bipolar disorder.

Procedure

The study employed a longitudinal RCT design. Data pertaining to participant confidence in online interventions and satisfaction were collected via self-report questionnaires administered at baseline (one week prior to commencement of the intervention), and at the conclusion of the 12-week intervention period.

Interventions

Participants were randomly allocated to receive one of four conditions: an ISG, which utilized a moderated bulletin board format to facilitate discussions between participants on topics primarily related to depression; a depression Internet training program (e-couch) comprising a depression literacy component and online versions of cognitive behavior therapy, interpersonal therapy, applied relaxation, and physical activity programs; a combination of the two (e-couch and ISG); or an attention control website (HealthWatch). HealthWatch comprised 12 online modules, each containing the following components: (1) a series of questions participants were asked to consider on topics potentially related to depression and well-being (eg, nutrition), and (2) online health information about a topic that may be related to well-being but did not address depression specifically (eg, environmental health). The content of each intervention has been described in further detail elsewhere [26,27].

Randomization was conducted by the trial statistician using a stratified block design procedure, with a fixed block size of 4. Stratification variables were level of psychological distress, gender, age, and location of residence [27]. The number of participants completing the baseline questionnaire and commencing the intervention following randomization was as follows: ISG (n=77), e-couch (n=74), e-couch and ISG (n=73), and HealthWatch (n=74).

Measures

This study explores participant confidence in the effectiveness of online interventions (collected prior to and after the intervention), and problems encountered, self-reported benefits, and behavior change following the intervention.

Intervention Benefits

Immediately following the intervention trial period, participants were asked to respond to 14 items reporting the extent to which the website helped them in areas such as “being productive at work” and “reducing the emotional pain they were experiencing”; and the extent to which the website helped them to “discuss subjects that I felt unable to discuss before”, “feel encouraged and supported emotionally”, “feel less isolated and lonely”, “feel proud of myself for helping others”, “learn more about depression and its treatment”, or “seek professional help for my depression”. Items were developed for the purpose of the study based on items developed in a UK study of depression ISG users [29], and the Consumer Reports Effectiveness Scale (CRES-4) [17,30]. Participants responded to each statement on a 5-point scale from 1 (*strongly agree/made things a lot better*) to 5 (*strongly disagree/made things a lot worse*). The scale was then dichotomized as 0 (*neither/no difference, disagree/made things somewhat worse, strongly disagree/made things a lot worse*), 1 (*agree/made things somewhat better, strongly agree/made things a lot better*) to assess the proportion of participants reporting benefit in each area.

User Confidence

At each assessment point participants rated their confidence that a website could both “help people understand depression better” and “help people learn skills for preventing depression”. Participants responded 0 (No) or 1 (Yes) to each statement.

Behavior Change

Participant self-reported behavior change was assessed across the sample using 4 items. Participants responded 0 (No) or 1 (Yes) to indicate if they had “given advice about depression to someone else”, “sought help from a health professional”, “sought more information”, or “tried a self-help treatment”.

Problems Encountered

Following the intervention trial period, participants were asked to indicate if they had encountered any problems as a result of using the website or participating in the trial. Responses were recorded as 0 (No) or 1 (Yes). Items were developed for the purpose of the study. The survey was tailored to the types of problems that may have been encountered in each trial arm. Items in the survey of participants exposed to the HealthWatch (control) or e-couch (including combined condition) websites were “Feeling bored”, “Feeling frustrated”, “Feeling more anxious”, and “Finding the program too impersonal”. Items received by ISG participants (including combined condition) were “Feeling annoyed or upset by the comments made by other members on the board”, “Feeling frustrated that I could not meet other members of the board in person”, “Feeling upset that I couldn't help other board members more”, and “Feeling very anxious about other members on the board”.

Statistical Analysis

All primary comparisons were conducted using chi-square analyses. Post-hoc comparisons identifying significant differences between the four intervention groups were based on the standardized residual for each cell. Values greater than ± 1.96 indicate a difference at a P value of .05, and values greater than ± 2.58 indicate a difference at a P value of .01.

Results

The numbers of participants in each condition at each wave of data collection (baseline and post-test) are shown in [Table 1](#). At post-test, drop-out was significantly lower in the HealthWatch control condition compared to the other conditions. Few significant differences were found between completers and non-completers on measures of depression or demographic characteristics [27].

Table 1. Number of participants in each condition at baseline and post-test.

	Total sample, N	Intervention condition, n (%)			
		HealthWatch	e-couch	ISG	e-couch and ISG
Baseline	298	74 (24.8)	74 (24.8)	77 (25.8)	73 (24.5)
Post	231	71 (30.7)	59 (25.5)	53 (22.9)	48 (20.8)

Confidence in Online Interventions

Across the sample it appeared that confidence in a website as a tool to improve depression literacy was high ([Table 2](#)). At baseline (prior to interacting with the website), 83.6% (249/298)

of participants were confident that a website could help people understand depression better. Confidence in the ability of a website to help people learn skills for preventing depression was less certain across the sample at baseline, with only 48.3% (144/298) of people making the endorsement.

Table 2. Number of people confident that a website could improve depression literacy or be used as a prevention tool.

	Depression literacy ^a		Prevention tool ^b	
	Baseline	Post	Baseline	Post
Total sample, n/N ^c (%)	249/271 (91.9)	195/212 (92.0)	144/235 (61.3)	135/203 (66.5)
Intervention condition, n/N (%)				
HealthWatch	62/71 (87.3)	62/67 (92.5)	38/62 (61.3)	40/64 (62.5)
e-couch	61/67 (91.0)	51/56 (91.1)	40/63 (63.5)	37/54 (68.5)
ISG	68/70 (97.1)	42/48 (87.5)	37/61 (60.7)	27/46 (58.7)
ISG and e-couch	58/63 (92.1)	40/41 (97.6)	29/49 (59.2)	31/39 (79.5)
<i>P</i> ^d	.200	.972	.372	.190
Current depression, n/N (%)				
Yes	164/184 (89.1)	131/141 (92.9)	91/160 (56.9)	87/134 (64.9)
No	82/84 (97.6)	62/69 (89.9)	52/72 (72.2)	47/68 (69.1)
<i>P</i> ^d	.019	.446	.026	.551

^aConfident that a website could help people understand depression better.

