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An Adjunctive Internet-Based Intervention to Enhance Treatment for Depression in Adults: Randomized Controlled Trial

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Abstract

Background: Internet-based interventions promise to enhance the accessibility of mental health care for a greater number of people and in more remote places. Their effectiveness has been shown for the prevention and treatment of various mental disorders. However, their potential when delivered as add-on to conventional treatment (ie, blended care) is less clear.

Objective: The aim of this study is to study the effectiveness of an internet intervention (ASCENSO) implemented in addition to face-to-face treatment as usual (TAU) for depression.

Methods: A 2-arm, parallel-group, randomized controlled trial was conducted in an outpatient private mental health care center in Chile. In all, 167 adults, diagnosed with major depressive disorder, without severe comorbidities, and with internet access, were included. Eighty-four participants were assigned to the intervention group and received medical and psychological TAU from the mental health center plus access to the ASCENSO online platform. The control group (n=83) received only TAU. The ASCENSO platform includes psycho-educational information, depressive symptom monitoring and feedback, and managing emergencies based on the principles of cognitive behavioral therapy. Emergency management was mental health provider–assisted. TAU includes access to primary care physicians and psychiatrists, to a brief individual psychotherapy, and to medication when needed. The baseline questionnaires were administered in person, and 6- and 9-months assessments were conducted online. Depression symptoms and quality of life were measured by self-administered questionnaires, and treatment adherence was determined via the Mental Health Center’s internal records. The usage of ASCENSO was assessed by server logs. Reduction on depressive symptomatology was considered as the primary outcome of the intervention and quality of life as a secondary outcome.

Results: Of the 84 participants in the intervention group, 5 participants (6%) never accessed the online platform. Of the remaining 79 participants who accessed ASCENSO, 1 (1%, 1/79) did not answer any of the symptom questionnaire, and most participants (72/79, 91%) answered the monitoring questionnaires irregularly. The ASCENSO intervention implemented in addition to face-to-face care did not improve the outcome of the usual care delivered at the mental health center, either in terms of reduction of depressive symptoms ($F_{2,6087}=0.48; P=.62$) or in the improvement of quality of life (EQ-5D-3L: $F_{2,7678}=0.24; P=.79$ and EQ-VAS: $F_{2,6670}=0.13; P=.88$). In contrast, for the primary ($F_{2,850}=78.25; P<.001$) and secondary outcomes (EQ-5D-3L: $F_{2,1067}=37.87$; EQ-VAS: $F_{2,4390}=51.69; P<.001$) in both groups, there was an improvement from baseline to 6 months ($P<.001$).
but there was no change at 9 months. In addition, no effects on adherence to or use of TAU were found. Finally, the dropout rate for the face-to-face treatment component was 54% (45/84) for the intervention group versus 39% (32/83) for the control group (P=.07).

**Conclusions:** The fact that the adjunctive access to ASCENSO did not improve outcome could be due to both the rather high effectiveness of TAU and to patients’ limited use of the online platform.

**Trial Registration:** ClinicalTrials.gov NCT03093467; https://clinicaltrials.gov/ct2/show/NCT03093467

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**KEYWORDS**
depression; e-mental health; blended care; internet

**Introduction**

**Background**
Depression is one of the most prevalent health problems and the leading cause of disability worldwide [1]. In Chile, the prevalence of this pathology is among the highest internationally. According to data provided by the National Health Survey 2016-2017 conducted by the Chilean Ministry of Health, 15.8% of the general population over 18 reported having experienced depressive symptoms in the past year [2]. Despite the high prevalence of depression and the costs implied for the health systems, a relevant percentage of those suffering from depression do not access treatment. The barriers to accessing effective mental health treatment include individual factors. For example, help-seeking behavior is influenced by the willingness to disclose problems, fear of stigma [3], lack of time for treatment, and sociocultural characteristics. Moreover, barriers regarding providers influence access to treatment, such as scarce screening and diagnose of mood and anxiety disorders within the primary care health setting. Finally, systemic factors, such as the availability of effective treatment, have also been reported to constitute a barrier to accessing mental health treatment [4,5].

The high depression prevalence, its complexity and chronicity [6], and the low rates of treatment access [4] have led to the design and implementation of comprehensive management strategies for the disorder [7-10] including interventions based on information and communication technologies [11].

Internet cognitive therapy (ICT)-based programs often include interactive elements, self-report questionnaires, psycho-education through audio-visual media, and different types of exercises, such as problem solving, recognizing and challenging dysfunctional thinking, activity planning, and behavioral experiments [12,13].

Over the past two decades, many studies have pointed to the effectiveness of ICT-based interventions for the reduction of depressive symptoms [11,14]. Most studies investigated self-management interventions based on internet cognitive behavior therapy (iCBT) with or without clinical guidance that were mostly used as stand-alone interventions (ie, independent of conventional face-to-face treatment). A recent meta-analysis based on 32 studies reported a pooled effect size of $g=0.67$ for the reduction of the depressive symptomatology of iCBT [14]. Nevertheless, most of the included studies addressed self-selected individuals with mild to moderate symptoms and mostly recruited online and outside of clinical settings. It is possible that these individuals differ from those who participate in traditional face-to-face therapies [15], which limits the generalizability of these results.

Another limitation of the available evidence is based on the fact that the majority of trials compared stand-alone iCBT against a weak comparator (ie, wait-list control groups). Furthermore, the comparisons against usual care or active interventions (eg, bibliotherapy) has shown mixed results, some indicating a small [14] or nonsignificant effect [16], whereas others studies conclude that iCBT could be as effective as face-to-face treatment [17-19]. However, there is still a clear lack of high-quality trials addressing this question in clinical samples in which iCBT is tested against evidence-based individual psychotherapy.

In addition to further investigating the potential of such stand-alone interventions, it is considered highly relevant from a service research perspective to investigate to what extent the additional use of ICT-based interventions parallel to conventional face-to-face treatment (ie, blended treatment approaches) may improve depression care. Blended care refers to a combination of online and face-to-face therapy [20]. Blended interventions can have two different objectives: on the one hand, they can aim at increasing the efficiency of treatment by reducing time in the face-to-face setting instead of delivering parts of the treatment via ICT (ie, the assumption is that similar outcomes can be achieved with less face-to-face treatment and therefore at a lower cost) [21]; on the other hand, blended interventions can aim at increasing the effectiveness of treatment by adding adjunctive ICT-based tools to regular face-to-face treatment (ie, the assumption is that the combined treatment will result in improved outcomes) [20,22].

Four recent randomized controlled trials (RCTs) investigated the effectiveness of blended care for depression but showed inconsistent results. Two trials reported statistically significant, medium effect sizes of blended treatment in both inpatient [23] and outpatient settings [24]. These 2 studies included German participants and used the web-based self-help program, Deprexis, for 12 weeks. This program consisted of 10 main modules plus an introductory and a summary module based on cognitive-behavioral techniques, positive psychology, emotion-focused therapy, and dream work. In contrast, 2 other trials found no [25] or only small effects [26] of adding an adjunctive computerized iCBT to face-to-face primary care. Both of these trials included European outpatient samples (UK)
and German patients) and used the MoodGYM, a web-based CBT program for depression, which consists of 5 interactive modules that are made available sequentially on a weekly basis with a 6-week total duration. Additionally, Gilbody, et al’s [25] 3-group study design allowed for the assessment of an adjunctive iCBT intervention using the Beating the Blues program, which is an interactive, multimedia, computerized CBT package comprising a 15-minute introductory video followed by 8 therapy sessions. The program is entirely online, and there is no interaction with clinicians or individualized feedback on the computer sessions [25]. It is possible that the lack of consistent results among the mentioned studies is due to the diverse samples (inpatients might have more severe symptoms than outpatients) and the different types and durations of the digital intervention program used.