^bConfident that a website could help people learn skills for preventing depression.

^cN values vary due to missing data.

^dChi-square significance level for the test of difference between groups.

Following the intervention period this indicator of confidence remained relatively stable with no significant change in the proportion of respondents making these endorsements. No significant differences were found based on intervention group. There were significant differences in the responses of participants who did and did not report depression at baseline. At baseline, participants reporting current depression were significantly less likely than those not reporting depression to be confident that a website could either improve people's understanding of depression ($P=.019$) or teach people skills for preventing it ($P=.026$). However, this significant difference was not maintained following the intervention. Following the intervention participants were asked to report on the usefulness of the website. Of the 226 respondents to the question, 76.5% (173/226) of people indicated they found the website useful or very useful. There were no significant differences between any

of the conditions, or on the basis of self-reported depression at baseline (Table 2).

User-Reported Benefits

The most frequently endorsed benefit of participating in the trial by participants across the sample was one of increasing depression literacy (Table 3). Across the total sample, 76.2% (170/223) of respondents indicated that the website helped them to "learn more about depression and its treatment". In particular, this benefit was strongly endorsed by participants in the e-couch and combined e-couch and ISG condition; participants in the ISG condition were significantly less likely to report that the website helped them to learn more about depression and its treatment when compared to the e-couch and combined ISG in combination with e-couch conditions ($P<.05$). No significant differences were found between those participants self-reporting current depression at baseline and those who did not.

Table 3. Reported benefits of engaging in the online interventions, by intervention condition.

	Total sample, n/N ^a (%) ^b	Intervention condition				<i>P</i> ^c
		HealthWatch, n/N (%) ^b	e-couch, n/N (%) ^b	ISG, n/N (%) ^b	e-couch and ISG, n/N (%) ^b	
The website helped me to...						
Discuss subjects that I felt unable to discuss before	94/220 (42.7)	22/65 (33.8)	25/58 (43.1)	26/50 (52.0)	21/47 (44.7)	.269
Feel encouraged and supported emotionally	104/218 (47.7)	23/64 (35.9)	29/57 (50.9)	28/51 (54.9)	24/46 (52.2)	.157
Feel less isolated and lonely	93/219 (42.5)	18/65 (27.7)	26/57 (45.6)	25/51 (49.0)	24/46 (52.2)	.033
Feel proud of myself for helping others	74/209 (37.1)	23/62 (37.1)	14/53 (26.4)	21/49 (42.9)	16/45 (35.6)	.370
Learn more about depression and its treatment	170/223 (76.2)	48/69 (69.6)	52/58 (89.7)	23/49 (46.9)	47/47 (100.0)	<.001
Seek professional help for my depression	35/204 (17.2)	8/62 (12.9)	10/53 (18.9)	6/46 (13.0)	11/43 (25.6)	.309
How much do you feel the website helped you in						
Being productive at work	62/209 (29.7)	14/63 (22.2)	22/55 (40.0)	8/48 (16.7)	18/43 (41.9)	.010
Coping with everyday stress	115/218 (52.8)	25/65 (38.5)	38/58 (65.5)	22/50 (44.0)	30/45 (66.7)	.003
Enjoying life more	96/215 (44.7)	23/65 (35.4)	31/57 (54.4)	17/50 (34.0)	35/43 (58.1)	.019
Personal growth and understanding	125/216 (57.9)	32/64 (50.0)	38/57 (66.7)	28/50 (56.0)	27/45 (60.0)	.309
Reducing the emotional pain you were experiencing	92/213 (43.2)	17/64 (26.6)	30/56 (53.6)	21/49 (42.9)	24/44 (54.5)	.007
Reducing the symptoms of your depression	97/214 (45.3)	18/62 (29.0)	34/57 (59.6)	17/52 (32.7)	28/43 (65.1)	<.001
Your ability to relate to others	105/218 (48.2)	22/65 (33.8)	35/58 (60.3)	24/50 (48.0)	24/45 (53.3)	.026
Your self-esteem and confidence	88/217 (40.6)	20/64 (31.3)	29/57 (50.9)	20/51 (39.2)	19/45 (42.2)	.179

^aN values vary due to missing data.

^bPercentage of respondents endorsing the statement as “agree-strongly agree” or “made things a lot or somewhat better”.

^cChi-square test of significance for the difference between groups.

When asked how much they felt that the website had helped them in areas such as coping with stress and reducing symptoms of depression, the benefit endorsed most by participants was that of promoting personal growth and understanding, reported by 57.8% (125/216) of respondents (Table 3). Comparing benefits obtained across the different intervention groups it was found that the e-couch and combined e-couch and ISG condition participants were again significantly more likely to report that

the website helped reduce symptoms of depression and increase productivity at work, the ability to cope with everyday stress, and enjoy life more, compared to the control and ISG alone conditions (significant at $P < .05$). Compared to the control condition, participants in the e-couch and combined condition were more likely to report that the website helped their ability to relate to others, and reduced their emotional pain ($P < .05$). The e-couch participants were also more likely to report that

the website helped with self-esteem and confidence compared to the control group (significant at $P<.05$). Again, no significant differences were found between those participants self-reporting current depression at baseline and those who did not. See [Multimedia Appendix 1](#) for each comparison.

When asked if they had done something different (eg, sought more information or treatment) as a result of the website, approximately 47.8% (109/228) of respondents indicated they had ([Table 4](#)). This was significantly higher amongst participants

in the e-couch and combined e-couch and ISG conditions. Respondents in both conditions were more likely to report have done something different because of the website compared to the control and ISG conditions ($P<.01$). Specifically, when asked what they had done, participants in both the e-couch and the combined condition were more likely to have tried a self-help treatment compared to control and ISG conditions (significant at $P<.01$), as was the combined condition (significant at $P<.05$).

Table 4. Reported help-seeking actions following participation, by intervention condition, in response to the question “Have you done something different because of the website?”

	Total sample, n/N ^a (%) ^b	Intervention conditions				<i>P</i> ^c
		HealthWatch, n/N (%)	e-couch, n/N (%)	ISG, n/N (%)	e-couch and ISG, n/N (%)	
Yes (total)	109/228 (47.8)	17/70 (24.3)	43/59 (72.9)	13/51 (25.5)	36/48 (75.0)	<.001
Yes, given advice about depression to someone else	28/228 (9.4)	4/71 (5.6)	10/58 (17.2)	5/52 (9.6)	9/47 (19.1)	.084
Yes, sought help from a health professional	16/228 (5.4)	2/71 (2.8)	5/58 (8.6)	2/52 (3.8)	7/47 (14.9)	.060
Yes, sought more information	33/228 (11.1)	6/71 (8.5)	7/58 (12.1)	8/52 (15.4)	12/47 (25.5)	.071
Yes, tried a self-help treatment	66/228 (22.1)	6/71 (8.5)	31/58 (53.4)	6/52 (11.5)	23/47 (48.9)	<.001

^aN values vary due to missing data.

^bPercentage of respondents endorsing the statement.

^cChi-square test of significance for the difference between groups.

Overall, those reporting depression at baseline were not more likely than their counterparts not reporting depression to have done something different because of participation in the program or website. However, when asked about what they had done, participants self-reporting current depression at baseline who had taken action were significantly more likely to have sought help from a professional ($P=.022$), and were more likely to have sought more information ($P=.055$). For tables representing each comparison, see [Multimedia Appendices 1-3](#).

User Problems

The investigation of concerns or problems encountered by participants indicated few stressors resulted from participation in the interventions ([Table 5](#)). When asked about problems

resulting from the use of the e-couch or control program, 27.6% (45/162) of respondents overall reported finding the program too impersonal. While no significant difference was found between conditions, the highest endorsement figure was for the HealthWatch condition which used impersonal content, followed by e-couch and the conditions involving an ISG. Problems of “Feeling frustrated and bored” were endorsed by less than 20% of the sample; 11% (18/165) of the participants reported feeling anxious as a result of using a program. Examining differences between conditions, respondents in the combined condition were more likely to report feeling more anxious or feeling frustrated compared to the control condition (significant at $P<.05$).

Table 5. Problems reported by trial participants by intervention condition.

	Total sample, n/N ^a (%) ^b	Intervention condition				<i>P</i> ^c
		HealthWatch, n/N (%) ^b	e-couch, n/N (%) ^b	ISG, n/N (%) ^b	e-couch + ISG, n/N (%) ^b	
Problems reported with the e-couch or HealthWatch program?						
Feeling bored	29/165 (17.6)	9/67 (13.4)	12/56 (21.4)	N/A	8/42 (19)	.489
Feeling frustrated	32/166 (19.3)	7/68 (10.3)	11/56 (19.6)	N/A	14/42 (33.3)	.012
Feeling more anxious	18/165 (10.8)	3/66 (4.5)	5/56 (8.9)	N/A	10/43 (23.3)	.008
Finding the program too impersonal	45/162 (27.6)	23/64 (35.9)	15/55 (27.3)	N/A	7/43 (16.3)	.084
Problems reported with the WellBeing Board?						
Feeling annoyed or upset by the comments made by other members on the board	8/94 (8.4)	N/A	N/A	5/51 (9.8)	3/43 (7.0)	.625
Feeling frustrated that I could not meet other members of the board in person	16/92 (17.0)	N/A	N/A	11/49 (22.4)	5/43 (11.6)	.172
Feeling upset that I couldn't help other board members more	27/91 (29.0)	N/A	N/A	14/49 (28.6)	13/42 (31.0)	.804
Feeling very anxious about other members on the board	14/93 (14.7)	N/A	N/A	8/50 (16)	6/43 (14)	.783

^aN values vary due to missing data.

^bPercentage of respondents endorsing the statement is indicated.

^cChi-square test of significance for the difference between groups.

When asked about problems resulting from participation in the ISG, 29% (27/91) of respondents overall reported feeling upset that they could not help the other members of the ISG more, and 17% (16/92) reported frustration that they could not meet the other members of the ISG in person (anonymity was a rule governing participation in the ISG).

No significant differences in concerns or problems encountered were found between those participants self-reporting current depression at baseline and those who did not (see [Multimedia Appendices 1-3](#) for tables presenting each comparison). Few participants reported being upset or annoyed by the comments of others in the ISG.

Discussion

To our knowledge, this is the most comprehensive quantitative investigation of consumer perspectives on Internet-based

depression interventions. Examining confidence and satisfaction with the online services, the benefits and changes in behavior reported by participants following participation in the trial, and problems encountered by participants, the study provides evidence to support the benefits of online psycho-education and cognitive behavior therapy programs from a consumer perspective. Overall, participants reported a high level of confidence in the ability of the online interventions to improve people's understanding of depression, and following participation in the program a clear majority reported the interventions were useful. Participants engaged in the e-couch intervention indicated that the website helped them to learn more about depression and its treatment and helped reduce symptoms of depression, increase productivity at work, improve their ability to cope with everyday stress, and enjoy life, compared to the control and ISG conditions. A minority of

participants reported concerns or problems resulting from participation in the interventions.