In addition, a large naturalistic study reported that blended interventions for depression and anxiety did not result in improved outcomes and were even associated with longer treatment duration and more costs than was outpatient treatment alone [27].

**Study Objective**

In this paper, we report on the first RCT on blended care for depression in Latin America where research on ICT-based interventions is still considered to be in an initial stage [28,29]. In Chile, the first internet-based program for depression, called ASCENSO (based on the acronym of its Spanish name: Apoyo, Seguimiento y Cuidado de Enfermedades a partir de Sistemas Operativos) was developed and evaluated in a feasibility and acceptance study in 2015 [30].

The main purpose of the present study was to evaluate the effectiveness of a blended treatment approach (ie, ASCENSO offered as adjunctive intervention to depression treatment as usual [TAU] for adult patients) compared to TAU alone.

Based on the high rates of acceptance and satisfaction among patients who actively used the ASCENSO program as well as their recognition of the program as a form of company and a source of help that complements their treatment as reported in the pilot study [30], we hypothesized that the intervention group (IG) would show higher adherence to TAU and a significant decrease in depressive symptoms over time when compared to the control group (CG).

**Methods**

**Trial Design**

This 2-arm parallel-group RCT compared standard face-to-face psychotherapy plus medication for patients with depression (TAU) with the blended treatment approach, including TAU plus ASCENSO, as a superiority trial. Assessments in both conditions were conducted at baseline (T1), at 6 months (T2), and after 9 months (T3).

**Recruitment, Randomization, and Blinding**

Recruitment occurred from May 2017 to February 2019, the study was short 5 participants of the estimated sample size. Recruitment was stopped due to study time lines (once 9-month follow-up assessment was completed) and budget constraints.

Patients seeking treatment for depression at a private, university-affiliated clinical and research mental health care facility in Santiago, Chile, were invited by a research assistant to join the study (offline recruitment).

Inclusion criteria were age between 18 and 64 years, a clinical diagnosis of a current major depressive episode by a staff psychiatrist or mental health–trained physician according to the International Classification of Diseases confirmed by the Spanish Version of the Mini International Neuropsychiatric Interview (MINI) [31], and internet access. Exclusion criteria were a previous suicide attempt (past 10 years); hospitalizations associated with a major depressive disorder (MDD) diagnosis; psychotic episodes; bipolar affective disorder; severe cognitive disability; drug abuse or dependence; antisocial, schizotypal, or borderline personality disorder; serious medical illness; and insufficiency in the Spanish language. Participants were randomized either to the CG receiving psychiatric or psychological TAU or to the IG receiving TAU plus access to ASCENSO. Randomization was balanced, based on a permuted block design, and stratified by MDD episode (first versus 2 or more episodes). The randomization allocation sequence was computer generated and was sent to the research assistant after the participant signed the informed consent. Patients did not receive any incentive or compensation for participating in the study.

Given the design of the study, participants knew to which study group they belonged. In order to avoid potential bias, physicians and psychotherapists were unaware of the group assignment at the beginning of TAU, but they could access this information if participants decided to disclose this information during sessions (for example, by sharing results of the monitoring). Researchers were also unaware of the group assignment (IG vs CG) at the time of analyzing the primary and secondary outcomes of the study. However, when the use of the online platform was being analyzed, this information was transparent.

**Interventions**

TAU includes the services typically provided to patients referred by private health insurance companies, within the framework of health difficulties that are covered by Explicit Health Guarantees for Chileans. The benefits are defined by the health authority in a minimum and common package for public and private providers.

The TAU delivered is based on the national clinical guideline for the treatment of depression in individuals age 15 years and older [32]. This indicates the need for nonpharmacological treatment for mild depression and a combination of pharmacological and nonpharmacological treatment for moderate and severe depression. In addition, it indicates follow-up actions for 6 months once the symptomatic decrease or remission is confirmed at 12 weeks of treatment.

In the case of a major depressive episode diagnosis, benefits include monthly care with a mental health–trained primary care physician or a psychiatrist for more severe clinical presentations, access to pharmacological treatment when required, and brief individual psychotherapy.
The usual pharmacological treatment consists of an antidepressant plus anxiolytic, which is prescribed by the physician or psychiatrist according to the severity of the condition, for a minimum period of 6 months. In this sample, 100% (n=167) of patients used antidepressants, 71.9% (120/167) also used anxiolytics, and 55.7% (93/167) used other pharmacological treatment. The psychotherapy considers weekly sessions for 6 to 12 weeks with an extension option upon need.

In more complex cases, the public health or insurance coverage package confers outpatient psychiatric care and short-stay hospitalization or day hospital treatment. At the provider level, regarding patient treatment decisions, benefits defined by the health authority are mostly a reference framework, allowing for clinically based individual adjustments (eg, selection of attending professionals and length and frequency of interventions).

ASCENSO is an online program (see Figure 1 and Multimedia Appendix 1) for monitoring and supporting patients with depression, delivered as adjunctive support to conventional face-to-face treatment. The ASCENSO intervention had a 9-month duration.

ASCENSO’s main aims are delivering psycho-educational information (welcome page, self-care recommendations, and blog components), supportive monitoring and feedback (depressive symptom–monitoring component), and managing emergencies (alarm, online consultation, and emergency information components). Its 7 main components are described as follows: (1) A welcome page that shows the ASCENSO platform objectives is included. (2) Self-care recommendations and psychoeducation involve psycho-educational resources that promote patient self-care and adherence to treatment, specifically, information about the causes, prevention, and treatment of depression. (3) The blog component includes general information about mental health and depression. (4) For the depressive symptom monitoring and feedback component, every 2 weeks, patients report the level of their depressive symptoms by completing the Patient Health Questionnaire-9 online questionnaire [33]. For this purpose, they receive a link to the questionnaire by email (they can also access it via the online ASCENSO platform). If the participant does not respond, a reminder is automatically sent within 5 days by email. The ASCENSO platform evaluates the status of the depressive symptoms with a predefined algorithm and determines whether the patient’s status is improved, unchanged, or deteriorated compared to the previous one. A short feedback message is then sent to the patient (Textbox 1). Each feedback fits the current symptomology and is selected and sent from a database (elaborated by a group of experts). All messages include a brief self-care recommendation, and they promote adherence to psychotherapeutic and psychiatric treatment.

**Textbox 1. Examples of feedback messages.**

- We are pleased to know that your current situation is good. We are committed to improving your situation as well. Don't forget to go for a walk or visit someone you like. Do simple things that you like and make you happy.
- We have observed that the last four weeks you have not been well, and that is lamentable news for us. We recommend that you seek a conversation with your therapist or physician. Please note that you can also request a consultation online or by phone in the ASCENSO program. Don't isolate yourself.
- In the questionnaire, you show that your mood has improved a little from your previous results. To continue improving, it is important that you do not forget the self-care recommendations that are available on the ASCENSO program website. Take care of your diet and exercise in moderation, according to your physical possibilities.
(5) An alarm based on symptom monitoring or a “suicide alert” is also included as a component. In the case that monitoring indicates suicidal ideation, the patient automatically receives an email instructing him or her to contact the health center where he or she is being treated and is referred to the “Emergency” section of the menu on the ASCENSO platform. In addition, a professional at the health center responsible for implementing ASCENSO receives an alert notification, evaluates the patient’s situation according to information in the clinical record and symptom report, and acts accordingly.