Confidence in Online Interventions

The successful development and implementation of online interventions for mental health conditions, such as depression, depend on consumers' confidence in the program and willingness to engage in this alternative treatment. As such, the present study first examined participant confidence that a website could help people understand and learn skills for preventing depression. Results found that overall confidence in the ability of a website to increase understanding of depression was high; however, only 61.3% (144/235) of participants at baseline reported confidence in a website (online intervention) as a tool to help people learn skills for preventing depression. The high level of confidence in the ability of a website to increase knowledge or literacy, particularly at baseline, is perhaps unsurprising given that the Internet is largely an information resource and the participants of this study had signed up for an online intervention trial. However, the comparatively lower confidence in websites as prevention strategies or tools is of importance since such perceptions may serve as a barrier to the use of the Internet for prevention programs for depression. Moreover, participants reporting current depression were significantly less confident in the ability of a website to either improve people's understanding of depression or teach people skills for preventing it, compared to those not reporting depression. Despite this scepticism, the willingness of participants to participate in the study (promoted as a trial designed to improve well-being) and to try new interventions is positive. Importantly, the differences (albeit small effects) in confidence that a website could help people understand depression or learn skills for preventing depression identified at baseline between participants self-reporting depression and those that did not, were not found following the intervention. While no significant increase was found across the sample in overall confidence in the ability of an online intervention, the results reflect small increases in confidence after having completed the intervention amongst those participants reporting current depression at baseline. Expectations are likely to play a significant role in whether a consumer seeks help from an online program. Accordingly, the continued monitoring of the acceptability and perception of e-mental health initiatives and programs should be central to the continued expansion and implementation of e-mental health services. This monitoring also should include items which determine consumer perspectives on the effectiveness of online programs for treating depression as well as preventing it. It is possible that perceived treatment effectiveness would be higher than perceived preventive effectiveness among consumers. However, this requires further consideration.

Reported Benefits of Participation

Participants reported benefits and behavior changes as a result of their participation in the trial. An increase in depression literacy was reported by over half of participants, with this benefit most strongly endorsed by those engaged with e-couch (either alone or in combination with the ISG). This is consistent with the fact that e-couch incorporates a specific depression

literacy and educational component and might therefore reasonably be expected to deliver greater improvements in literacy than either an ISG or the control condition. One question of interest is whether self-reported improvements in depression literacy should be greater among the ISG participants than the control group given that depression ISGs are often used as a means of communicating information between members [31]. Here they were not. In fact, a surprising large percentage of the HealthWatch control participants perceived an improvement in their knowledge about depression and treatments after completing the condition. This may be explained by the fact that in the quiz sections of the HealthWatch condition participants were asked to think about the role of different lifestyle issues in depression (eg, humor in depression). Participants may have interpreted this as information about depression and its treatment. Further, the ISG used was an experimental group that was established for the purpose of the research trial. Research is required to investigate the perceived benefits of well-established Internet groups with large numbers of participants including those with strong depression literacy.

Participants allocated to e-couch (more than other intervention groups) reported the website as helping to reduce symptoms of depression, increase productivity at work, improve ability to cope with everyday stress and enjoy life more. Further, they reported an improved ability to relate to others and reduced emotional pain compared to control participants. These findings provide corroboration that e-couch is a helpful online intervention for depression. Specifically, these reports complement the initial evaluation of the WellBeing trial that found a significant objective reduction in depressive symptoms at 6 and 12 months following the combined e-couch and ISG intervention [27]. Moreover, it provides support that there are additional benefits from participating in such an automated training program [28]. The lack of significant difference in findings between participants self-identifying as currently depressed versus those that did not is important. It suggests that these benefits may be conferred despite a lack of individual awareness and self-identification of depression. Finally, while it may be anticipated that participation in an ISG should offer stronger perceived benefits for loneliness and isolation, and improved ability to relate to others and cope with everyday stress this was not evidenced in the present study. However, further research examining established ISGs is needed to provide a more ecologically valid consumer evaluation of the benefits.

Perceived Difficulties

Difficulties or problems were reported by some participants. The primary concern of those participating in the automated training program (e-couch) was that it was too impersonal. Although this represented a minority of participants (27.3%, 45/162) and the intervention aims to incorporate engaging graphical and written content, the findings suggests the need to focus on innovative strategies to increase the personalization of automated online interventions. Participants engaged with the ISG reported that they were upset and anxious that they could not help other members more. This may stem in part from rules of the board which required anonymity and are not a characteristic of all support groups. However, it may also be an intrinsic aspect of online support groups where participants lack

face-to-face contact, or the asynchronous nature of the bulletin board format. Further, the concerns about not being able to assist more may arise regardless of the communication format (face-to-face or online). A peer supporter may not have the resources to solve all the problems of their peer with depression; this may be an inherent disadvantage of participation in ISGs for some potential participants.

Limitations and Conclusions

Complementary to other more objective outcome evaluations [8-10,27], this study reports the experience and outcomes of this type of online intervention from the perspective of the participants. However, the findings must be considered in the context of several limitations. The analyses did not include participants who failed to provide follow-up data. They may have been less satisfied and less positive than those who were retained in the trial.

In addition, items used to assess the problems encountered and user confidence was adapted for the purpose of the study and

as such has not been externally validated. While responses were accepted based on how the participant interpreted the meaning of the items, it is possible that individuals may differ in their understanding of terms such as prevention. Moreover, while tailoring the types of problems participants were asked about to the different interventions reduced the number of perceived irrelevant items being completed by participants, this approach offers limitations in that it makes comparisons between interventions difficult. Further research should consider assessing more generic issues that may be associated with all online interventions.

While further investigation of consumer reports across online mental health interventions is required, the results of the present study offer an important consumer perspective on program effectiveness which complements existing objective and empirical evaluations [27,28]. This enables a more complete understanding of the experiences of participants which may assist in the development and evaluation of future programs.

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Conflicts of Interest

KG is the Director of e-hub at the ANU which developed the e-couch program, is a co-author of e-couch and established BlueBoard, the Internet support group on which the ISG described in this paper was based. However, she derives no personal financial benefit from the operation of e-hub.

Multimedia Appendix 1

Reported benefits of engaging in the online interventions.

[PDF File (Adobe PDF File), 192KB - [mental_v3i1e4_app1.pdf](#)]

Multimedia Appendix 2

Reported help-seeking actions.

[PDF File (Adobe PDF File), 100KB - [mental_v3i1e4_app2.pdf](#)]

Multimedia Appendix 3

Problems encountered by trial participants.

[PDF File (Adobe PDF File), 96KB - [mental_v3i1e4_app3.pdf](#)]

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Abbreviations

ISG: Internet support group

RCT: randomized controlled trial

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Original Paper

Usability Evaluation of a Mobile Monitoring System to Assess Symptoms After a Traumatic Injury: A Mixed-Methods Study

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Abstract

Background: Victims of trauma are at high risk for mental health conditions such as posttraumatic stress disorder and depression. Regular assessment of mental health symptoms in the post-trauma period is necessary to identify those at greatest risk and provide treatment. The multiple demands of the acute post-trauma period present numerous barriers to such assessments. Mobile apps are a method by which to overcome these barriers in order to regularly assess symptoms, identify those at risk, and connect patients to needed services.