Regarding the standard operating procedure for suicidality of the trial, the suicide alert was activated by the patient when responses in the ASCENSO platform questionnaire indicated suicide ideation. This alert was automatically sent via email from the platform to a person designated by the health center and the research team; generating 2 different but complementary routes of action. The first was managed by the research team, in which a research assistant (clinical psychologist) contacted the patient within 48 hours after the alert was triggered. It involved verifying the patient’s condition, motivating the continuity of the treatment, and remembering the options available on the ASCENSO platform (use of consultation online or by phone). In case the participant could not be contacted, the research assistant made 2 additional attempts in the following days. The second and parallel route of action was the responsibility of the health care center staff. CC reviewed the patient’s care and identified if there was a scheduled appointment (either a doctor or a psychologist) during the next 7 days. If the patient did not have an appointment, the health center staff would contact the patient by phone to verify their situation and proceed to follow the internal protocol of the health center for the management of suicidal ideation and suicide attempts.

(6) In the online consultation component, patients can schedule a 30-minute session with a psychologist, which is conducted in a private text-based chatroom or over the phone. Guidance and counseling are provided during the online consultation (sessions do not constitute an online psychotherapeutic process). This component was provided by the mental health center.

(7) For the emergency information component, standard information on what to do and whom to contact in a crisis is provided.

Research assistants registered participants of the IG in the ASCENSO platform and gave them a password to access the intervention. They also offered information on how to access and use the platform. If a participant failed to respond to the first monitoring assessment after 2 weeks, he or she was contacted by phone to clarify potential technical problems. Additionally, during the course of the intervention, the IG participants could contact the research assistants via email when encountering any technical problems on the use of the platform. Participants could access the platform for 9 months.

Assessment Instruments and Methods
The MINI Spanish version 6.0.0 was used for assessment in this study. The MINI is a brief and structured interview for major psychiatric disorders of axis I of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, and the International Classification of Disease 10. It was specifically designed for implementation in clinical practice and research in psychiatric and primary health care settings and was used in this study at baseline to determine the inclusion and exclusion criteria. The following modules were applied: major depressive episode, suicidality, manic and hypomanic episodes, alcohol and other substance dependence abuse, psychotic and mood disorder with psychotic features, and antisocial disorder. Each module starts with a screening question to exclude the diagnoses and possibly skip the module accordingly if answered negatively or to explore symptoms severity when responded positively. Several validation studies [34] have demonstrated excellent interrater and test reliabilities of the MINI.

The International Personality Disorder Examination (IPDE) Questionnaire and Interview was also used for assessment [35]. The IPDE is a semistructured interview used to assess personality disorders. It has been approved by the World Health Organization and has been translated into Spanish [36]. In this study, it was used to identify exclusion criteria of schizotypal and borderline personality disorders. It also has a brief self-applied screening questionnaire, in which, using dichotomous answers to questions, the individual describes his or her usual behavior in the past 5 years. This questionnaire provides the interviewer with quick information about which personality disorder is likely to be present. The corresponding module of the IPDE interview is then administered, which allows for the confirming or ruling out of the diagnosis.

Demographic information (age, gender, marital status, etc), internet accesses and use, and self-perception of internet expertise were collected through an ad hoc questionnaire.

The primary outcomes were depressive symptoms as assessed by the Chilean adaptation of the Beck Depression Inventory [37]. The Beck Depression Inventory is a 21-item, self-rated scale that evaluates key symptoms of depression; among other items, it includes sadness, pessimism and sense of failure, self-dislike, suicidal ideas, crying, irritability, social withdrawal, indecisiveness, and several somatic preoccupations [38]. Items are scored on a 4-point continuum (0=least, 3=most), with a total score range of 0 to 63. The Chilean adapted inventory has a .92 Cronbach’s α and 1-factor solution [37]. Higher scores indicate greater depressive severity. In this study, the internal consistency was .84, .92, and .94 at basal, 6-month and 9-month assessment, respectively.

Secondary outcomes were quality of life and treatment adherence. Quality of life was measured by the Spanish version of the EuroQol/EQ-5D-3L [39,40]. It includes a short descriptive questionnaire and a visual analogue scale (EQ VAS). The former comprises 5 items: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Items are scored on 3 levels: (1) no problems, (2) some problems, or (3) extreme problems. The EQ VAS assessing the respondent’s self-rated health uses a vertical scale where the highest end point is labeled as “The best health you can imagine” (100 points) and the lowest as “The worst health you can imagine.”

Treatment adherence was determined via the Mental Health Center’s internal records. Specifically, we assessed the percentage of treatment sessions attended, including...
appointments for medical control, psychiatry, and psychotherapy; and percentage of participants who dropped out from TAU (face-to-face interventions).

Finally, for IG participants, the usage of ASCENSO was assessed by server logs.

Procedures

Regarding the timing when the measurements took place, the MINI, IPDE, and ad hoc questionnaire were applied at baseline measurement, while the Beck Depression Inventory and EuroQol/EQ-5D-3L were used at baseline, 6 months, and 9 months. Information from the health center records and ASCENSO use was collected 9 months after treatment initiation.

As the duration of TAU varied depending on patients’ impairment and their adherence to treatment, fixed assessment intervals were defined as opposed to patients being surveyed at the end of their face-to-face treatment. The assessment at T2 was conducted after 6 months in order to include the recommendation for a minimum time of pharmacological treatment. The assessment at T3 was conducted after 9 months in order to cover the duration of the ASCENSO intervention.

The baseline assessment consisted of web-based self-administered questionnaires that patients completed at a computer provided by the research assistant after they had signed the informed consent. Follow-up assessments consisted of the same web-based self-administered questionnaires but were not completed in the health care center.

Sample Size

With a medium effect size ($d=0.5$), .05 $\alpha$ error, and .90 of power, G*Power software [41] indicated a sample size of 140 participants (70 in each group). The final sample size established was 172 participants, with a potential attrition of approximately 20% being accounted for.

A medium effect size was assumed, based on the effectiveness of previous eHealth interventions for depression. The reported effect varies from medium-large effect size (0.78) superiority of the computerized CBT over the control group [42] to small-medium (0.41 or 0.34) effect size when internet-based psychological interventions are compared to active control conditions [43,44]. The effect size assumed in our trial was comparable to the effects reported for other blended interventions in 2 recent RCTs [23,24].

A similar approach was used to estimate the sample attrition. Two previous Chilean studies on eHealth technologies reported 10% [45] and 34% [30] sample attrition. In this context, an average estimate of the sample loss was calculated at 20%.

Analytical and Statistical Approaches

The primary analysis was based on the intention-to-treat principle. A multiple imputation procedure was used to generate 100 multiply imputed data sets, which were further analyzed by using standard procedures for complete data and by combining the results from these analyses [46]. The imputation model considered sex, age, and whether or not the MDD episode was the patient’s first.

Effects on depressive symptoms and quality of life were tested using mixed analysis of variance (based on a mixed models’ approach) to compare changes in assessments from baseline to 6 and 9 months (time factor) between the IG and CG (group × time factor). Additionally, within- and between-group effect sizes were estimated by Cohen’s $d_z$ and $d_s$ respectively [47].

Because of their nonnormal distributions, face-to-face treatment adherence indicators were tested with Mann-Whitney tests and chi-square tests (Yates correction). A result was considered statistically significant at $P<.05$. All analyses were performed using SPSS version 20 (IBM Corp) except for some imputed parameters (P values) which were estimated by R software ("miceadds" package; The R Foundation for Statistical Computing).

Ethics and Clinical Trial Registration

The Ethical Committee of the Mental Health Center Psicomédica Research Group, Santiago, Chile, approved the study protocol. Clinical trial registration was made under ClinicalTrials.gov (NCT03093467).

Results

Participant Characteristics

Of the 729 patients screened for eligibility, 167 were randomized. The rest either refused to participate, could not be contacted, or did not meet inclusion criteria. Of the 120 patients that did not meet the inclusion criteria; 40% (48/120) had a previous suicide attempt; 18.3% (22/120) did not have confirmed MDD; 12.5% (15/120) had been in treatment for more than 1 month, 8.3% (10/120) had borderline personality, 6.7% (8/120) had a bipolar disorder; 4.2% (5/120) were older than 65 years old; 3.3% (4/120) had no internet access; 1.7% (2/120) had a psychotic episode, and 5% (6/120) were excluded for other reasons. In terms of assessment, 81% (68/84) of the IG and 86% (71/83) of the CG patients completed the 6-month assessment, and 80% (67/84) of the IG and 78% (65/83) of CG patients completed the 9-month assessment (Figure 2).
Of the 167 participants, 76.0% (127/167) were women, 46.1% (77/167) did not have previous MDD episodes, and 82.6% (138/167) were employed. The average age was 39.31 years (range 20-63 years). Most of the participants (49.1%, 82/167) were married or cohabiting and had more than 12 years of education (76%, 127/167). In terms of internet access, 92.8% (155/167) had access at home and 95.2% (159/167) had access through their cell phone; most participants (55.1%, 92/167) self-identified as intermediate internet users. With respect to clinical characteristics, there were no differences between the IC and CG in depressive symptoms or quality of life (Table 1).

Quality of life measured by EQ VAS was associated with a lower probability of missing data at 6 months (odds ratio [OR]=0.97, 95% CI 0.94-0.99; P=.04) and 9 months (OR=0.96, 95% CI 0.94-0.99; P=.01). Sex, age, first MDD episode, marital status (married or cohabiting vs single, divorced, or widowed), educational level, baseline depressive symptoms, and quality of life (measured with EuroQol/EQ-5D-3L) were not associated with the presence of missing data at either measurement interval.
Table 1. Participant characteristics at baseline.

<table>
<thead>
<tr>
<th>Demographic variables</th>
<th>Total (N=167)</th>
<th>CG(^b) (N=83)</th>
<th>IG(^c) (N=84)</th>
<th>Contrast and/or P values(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>39.31 (10.84)</td>
<td>39.06 (10.67)</td>
<td>39.56 (11.06)</td>
<td>(t_{165}=0.30, P=.77)</td>
</tr>
<tr>
<td>Age (years), range 20–63</td>
<td>21–62</td>
<td>20–63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>127 (76)</td>
<td>62 (75)</td>
<td>65 (77)</td>
<td>(\chi^2=0.17, P=.69)</td>
</tr>
<tr>
<td>First MDD(^e) episode, n (%)</td>
<td>77 (46)</td>
<td>37 (45)</td>
<td>40 (48)</td>
<td>(\chi^2=0.16, P=.69)</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>58 (35)</td>
<td>27 (33)</td>
<td>31 (37)</td>
<td></td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>82 (49)</td>
<td>40 (53)</td>
<td>42 (50)</td>
<td></td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>24 (14)</td>
<td>15 (18)</td>
<td>9 (11)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>3 (2)</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>Living with children, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>(\chi^2=2.92, P=.40)</td>
</tr>
<tr>
<td>No children</td>
<td>79 (47)</td>
<td>36 (43)</td>
<td>43 (51)</td>
<td></td>
</tr>
<tr>
<td>1 child</td>
<td>42 (25)</td>
<td>21 (25)</td>
<td>21 (25)</td>
<td></td>
</tr>
<tr>
<td>2 children</td>
<td>35 (21)</td>
<td>18 (22)</td>
<td>17 (20)</td>
<td></td>
</tr>
<tr>
<td>3 or more children</td>
<td>11 (7)</td>
<td>8 (10)</td>
<td>3 (4)</td>
<td></td>
</tr>
<tr>
<td>Formal education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>(P=.45) (^e)</td>
</tr>
<tr>
<td>Fewer than 8 years</td>
<td>4 (2)</td>
<td>3 (4)</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>8-12 years</td>
<td>36 (22)</td>
<td>16 (19)</td>
<td>20 (24)</td>
<td></td>
</tr>
<tr>
<td>More than 12 years</td>
<td>127 (76)</td>
<td>64 (77)</td>
<td>63 (75)</td>
<td></td>
</tr>
<tr>
<td>Occupational status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>(\chi^2=2.33, P=.31) (^b)</td>
</tr>
<tr>
<td>Housewife</td>
<td>9 (5)</td>
<td>4 (5)</td>
<td>5 (6)</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>11 (7)</td>
<td>3 (4)</td>
<td>8 (10)</td>
<td></td>
</tr>
<tr>
<td>Worker</td>
<td>138 (83)</td>
<td>70 (84)</td>
<td>68 (81)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>9 (5)</td>
<td>6 (7)</td>
<td>3 (4)</td>
<td></td>
</tr>
<tr>
<td>Self-reported internet access and use, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internet at work (yes)</td>
<td>111 (67)</td>
<td>55 (66)</td>
<td>56 (67)</td>
<td>(P=.99) (^i)</td>
</tr>
<tr>
<td>Internet at home (yes)</td>
<td>155 (93)</td>
<td>78 (94)</td>
<td>77 (92)</td>
<td>(P=.77) (^i)</td>
</tr>
<tr>
<td>Internet by cell phone (yes)</td>
<td>159 (95)</td>
<td>77 (93)</td>
<td>82 (98)</td>
<td>(P=.17) (^i)</td>
</tr>
<tr>
<td>Checks email (\geq) 2 times a day</td>
<td>118 (70)</td>
<td>51 (61)</td>
<td>67 (80)</td>
<td>(P=.01) (^i)</td>
</tr>
<tr>
<td>Self-perception of internet expertise, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>(\chi^2=0.07, P=.96)</td>
</tr>
<tr>
<td>Basic(^j)</td>
<td>33 (20)</td>
<td>17 (21)</td>
<td>16 (19)</td>
<td></td>
</tr>
<tr>
<td>Intermediate(^k)</td>
<td>92 (55)</td>
<td>45 (54)</td>
<td>47 (56)</td>
<td></td>
</tr>
<tr>
<td>Advanced(^d) or expert(^m)</td>
<td>42 (25)</td>
<td>21 (25)</td>
<td>21 (25)</td>
<td></td>
</tr>
<tr>
<td>Clinical variables, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression Symptoms</td>
<td>26.14 (SD 8.71)</td>
<td>25.00 (SD 8.65)</td>
<td>27.27 (SD 8.67)</td>
<td>(t_{165}=1.70, P=.09)</td>
</tr>
<tr>
<td>Quality of life: EuroQol/EQ-5D-3L</td>
<td>8.43 (SD 1.55)</td>
<td>8.25 (SD 1.40)</td>
<td>8.61 (SD 1.68)</td>
<td>(t_{165}=1.48, P=.14)</td>
</tr>
<tr>
<td>Quality of life: EQ VAS</td>
<td>50.26 (SD 17.14)</td>
<td>51.34 (SD 17.69)</td>
<td>49.20 (SD 16.61)</td>
<td>(t_{165}=-0.80, P=.42)</td>
</tr>
</tbody>
</table>

\(^a\) CG: control group (treatment as usual).

\(^b\) IG: intervention group (ASCENSO + treatment as usual).

\(^c\) \(t\) test.

\(^d\) \(\chi^2\) test.

\(^e\) MDD: major depressive disorder.

\(^f\) \(P\) value.

\(^g\) BSI: Brief Symptom Inventory.

\(^h\) BMI: Body Mass Index.

\(^i\) \(P\) value.

\(^j\) \(P\) value.

\(^k\) \(P\) value.

\(^l\) \(P\) value.