Objective: The current study conducted a usability evaluation of a system to monitor mental health symptoms after a trauma. The system was developed to promote ease of use and facilitate quick transmission of data.

Methods: A sample of 21 adults with a history of trauma completed a standardized usability test in a laboratory setting followed by a qualitative interview.

Results: Usability testing indicated that the app was easy to use and that patients were able to answer several questions in less than 1 minute (mean [SD] 29.37 [7.53]; range 15-57). Qualitative analyses suggested that feedback should be included in such an app and recommendations for the type of feedback were offered.

Conclusions: The results of the current study indicate that a mobile app to monitor post-trauma mental health symptoms would be well received by victims. Personalized feedback to the user was identified as critical to promote the usability of the software.

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KEYWORDS

mobile phone; trauma; posttraumatic stress disorder; usability

Introduction

Approximately one in three victims of a traumatic injury will develop a chronic mental health disorder including posttraumatic stress disorder (PTSD) within 1 year after the trauma [1,2]. Victims of trauma often experience a range of symptoms in the acute post-trauma period [3] that may serve as early indicators of long-term chronic outcomes. Given the trauma is a known event, early intervention delivered shortly after exposure can

prevent these outcomes [4]. Indeed, several studies have shown that brief interventions that begin within hours to days after the trauma can mitigate early distress and prevent long-term psychopathology [5,6]. Such early interventions address a major public health concern [7] as PTSD is associated with persistent functional impairment, even in those who have resolved symptoms [8]. Furthermore, relatively few victims of trauma independently seek out mental health treatment in the acute aftermath of a trauma [1,9], which highlights the need for

protocols that begin within an acute care setting when patients can be engaged in care while receiving treatment for their specific event.

There are several barriers, however, in implementation of such early interventions [4]. First, it is unclear who is at risk for PTSD immediately after a trauma, such that repeated assessments are necessary [10,11]. Conducting such assessments with interviewers is costly and burdensome [12]. Second, the clinical presentation of patients varies greatly in the acute post-trauma period and in those with chronic presentations of the disorder [13]. Effective early intervention requires targeting a patient's specific clinical needs [3]. Third, rates of refusal for treatment that begins within hours of the injury and attrition rates for those that engage in such treatment are high [6,14]. Finally, the considerable clinical demands of acute care centers often limit the type of treatment available. Technological solutions, such as mobile apps, have the potential to overcome these barriers, reduce provider burden, and facilitate critical early post-trauma intervention [15]. Indeed, similar monitoring strategies have been accepted for monitoring depression in outpatient clinical settings [16,17], but none has been evaluated for addressing early symptoms that may lead to PTSD in acute care settings.

Mobile apps can advance acute post-trauma care and mental health treatment more broadly [18]. Mobile devices are near ubiquitous among adults in the United States [19]. Approximately half of American adults have downloaded apps to their mobile phones. Health apps can provide education and intervention, facilitate communication between patients and providers, and provide disorder-specific feedback. Communication with patients and providers can occur asynchronously to accommodate patient and provider schedules. Mobile apps are easily disseminated, low cost, and easily integrated with electronic medical records [20]. Finally, mobile apps can be tailored to assess the wide range of possible post-trauma mental health symptoms and those of related conditions. This flexibility is important given that post-trauma symptoms develop at different rates after a trauma [21,22].

In order for mobile app post-trauma care to have the proposed impact on health care, it is necessary to design systems that address the needs of this patient population. Those recently exposed to a trauma have multiple competing concerns in the acute aftermath of an event that place significant demands on their time [3]. Apps created by the Veterans Health Administration and the Department of Defense for chronic PTSD were well received by patients [23,24] and providers [25]. However, these apps may be inappropriate for use in the acute post-trauma period given that symptoms may not have fully developed. Indeed, PTSD symptoms fluctuate in the post-trauma period [21]. Relatedly, the concerns of the patient are likely to vary during the acute period. The best method to ensure that an app addresses the concerns is with a usability evaluation [26]. The belief is that an assessment method should place minimal burden on the patient so as not to interfere with recovery. The mobile app should allow question content to change during the assessment period to capture the course of

symptoms. Including a method to capture the dynamic concerns of the patient so intervention and assessment can be tailored accordingly is necessary. To determine if these features are useful in post-trauma care, a mixed-method usability evaluation is needed. The current study conducted a usability evaluation of a system that includes a mobile app to monitor post-trauma symptoms. The primary aim of the current study was to highlight key usability and design components of this platform that will inform development of systems designed to track patient progress.

Methods

Participants

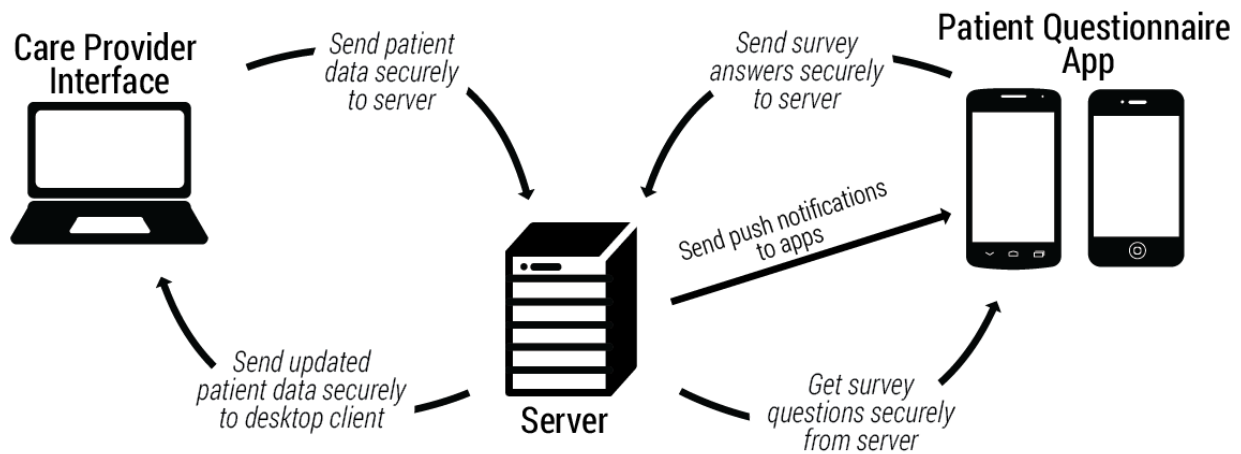
A total of 21 college-aged adults with a history of a trauma exposure that resulted in a hospital visit participated in the study. Participants were 19 years old (mean [SD] 18.8 [0.87]), and the majority were female (16/21, 76%) and White (15/21, 71%). All participants owned a smartphone, primarily iPhones (15/21, 71%). Participants all texted, took pictures, listened to music, downloaded apps, recorded videos, and accessed the Internet on their phones. A majority used their devices to obtain information about physical health (17/21, 81%) and mental health (14/21, 67%). All participants provided verbal consent as the Institutional Review Board did not require written consent. Consent was recorded using a required documentation form.