\(^m\) \(P\) value.
Usage of ASCENSO

Of the 84 participants in the IG, 79 (94%) accessed ASCENSO during the intervention period (9 months); among these, 33 (42%, 33/79) visited the “Welcome” section, 29 (37%, 29/79) visited the “Self-Care Recommendations” section, and 15 (19%, 15/79) visited it multiple times (between 2 and 5 times). The “Emergency Information” section was accessed by 20 participants (25%, 20/79), and 23 participants (29%, 23/79) accessed the online consultation section, but only 6 participants reserved an appointment for a chat (n=3) or telephone (n=3) consultation. Only 5 participants (6%, 5/84) never accessed the online platform.

IG participants answered 49% (785 out of 1595 emails) of the biweekly symptom monitoring questionnaires. Of the platform users (n=79), most participants answered the monitoring questionnaires irregularly. Specifically, 6 participants (8%, 6/79) completed all of the monitoring questionnaires, 24 (30%, 24/79) completed 75% to 99% of the monitoring questionnaires, 14 (18%, 14/79) completed 50%–74%, 8 (10%, 8/79) completed 25%–49%, 26 (33%, 26/79) completed 1%–24%, and only 1 (1%, 1/79) did not answer any symptom questionnaires.

Based on the participants’ responses to monitoring (n=79), a total of 167 suicide alerts were triggered by 51 participants (65%, 51/167): 18 of them (18/51, 35%) triggered it once, 14 (14/51, 27%) triggered it 2 to 3 times, 7 (7/51, 14%) 4 times, and 12 (12/51, 24%) 5 times or more. The participants who triggered alarms reported suicidal ideation on average 3.27 times (SD 2.86, range 1 to 16).

Primary Outcome

For the primary outcome of depressive symptoms, the mixed-model indicated that group (F_{1,10689}=1.03; P=.31) and group x time (F_{2,6087}=0.48; P=.62) effects were not statistically significant. In contrast, there was a time effect (F_{2,850}=78.25; P<.001; see Table 2), indicating that depressive symptoms decreased from baseline (mean 26.14; 95% CI 24.57-27.71) to 6 months (mean 14.14; 95% CI 12.38-15.88; P<.001) in both groups, but no such change at 9 months was observed (mean 13.80; 95% CI 12.03-15.57; P=.76). Consistent with previous results, within-group effect sizes were large (d=−0.95 to −1.08) at 6- and 9-month assessments in both the CG and IG.
Table 2. Imputed means, SDs, and effect sizes for quality of life and depressive symptoms.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Baseline (T1), mean (SD)</th>
<th>6 months (T2), mean (SD)</th>
<th>9 months (T3), mean (SD)</th>
<th>Within-group effect sizes ($d_z$) T1-T2</th>
<th>T1-T3</th>
<th>Between-group effect sizes ($d_s$) T2&lt;sup&gt;a&lt;/sup&gt;</th>
<th>T3&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>T3&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td>T2&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Depressive Symptoms (BDI-IA&lt;sup&gt;c&lt;/sup&gt;)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG&lt;sup&gt;d&lt;/sup&gt;</td>
<td>25.00 (8.65)</td>
<td>13.62 (9.87)</td>
<td>13.52 (11.49)</td>
<td>−1.03</td>
<td>−0.95</td>
<td>−0.10</td>
<td>−0.05</td>
</tr>
<tr>
<td>IG&lt;sup&gt;e&lt;/sup&gt;</td>
<td>27.27 (8.67)</td>
<td>14.65 (11.36)</td>
<td>14.07 (11.75)</td>
<td>−0.98</td>
<td>−1.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality of life (EuroQol/EQ-5D-3L)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG</td>
<td>8.25 (1.40)</td>
<td>6.93 (1.80)</td>
<td>6.95 (1.85)</td>
<td>−0.69</td>
<td>−0.63</td>
<td>−0.14</td>
<td>−0.10</td>
</tr>
<tr>
<td>IG</td>
<td>8.61 (1.68)</td>
<td>7.17 (1.63)</td>
<td>7.12 (1.67)</td>
<td>−0.72</td>
<td>−0.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality of life (EQ VAS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG</td>
<td>51.34 (17.69)</td>
<td>69.16 (19.96)</td>
<td>69.48 (21.34)</td>
<td>0.60</td>
<td>0.76</td>
<td>0.16</td>
<td>0.10</td>
</tr>
<tr>
<td>IG</td>
<td>49.20 (16.61)</td>
<td>65.92 (20.72)</td>
<td>67.39 (21.74)</td>
<td>0.75</td>
<td>0.74</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Between-group effect sizes comparing CG versus IG at time 2 (T2).
<sup>b</sup>Between-group effect sizes comparing CG versus IG at time 3 (T3).
<sup>c</sup>BDI-IA: Beck Depression Inventory-Spanish version.
<sup>d</sup>CG: control group (treatment as usual).
<sup>e</sup>IG: intervention group (ASCENSO + treatment as usual).

**Secondary Outcomes**

The secondary outcome of quality of life (EuroQol/EQ-5D-3L) improved in both groups ($F_{2,1067}=37.87; P<.001$), but group ($F_{1,955}=1.64; P=.21$) and group x time effects ($F_{2,767}=0.24; P=.79$) were not statistically significant (Table 2). The scores decreased from baseline (mean 8.43; 95% CI 8.18-8.68) to 6 months (mean 7.05; 95% CI 6.76-7.33; P=.001); however, there was no change at 9 months (mean 7.03; 95% CI 6.74-7.33; P=.93). Within-group effect sizes were medium-large ($d=−0.63$ to $−0.72$) at 6- and 9-month assessments in both the CG and IG.

Similarly, for the EQ VAS (scale from 1 to 100), the model did not indicate statistical significance for either group ($F_{2,1186}=1.23; P=.27$) or group x time ($F_{2,667}=0.13; P=.88$) effects; that is, the quality of life did not differ between the groups over time. In addition, there was a time effect ($F_{2,4390}=51.69; P<.001$) in both groups’ quality of life increase from baseline to 6 months (baseline: mean 50.27, 95% CI 47.30-53.24; 6 months: mean 67.54, 95% CI 64.32-70.76; $P<.001$), but there was no change at the 9-month assessment (mean 68.44; 95% CI 65.13-71.75; P=.91). Again, within-group effects were medium-large size ($d=−0.60$ to $−0.76$) at 6- and 9-month follow-up in both the CG and IG.

**Treatment Adherence**

Table 3 shows that there were no differences between groups (all $P$ values $>.05$) when considering both the number of appointments and percentage of attended sessions with each type of face-to-face treatment professional: psychiatrist, physician, or psychologist. Across the different components of TAU, the median of participants attended approximately 70% of appointments (except for CG participants at psychiatry sessions).

Additionally, health center reports at the 9 months follow-up indicated that there were no differences between the groups related to dropout rates ($P=.07$). The dropout rate for face-to-face treatment component was 54% (45/84) for IG versus 39% (32/83) for CG.
Table 3. Face-to-face treatment adherence.

<table>
<thead>
<tr>
<th>Face-to-face intervention rate</th>
<th>IG(^a) values</th>
<th>CG(^b) values</th>
<th>P value(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
<td>Number</td>
</tr>
<tr>
<td><strong>Medical/physician control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointments</td>
<td>7.44 (3.87)</td>
<td>8 (6)</td>
<td>82</td>
</tr>
<tr>
<td>Attendance percentage(^d)</td>
<td>71.27 (20.66)</td>
<td>75 (26.16)</td>
<td>82</td>
</tr>
<tr>
<td><strong>Psychiatry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointments</td>
<td>5 (5.07)</td>
<td>2 (10)</td>
<td>14</td>
</tr>
<tr>
<td>Attendance percentage</td>
<td>51.51 (47.12)</td>
<td>73.90 (100)</td>
<td>14</td>
</tr>
<tr>
<td><strong>Psychotherapy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointments</td>
<td>14.99 (9.77)</td>
<td>12.50 (14)</td>
<td>84</td>
</tr>
<tr>
<td>Attendance percentage</td>
<td>74.35 (17.37)</td>
<td>76.33 (24.18)</td>
<td>84</td>
</tr>
</tbody>
</table>

\(^a\)IG: intervention group (ASCENSO + treatment as usual).
\(^b\)CG: control group (treatment as usual).
\(^c\)P=bilateral significance of the Mann-Whitney test.
\(^d\)Percentage of attendance: number of attended sessions divided by the total number of appointments.

Discussion

Principal Findings

The aim of this study is to evaluate the effectiveness of an adjunctive online intervention to enhance face-to-face treatment of patients with depression. This is the first RCT carried out in a Latin American health care setting on this type of blended care, in which part of the treatment was carried out face to face, with other parts being delivered online and with no reduction of any component of the TAU in either the duration or frequency of sessions.

Currently, there is an ongoing discussion about the optimal way to blend internet and face-to-face interventions [18,48-50], with some limited evidence existing regarding the effectiveness of these blended treatments [23-27,51].

As the results indicated, while both groups showed large within-group effect sizes, the blended approach did not improve the effectiveness of the usual care delivered at the mental health center either in terms of reduction of depressive symptoms or in the improvement of quality of life. One possible explanation for this lack of superiority may be the type and intensity of face-to-face treatment and the high effectiveness of TAU.

Comparison With Prior Work

Previous studies have shown that internet interventions are effective in reducing depressive symptomatology when they are compared to a waiting list and placebo [14,52,53]. In fact, ICT-based interventions compared to a waiting list have shown increased effect compared to those including TAU as a control group [14] but have shown no superiority compared to active control groups [16]. The pre-post effect sizes of TAU and the face-to-face treatment adherence results of our study indicate that this comparator consisting of comprehensive medical and psychological care might have been too strong to leave room for ASCENSO to improve outcomes. In contrast, in the 2 previous RCTs that demonstrated the effectiveness of blended care for depression, TAU was associated only with small or moderate effect sizes [23,24].

A second explanation for the results obtained is related to the heterogeneous use of the ASCENSO platform by patients. In fact, a common problem on internet-delivered psychological treatments is the high degree of nonadherence or dropouts [54,55], which limit their effectiveness. This has also been observed in 2 other RCTs on blended interventions for depression in primary care. Both the studies of Gilbody et al [25] and Löbner et al [26] reported extremely low utilization of their very brief internet-based interventions. Compared to these studies, the uptake and utilization of the online intervention in the our study were higher, with only 6% (5/84) participants never logging in to the program and 52% (44/84) of them completing half or more than half of the supportive monitoring assessments over an intervention period of 9 months.

In fact, some theoretical models have been proposed to account for the nonadherence phenomenon in the eHealth literature. For example, Johansson and colleagues [56] indicated that internet treatment characteristics such as workload, text-content complexity, and a demanding treatment process, which do not match personal prerequisites such as daily routines, language skills, and treatment expectations, respectively, are at the base of this nonadherence phenomenon. Other reasons for nonadherence indicated by the authors were presence of negative effects and lack of face-to-face contact.

Also, regarding the possible causes of the heterogeneous use of the ASCENSO platform, aspects such as the credibility of eHealth interventions should also be taken into account and could be at the base of the differences found in the use among the IG participants. In regard to face-to-face psychotherapy, patient-perceived treatment credibility represents a personal belief about a treatment’s logicalness, suitability, and efficaciousness, which varies in a continuum from negative to positive [57]. Meta-analyses have shown both that positive expectations [58] and the perceived credibility toward the
treatment [59] are associated with symptom improvement although their impact is small in magnitude. Given the relative novelty of the use of technologies in the treatment of mental health problems or their use as a complementary tool to usual treatment in local settings, it could be hypothesized that the lack of a user’s personal experience with these technologies (or their lack of presence in a potential user’s social network) could generate negative expectations toward them, and therefore individuals might be less willing to use them.

In comparison to the aforementioned internet treatment characteristics, the ASCENSO platform can be considered a low-demand intervention. Its design is such that it is the patients’ themselves who decide when and how to use the platform since the patients have to access the website and read simple psychoeducational information or actively request assistance through telephone or chat. Only the supportive monitoring goes “from the platform to the end user” and demands the patient’s attention. Therefore, it is the only situation that could be perceived as an overload. However, future research should focus on ways to enhance adherence to ASCENSO and allow us to distinguish when the non-use of this platform indicates that people are using it according to their perceived needs.

Despite there being a dearth of studies in the Latin American context on internet-based interventions in mental health, the few studies conducted tend to show high levels of acceptability but relatively low levels of use and adherence [28,30]. The differential use of technology has been related in some investigations to the levels of patients’ familiarity with technological devices and interventions; that is, their technological literacy [60]. Additionally, the levels of personalization of the interventions and the proximity of the content are important [61].

A subsequent qualitative study that addresses expectations and experiences of patients may help to clarify the reasons for (non)adherence and dropout from the online intervention and would help us to clarify to what extent patients adapt the use of the available eHealth components to their needs. Moreover, this kind of research could inform us how to improve future online and blended interventions along the lines of persuasive design and user-developer co-design tools to favor user adherence [62-66].

Although the appropriate way to measure effectiveness in clinical trials is through intention-to-treat analysis, it accounts for intervention effectiveness regardless of the degree of treatment compliance. However, the effect of offering a program is not necessarily the same thing as the impact of participating on it. Therefore, intention-to-treat analysis does not make “what works for whom” clear [55,67]. Thus, using a “treatment on the treated” analysis that is able to show the impact of program participation could be another future line of research, which would be particularly interesting if used in contexts where it is feasible to encourage more participation.

**Strengths and Limitations**

The strengths of this study are its design (an RCT with an active control group), the use of structured interviews to confirm clinical diagnosis, and the measurement of treatment utilization and adherence to TAU via objective records from the health care provider. Although many studies on ICT-based interventions have been criticized for the online and community-based recruitment of participants with mild to moderate symptom severity, participants in this study were recruited in a clinical setting and showed medium to severe depression.

This study also has several limitations including difficulties in the blinding group assignment to patients and medical staff, difficulties in standardizing the measurement time (based on the complex nature of the intervention which contains different interacting components), the use of self-report scales for clinical variables, and the limited availability of adequate indicators to measure the use. These factors limit the generalizability of the results to medium to severe depressive patients with low comorbidities. This is a relevant limitation since the recruitment process showed that a considerable number of individuals had 1 or more comorbidities, which was considered to be an exclusion criterion in this study, particularly a history of previous suicidal ideation or attempts.

Additionally, the fact that the face-to-face treatment was carried out in a private health center could have biased the sample by excluding people with low socioeconomic status and those who lack health insurance (eg, undocumented immigrants). Although the Chilean explicit health guarantee system has expanded the coverage of depression treatment, guaranteeing care, ensuring its quality, and establishing a financial protection system (by defining a maximum copayment), the existence of a payment requirement could be an access barrier for people with fewer economic resources.

Finally, one of the limitations of the current study is its limited replicability since it was implemented in the context of routine health care, which might have been influenced by extraneous variables despite the use of randomization. Nonetheless, it is important to point out that although carrying out a study in a natural context makes replication difficult, doing so provides ecological validity [68], showing the usefulness (or not) of the intervention tool as it would be used in routine health care. In fact, there is extensive research that reports difficulties in replicating the results of manualized or highly standardized interventions in applied contexts, in which results are often less promising [69]. Thus, our findings may be a valuable contribution to decision-makers in routine health care settings.