Development of the Mobile App

A development team with expertise in mobile app development, database creation, acute trauma care, and post-trauma mental health care created a prototype app. Design was guided by the Technology Acceptance Model (TAM) [27], which posits that adoption and continued use of software is a function of perceived usefulness and perceived ease of use. Perceived usefulness is the extent that a technology will increase the likelihood of a given outcome. Applied to the current problem, monitoring may improve the likelihood that an individual receives mental health care after a trauma. Perceived ease of use is the extent that minimal effort is needed to use the technology.

A distributed system comprising several major software components was created (Figure 1). The patient-facing component is a mobile app that administers self-report assessments. The system also includes a database and a Web interface for care providers. The Web interface allows providers to manipulate patient data (add new patients, view existing patients, obtain reports of responses provided by patients) and manipulate questions (create, edit, and delete). Creation and modification of questions can be done quickly and efficiently with a series of menus and text fields through the Web portal. Notifications can be assigned to alert the patient to complete an assessment at a specific time or randomly within a pre-specified interval [28]. Notifications are automatically pushed to the mobile app. The following areas were prioritized during the development process.

Figure 1. Schematic diagram of the components of the system used to monitor symptoms after a trauma.



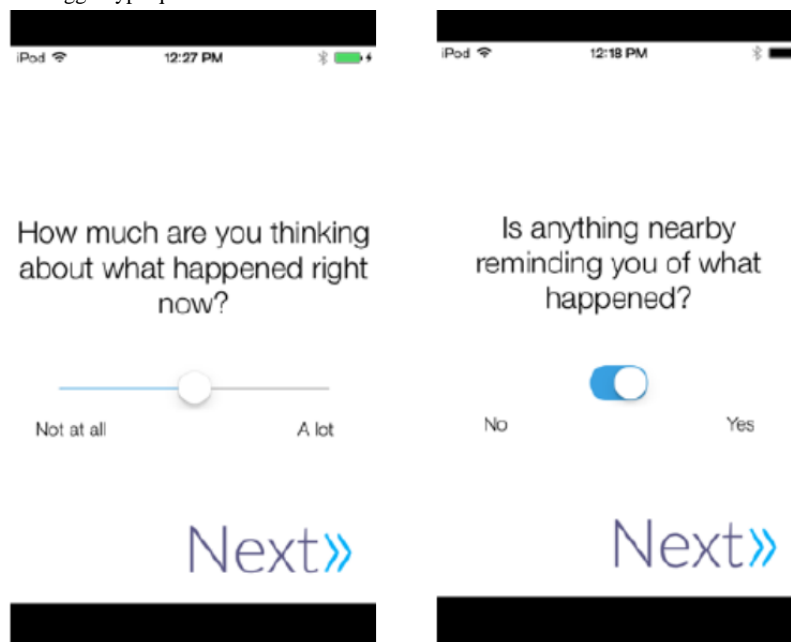
Speed of Completing Assessments

Several steps were taken to ensure question sets could be completed quickly. First, two types of question responses were implemented: Sliders and Toggles (Figure 2). Sliders were visual analogue scales, a commonly used method to assess symptom severity in health research [29]. A slider allows participants to make choices more rapidly than other commonly used methods such as a Likert scale. Mobile device screen size limits the amount of text that can be presented, which imposes a challenge presenting a question and corresponding text for 5-9 discrete

options on a single screen. Toggle questions were used to ask question with a dichotomous response (eg, Yes/No).

Second, app speed was prioritized. Initial prototypes included multiple icons on the home page that ultimately interfered with speed of use. A home page with a single icon “Begin Questions” in the center was used instead. Transitions between screens were removed. Responses were stored locally on the device and transmitted when the assessment was completed, to eliminate network latency that is common in Web forms [30]. Responses were sent automatically rather than prompting the user to upload their responses.

Figure 2. Screenshot of slider and toggle type questions.



Ease of Use

The types of questions allowed were selected to improve the ease of use. Consideration was given to presenting multiple items on a single screen in which users would scroll through all items or presenting multiple screens. The use of a native app, as opposed to a Web survey, reduced load times to overcome the limitation of using multiple screens to complete a survey [30].

Flexibility in Assessment Content

Considerable flexibility was needed to assess a range of symptoms. For example, there are 20 possible symptoms that make up the diagnosis for PTSD. Surveys were allowed to be of unlimited length, have editable content, and have additional items added or removed via the Web interface. Furthermore, participants could be assigned different surveys based on the time of day.

Usability Measures

Usability was assessed with the Perceived Useful and Ease of Use Survey (PUEU) [27] and a qualitative interview. The PUEU is a 12-item self-report survey with subscales assessing the perceived usefulness of a given technology (eg, “The app would enable me to communicate with my doctor more quickly”) and the perceived ease of use of a given technology (eg, “It would be easy for me to become skillful at using the system”). Each item is rated on a 7-point Likert scale with higher scores indicating a more favorable rating. A qualitative interview was conducted to assess impressions of the app and guide subsequent development. Participants were asked for their thoughts on the app, components they liked most, components they liked least, and to suggest features to improve the app. Responses were audio recorded and transcribed for review.