**Conclusions**

This study allows us to progress the understanding of the effectiveness of blended therapy. The study adds to previous studies that have demonstrated that ICT-based interventions can feasibly be implemented in Latin America [28,29,62], a context with high levels of mental health problems [1] and low access to professional treatment [5]. However, the blended treatment approach of ASCENSO did not prove superior in this trial compared to TAU alone. This result has ecological validity since it was implemented in a routine health care setting, offering valuable information for decision-makers about the usefulness of implementing automated systems as a complement to usual care.
At a local level, the results obtained regarding the low use of the platform and lack of improvement in depressive symptoms compared to the effect of only face-to-face treatment are different from what was observed in the European context [70]. These differences might indicate that it is not enough to adapt interventions and that it is increasingly necessary to develop them based on the particular sociocultural, economic, and social health characteristics of the users [61]. Mental health treatment in Latin America is still limited, with scarce specialized human resources, low frequency of treatment sessions, and insufficient postdischarge controls, especially in rural and remote areas. For this reason, it is necessary to continue exploring remote internet-based interventions, especially in Chile where internet penetration is massive [71] and because it has one of the highest prevalences of depressive disorders worldwide [72].

The relevance of the development of effective treatment strategies that reduce or do not require face-to-face contact has increased due to the recent global pandemic we have been facing since the COVID-19 outbreak. It is important to make treatment accessible even in lockdown conditions and respond to the reported associated negative impact this pandemic has had on mental health. This is particularly relevant for the Chilean context where it has been reported that after the COVID-19 outbreak, more than 60% of assessed individuals are experiencing a negative emotional impact and are expressing concerns about the future, general health, work instability, and the current political instability the country [73].

Future interventions might benefit from more actively and explicitly integrating the contents and activities of the ASCENSO platform into the face-to-face therapeutic space. For example, using the results of questionnaires or suicide alarms (among others) as part of the information discussed in the therapeutic session may be useful. Thus, achieving greater integration between the technological and face-to-face treatment components may potentially enhance these components. This would allow patients to process the information provided by the algorithms of the platform, so that they do not feel a mismatch between what the program is offering them and their true state or necessities, a condition that has previously been identified as an important barrier to the use of internet-based interventions [56,74].

Furthermore, future interventions need to carefully study the motivation and preferences of potential users. In addition, public health efforts to increase awareness about mental health issues and provide guidance on where to seek and receive help seem to be required to ensure that more patients receive appropriate, professional help.

Acknowledgments

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Authors' Contributions

JCP, AEC, CC, MK, MM, SB, DED, and SG contributed to the conception and design of study. JCP, AEC, CC, SB, and MK obtained study funding. JCP, OF, and CC supervised the implementation of the study. CC and SG facilitated the contact for recruiting the study participants. JCP and MM conducted data analysis and interpretation of article data. All authors contributed to drafting the article and revising it critically for important intellectual content. All authors gave final approval of the version to be published.

Conflicts of Interest

Intellectual property of the content of ASCENSO platform belongs to “Fundación para la Investigación en Depresión y Personalidad, Chile,” this paper’s authors (AEC, CC, SB, MM, DED, and MK), and other researchers (Jorge Olivares and Graciela Rojas). The Center for Psychotherapy Research, University Hospital Heidelberg, owns the copyright of the computer source code and software that support the ASCENSO platform. The authors have no other financial or nonfinancial conflicts of interest to declare.

Multimedia Appendix 1
ASCENSO platform overview.
[MOV File , 31331 KB - mental_v8i12e26814_app1.mov ]

Multimedia Appendix 2
CONSORT eHealth checklist (version 1.6.1).
[PDF File (Adobe PDF File), 1150 KB - mental_v8i12e26814_app2.pdf ]

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**Abbreviations**

- CBT: cognitive behavioral therapy
- CG: control group
- iCBT: internet-based cognitive behavioral therapy
- ICT: internet cognitive therapy
- IG: intervention group (IG)
- IPDE: The International Personality Disorder Examination
- MDD: major depressive disorder
- MINI: The Mini International Neuropsychiatric Interview
- RCT: randomized controlled trial
- TAU: treatment as usual

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Examining the Theoretical Framework of Behavioral Activation for Major Depressive Disorder: Smartphone-Based Ecological Momentary Assessment Study

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Abstract
**Background:** Behavioral activation (BA), either as a stand-alone treatment or as part of cognitive behavioral therapy, has been shown to be effective for treating depression. The theoretical underpinnings of BA derive from Lewinsohn et al.’s theory of depression. The central premise of BA is that having patients engage in more pleasant activities leads to them experiencing more pleasure and elevates their mood, which, in turn, leads to further (behavioral) activation. However, there is a dearth of empirical evidence about the theoretical framework of BA.

**Objective:** This study aims to examine the assumed (temporal) associations of the 3 constructs in the theoretical framework of BA.

**Methods:** Data were collected as part of the “European Comparative Effectiveness Research on Internet-based Depression Treatment versus treatment-as-usual” trial among patients who were randomly assigned to receive blended cognitive behavioral therapy (bCBT). As part of bCBT, patients completed weekly assessments of their level of engagement in pleasant activities, the pleasure they experienced as a result of these activities, and their mood over the course of the treatment using a smartphone-based ecological momentary assessment (EMA) application. Longitudinal cross-lagged and cross-sectional associations of 240 patients were examined using random intercept cross-lagged panel models.

**Results:** The analyses did not reveal any statistically significant cross-lagged coefficients (all \( P > .05 \)). Statistically significant cross-sectional positive associations between activities, pleasure, and mood levels were identified. Moreover, the levels of engagement in activities, pleasure, and mood slightly increased over the duration of the treatment. In addition, mood seemed to carry over, over time, while both levels of engagement in activities and pleasurable experiences did not.

**Conclusions:** The results were partially in accordance with the theoretical framework of BA, insofar as the analyses revealed cross-sectional relationships between levels of engagement in activities, pleasurable experiences deriving from these activities, and enhanced mood. However, given that no statistically significant temporal relationships were revealed, no conclusions could be drawn about potential causality. A shorter measurement interval (eg, daily rather than weekly EMA reports) might be more attuned to detecting potential underlying temporal pathways. Future research should use an EMA methodology to further investigate temporal associations, based on theory and how treatments are presented to patients.


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**KEYWORDS**
depression; behavioral activation; theoretical framework; ecological momentary assessment; random-intercept cross-lagged panel model; behavior; framework; EMA; smartphone; mental health; treatment; engagement; mood

**Introduction**

Most psychotherapeutic treatments for depression are underpinned by a clear theoretical framework of how a specific therapy is supposed to engender change in patients’ mood states. In light of the fact that various psychotherapies have been proven to be effective for treating depression (eg, [1-4]), one would perhaps assume that theoretical frameworks are also evidence based. However, demonstrating that a therapy is effective is not the same as providing evidence or explanations as to how it actually works [5-8], that is, the process through which a certain variable leads to change in another variable [6,7]. In addition to effectiveness studies that target an overall treatment package, understanding how therapy targets the interplay between specific factors that are believed to be of importance can ultimately give rise to specific treatment recommendations or improvements to treatment protocols (eg, [6-10]). Conducting a verification of the underlying theoretical framework of a form of psychotherapy can help optimize treatment strategies (eg, [6-10]), that is, direct better, stronger, or different treatment strategies that underpin the critical processes of the treatment (eg, [6-10]).