Mobile Devices

The mobile app was evaluated on an iOS (iPod Touch 5th Gen) and an Android device (Motorola Moto G). The interface was nearly identical across both platforms. Half of the sample used each device. Use of the mobile app was monitored using a universal serial bus (USB) camera mounted to the device.

Procedure

Standardized tasks took place within a laboratory. To standardize the use of the app, participants were read a script describing a motor vehicle accident that required immediate and sustained medical attention. They were told that this app was being given to them to monitor their recovery after they left the hospital and they were asked to complete a set of self-report assessments in the coming weeks. Participants used the app a total of 5 times, each time progressing further in their recovery. Trained research assistants observed the participants during their interaction with the app and interactions were recorded with a usability mounted camera [31]. They then completed a brief qualitative interview to assess their thoughts on using the app. Videos were reviewed to identify user interaction errors, defined as errors made by the user due to the interface. These include tapping an icon that is not a responsive icon or being unable to determine how to

complete a specific task. The university’s Institutional Review Board approved all procedures.

A clinical psychologist analyzed the qualitative data. A constructivist grounded theory approach was used in which comments and interviews were reviewed multiple times, coded, and primary themes were extracted. Themes that were present for more than three cases were retained. Themes that were present in three or fewer cases were reviewed, merged with other themes, or discarded. Coding and thematic analyses were conducted after each wave to determine the point at which saturation had been obtained and when no new bugs were identified. A hierarchical structure in which themes were evaluated as representing perceived usefulness or perceived ease of use was then evaluated to determine the extent that the qualitative data corresponded to the quantitative data. Several passes of the data determined that this structure represented the data well. Matrix analyses combined the quantitative data from the PUEU and the qualitative data from the interview. Triangulation of the mixed-method yielded a high degree of overlap across the quantitative and qualitative data, which adds validity to the conclusions drawn from the qualitative analysis.

Results

Participants used the app a total of five times. Participants completed a standard question set that contained 7 items (6 slider-type and 1 toggle-type). Questions assessed symptoms of PTSD (re-experiencing, avoidance, hyperarousal, numbing), pain, and social support, and the presence of trauma-related cues. The time to complete the question sets was mean (SD) 29.37 (7.53) seconds (range 15-57). A review of the video recordings of participant interaction revealed minimal user interaction errors. Participants were able to navigate each use of the app without error. The app stalled for approximately 30 seconds for 2 participants after all responses were logged. No other usability issues were observed. [Table 1](#) shows the results from the qualitative and quantitative data according to the two TAM themes.

Table 1. Results of the perceived usefulness and perceived ease of use survey.

	1 (Unlikely)	2	3	4	5	6	7 (Likely)
Perceived usefulness, %							
The app would enable me to communicate with my doctor more quickly.	0.0	4.8	0.0	0.0	28.6	38.1	28.6
The app would improve my recovery from a traumatic event.	0.0	14.3	9.5	23.8	28.6	19.0	4.8
The app would improve the quality of medical care I received after a traumatic event.	0.0	4.8	28.6	4.8	28.6	14.3	19.0
The app would make it easier for me to remember to follow the doctor's instructions after a traumatic event.	0.0	0.0	4.8	23.8	28.6	23.8	19.0
The app would make it easier for me to seek additional medical care after a traumatic event.	0.0	4.8	4.8	9.5	33.3	23.8	23.8
I would find this app useful after a traumatic event.	0.0	4.8	9.5	14.3	28.6	19.0	23.8
Perceived ease of use, %							
Learning to use the app would be easy for me.	0.0	0.0	0.0	9.5	4.8	23.8	61.9
I would find it easy to get the app to do what I want it to do.	4.8	0.0	0.0	19.0	19.0	14.3	42.9
My interaction with the app would be clear and understandable.	0.0	0.0	0.0	28.6	14.3	4.8	52.4
I would find the app to be flexible to interact with.	0.0	4.8	0.0	14.3	23.8	33.3	23.8
It would be easy for me to become skillful at using the system.	0.0	0.0	0.0	4.8	23.8	19.0	52.4
I would find the system easy to use.	4.8	0.0	0.0	14.3	9.5	9.5	61.9

Perceived Usefulness

Ratings of overall perceived usefulness according to the PUEU suggested that participants thought a mobile monitoring system would be useful in improving post-trauma recovery (mean [SD] 5.14 [1.10]). Participants reported the app would facilitate communication with their provider (mean [SD] 5.81 [1.17]). A substantial portion (11/21, 52%) reported that this app would improve communication above and beyond traditional follow-up methods in the qualitative interview. Participants requested two-way communication with their provider through the app (12/21, 57%). That is, they wanted a provider to give feedback, but the type varied. A portion wanted personalized feedback (6/21, 29%), whereas others preferred a notification that the doctor received or viewed their responses (12/21, 57%). Several (3/21, 14%) recommended the app list contact information for a provider. Last, several participants (5/21, 24%) reported that reminders for intervention (eg, take medication, complete physical therapy) would be helpful.

Participants rated the app as moderately likely to improve their recovery from the traumatic event (mean [SD] 4.42 [1.43]) and thought it would be useful after a trauma (mean [SD] 5.19 [1.47]). A majority thought a monitoring system would be helpful (13/21, 62%), with a portion stating it would indicate their provider cared about their recovery (4/21, 19%). However, several participants voiced concerns that this app would replace face-to-face provider contact (2/21, 10%).

Perceived Ease of Use

Overall ratings suggested the app was easy to use (mean [SD] 5.92 [1.05]; mean calculated out of 7), easy to learn to use (mean [SD] 6.38 [0.97]), and it would be easy to become skillful with the app (mean [SD] 6.19 [0.98]). Qualitative responses were supportive of these data. Nearly all (19/21, 90%) reported the

app was easy to use and they enjoyed the simplicity of the design. Several found the design calming and engaging (5/21, 24%). A substantial majority reported assessments took minimal time to complete and would impose minimal burden (17/21, 81%). Indeed, participants reported they would be willing to answer mean (SD) 2.86 (1.85) question sets per day, mean (SD) 4.90 (2.41) days per week.

Participants had several recommendations to enhance the design and features of the app. Half (11/21, 52%) suggested that personalizing the app would be helpful. Specific recommendations included changing colors, setting backgrounds, and personalizing the question content. Personalized content involved using specific details about the individual (eg, name) and questions about their trauma (eg, "how is the pain in your left leg?"). Second, it was recommended that each question have a free text response option to clarify ratings (7/21, 33%).

Participants reported they wanted the app to provide feedback, including a graph of their responses (10/21, 48%). Participants wanted to receive positive feedback that informed them of areas where they were improving and did not wish to be notified if symptoms were worsening (8/21, 38%). Rather, they preferred that worsening outcomes be reported to their provider and the provider contact them.

Discussion

Principal Findings

The current study obtained important information about user preferences for a monitoring system for mental health symptoms following a trauma. Participants preferred an app that was easy to use, would not impose a significant burden, and was customizable. The findings are consistent with the TAM [27].

Prior work with websites for health care have also shown that ease of use is correlated with sustained use [32]. The app was focused on a single purpose, obtaining self-report data, which allowed participants to respond to 7 questions in less than 30 seconds on average and showed increased willingness to use the app for a sustained period. The speed with which individuals were able to respond suggests that longer question sets are likely to impose minimal burden. Difficulty providing responses may undermine the utility of mobile monitoring apps [33].

Participants were moderately positive that a mobile monitoring app would help their recovery. This is consistent with evidence suggesting that monitoring is helpful in reducing symptoms of PTSD [34] and that interactions via SMS after a trauma are perceived as helpful [35]. To increase perceived helpfulness, participants should be given a rationale as to the benefit of monitoring. In addition, participants should be told how their data will be used if no other feedback mechanism is available.

A key theme was the importance of providing feedback. Participants were unanimous in their request to interact with their provider through the app rather than as a one-way communication tool. Most users wanted immediate feedback from their provider after completing an assessment. An immediate response, however, would be challenging given the burden this would impose on a provider [12]. Rather, a two-tiered feedback method is recommended. The first would involve an immediate response. This could include a graph of responses, positive praise for completing the assessment, or notification that their provider will review their responses. More patient-specific responses may become feasible as the computational power of mobile devices increases. That is, devices may be able to generate a specific response to a patient based on their answers with a more powerful mobile device. The second type of feedback would involve provider interaction at a later point, such as a phone call or session. Interactions with providers should explicitly highlight that the data obtained from the mobile app triggered this contact. Additional work is needed to determine how to best tailor this feedback and use these data in clinical practice.

A related theme was the personalization of the app to the needs of the patient. Personalized feedback is highly relevant to outcomes and sustained use [36,37]. Advanced analytic methods, such as machine learning, may be especially well suited to provide personalized feedback. These methods can use the large quantities of data generated by these apps to provide specific feedback to an individual [38]. For example, a patient with poor sleep, increased arousal, increased pain, and a prescription for narcotic pain medicine may be at risk for substance abuse. The system could use these data to provide very specific questions or information to the individual about their medication use. Such information would then facilitate care interactions. Relatedly, this ability to tailor question content should specifically address the traumatic event that the participant experienced. Rather than using generic language, it would likely be beneficial to ask targeted questions about specific symptoms, injuries, or events that reference the participant's experience. Such an approach will assure the participant that this app is tailored to their needs. When implemented successfully, this strategy would improve the efficiency and quality of care for

patients in settings with considerable clinical demands, such as the emergency department. As an example, a recent study used mobile telehealth to monitor healing after surgery [39]. The system allowed physicians to monitor healing, provide targeted feedback, and eliminate unnecessary follow-up appointments for those healing as expected while spending more time with those who had complications.

Participants provided two areas of caution. First, participants wanted automated feedback to be positive and preferred that negative outcomes trigger a provider touchpoint. Within the context of TAM, it is possible that negative feedback may diminish the perceived usefulness of an app. Those who are not recovering likely do not want feedback reinforcing their lack of progress but rather want intervention. Alternatively, providing positive feedback about their progress may be perceived as encouraging and supportive. Second, participants cautioned that such monitoring systems should not replace interpersonal care. It is unclear if this concern could be addressed by providing a more personalized experience, such as telehealth or telephone sessions, or additional contact from their provider. Wound care after surgery using telehealth reduced the need for in-person follow-ups, which was preferred by patients [39].

Limitations

Our conclusions should be considered within the context of several limitations. The sample size for the current study was within the recommended size for usability studies [40] but is still relatively small. The current study was conducted within a laboratory setting with patients who had a trauma history but were not currently dealing with the repercussions of their event. As such, the ecological validity of the current study is limited [26]. Additional usability and feasibility testing is needed with a sample of patients who have recently experienced a traumatic event. Such studies should coincide with validation studies in which responses to the surveys administered via the mobile platform are compared with responses to a gold-standard measure. The majority of the participants in the current study were young, White, female, iPhone-owners, which may limit the generalizability of the findings to other populations. Indeed, recent work has highlighted the ethnic, racial, and economic diversity of patients in an acute setting [15], such that evaluation across a more diverse group of participants is warranted. Finally, the current study focused primarily on the use of a mobile app by patients. The current framework, however, involves a provider dashboard that displays results, allows providers to create and edit question sets, and reviews their patient priorities. Additional usability testing is needed to evaluate this component.

Conclusion

The results of this study provide several points of feedback to advance modern methods for monitoring mental health recovery after a trauma. The need for personalized feedback, the type of feedback provided, and how patients view such a system has broad implications for other conditions. These recommendations should guide the refinement of current systems and the development of new strategies that leverage novel technology. Although technology changes rapidly, the principles obtained from this study and related projects are applicable to systems that address mental health. Such work is essential to the

development of systems that will be used by patients to improve outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

PTSD: posttraumatic stress disorder
PUEU: Perceived Useful and Ease of Use Survey
TAM: Technology Acceptance Model

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