One such effective psychotherapeutic intervention for depression is behavioral activation (BA). The empirical evidence for BA is both extensive and convincing; it can be offered either as a stand-alone treatment or within the setting of cognitive behavioral therapy (CBT) [11-13]. BA is based on Lewinsohn et al’s [14,15] theory of depression, which purports that when a person is depressed, they tend to engage less in pleasant or meaningful activities, resulting in them experiencing less pleasure, which, in turn, leads to an increased depressed mood, and so on. From this perspective, persons end up in a vicious circle of depression [14,15], as depicted in the left panel of Figure 1.
Through BA, patients learn from self-monitoring their everyday activities and related mood that the way they behave affects the way they feel, while conversely, the way they feel affects the way they behave [11,12,16]. Therapists motivate their patients to schedule and engage in everyday pleasant activities [12,17]. Patients are informed that engaging in these activities may not lead them to immediately experience greater pleasure and that experiencing pleasure may not enhance their mood straightaway. Rather, they are told that this is a process that requires time and that positive results will follow in due course as they continue to engage in pleasurable activities [12,17]. The circle of BA, as it is referred to in Lewinsohn et al’s [14,15] model is shown in the right panel of Figure 1. As one can see in Figure 1, BA aims to break the vicious circle of depression by increasing the patient’s engagement in pleasant activities.

Currently, there is a relative dearth of empirical evidence available concerning the assumed causal pathways in the theoretical framework of BA [10,18-20]. Janssen et al [20] sought to address this gap in extant knowledge by conducting a systematic review in which they investigated the mediators of BA for depression. In this review [20], the evidence for the mediating role played by both engaging in pleasant activities and experiencing pleasure was not consistently replicated across the considered studies. However, the authors did conclude that their review was not without its limitations. First, some of the included studies were of poor methodological quality, while different questionnaires were used to assess the mediators. Moreover, the results of the mediational analysis did not necessarily explain the processes via which change occurs, insofar as most studies solely focused on unidirectional relationships, in addition to lacking temporal dependency [9,20]. It is thought that the reciprocal interactions and longitudinal associations between different variables determine psychological functioning [21]. Thus, to successfully delineate the theoretical framework of BA, further research is needed that considers reciprocal interactions and longitudinal associations by using ecological momentary assessment (EMA) methods [8,10,20].

EMA methods allow us to trace temporal pathways of change across different variables among patients during the course of treatment [9,10,20,22]. With EMA methods, or real-time monitoring, persons are routinely asked to report on their mood and other related phenomena while they are in their own ecological habitat (eg, [23-25]). Traditionally, EMA was conducted via paper-and-pencil diaries as well as via stand-alone technical devices [25,26]. Today, EMA is often facilitated by smartphone-based applications [25,27,28]. The fact that phenomena are measured close to their occurrence helps to avoid recall bias as much as possible [29,30]. This fact is especially pertinent with respect to patients suffering from mood disorders, as prior research has shown that recall among this patient group is confounded by current feelings, not to mention greater recall of unpleasant activities than pleasant activities [31-33]. The past several decades have seen a surge in the use of EMA methods in mood disorder research.

This paper aims to examine the assumed (temporal) associations of the 3 constructs in the theoretical framework of BA among major depressive disorder (MDD) patients, who monitored their engagement in pleasant activities, the pleasure they experienced as a result of conducting these activities, and their related mood states using smartphone-based EMA during the course of blended CBT (bCBT) in routine mental health care (MHC). bCBT integrates face-to-face (f-t-f) sessions with both web- and smartphone-based components into 1 treatment protocol [34]. Data from a subsample of the patients receiving bCBT and smartphone-based EMA (N=240) as part of the European Comparative Effectiveness Research on Internet-based Depression Treatment treatment-as-usual (TAU) (E-COMPARED) trial were used to investigate the longitudinal reciprocal associations [35,36].
Methods

Participants, Procedure, and Treatment Protocol

E-COMPAReD is a randomized controlled, non-inferiority trial that was conducted across 8 European countries. The principal aim of the trial was to compare both the clinical effectiveness and cost-effectiveness of bCBT to treatment-as-usual (TAU) for MDD. For the trial, a generic bCBT protocol was established [35,36]. The study protocol of E-COMPAReD gives a complete overview of the bCBT protocol [36]. In short, the core components of the bCBT protocol mirrored traditional f-t-f CBT: (1) psychoeducation, (2) BA, (3) cognitive restructuring, and (4) relapse prevention. However, with bCBT, f-t-f sessions were replaced by and alternated with online modules [34,37]. The themes of the f-t-f sessions matched the content of the online sessions. The more practical components were delivered online (ie, psychoeducation, completing homework assignments). The focus of the health care professional during the f-t-f session was on process-related treatment outcomes (ie, discussion of feelings and thoughts), discussing homework assignments, and providing support [36]. Although the protocols included the same core components (including BA), bCBT was delivered in the primary care of specialized MHC and therapists were granted some freedom to customize the protocol to their local needs. To make sure the protocol suited their local context, the therapists were allowed to adapt the treatment duration and the ratio between the number of f-t-f and online sessions. In addition, therapists were allowed to include some additional components (eg, mindfulness or problem solving), but this could not take up more than 25% of the total treatment (f-t-f and online sessions combined). Moreover, based on local availability, different web- and smartphone-based applications were used. Table 1 shows the bCBT format per country.

Table 1. Blended cognitive behavioral therapy format per country.

<table>
<thead>
<tr>
<th>Country</th>
<th>Type of care</th>
<th>Treatment duration (weeks)</th>
<th>Face-to-face sessions, n</th>
<th>Web-based modules, n</th>
<th>Total number of sessions, n</th>
<th>Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>Primary</td>
<td>11-13</td>
<td>6</td>
<td>10</td>
<td>16</td>
<td>Alternate</td>
</tr>
<tr>
<td>Poland</td>
<td>Primary</td>
<td>6-10</td>
<td>7</td>
<td>6</td>
<td>13</td>
<td>Alternate</td>
</tr>
<tr>
<td>England</td>
<td>Primary</td>
<td>11</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>Alternate</td>
</tr>
<tr>
<td>Spain</td>
<td>Primary</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>20</td>
<td>Alternate</td>
</tr>
<tr>
<td>Sweden</td>
<td>Primary</td>
<td>10</td>
<td>4</td>
<td>6</td>
<td>10</td>
<td>Alternate</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>Specialized</td>
<td>18-20</td>
<td>10</td>
<td>9</td>
<td>19</td>
<td>Alternate</td>
</tr>
<tr>
<td>France</td>
<td>Specialized</td>
<td>16-20</td>
<td>8</td>
<td>8</td>
<td>16</td>
<td>Alternate</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Specialized</td>
<td>18</td>
<td>9</td>
<td>9</td>
<td>18</td>
<td>Alternate</td>
</tr>
</tbody>
</table>

As with traditional f-t-f CBT, the BA component in this study was based on Lewinsohn et al’s [14,15] theory of depression and aimed at increasing patients’ engagement in activities. The BA component started early in treatment and remained a recurring topic in the (f-t-f) sessions throughout the course of treatment. During the f-t-f sessions, the patient was motivated by the health care professional to schedule and engage in (potential) pleasant activities. The patient could (re)read the rationale of BA online, read a so-called activity-list that could be used for inspiration, and use the platform as a tool to specify and schedule which activities to engage in that week. A smartphone-based EMA application was used to monitor engagement in activities, pleasure experienced as a result of these activities, and the mood state over the course of treatment. Although the f-t-f and online sessions were only approximately (alternated) once a week, the patient was encouraged to take an active role in their therapy and to practice in their own environment in between the sessions.

Between February 2015 and December 31, 2017, patients were recruited from primary care (Germany, Poland, Spain, Sweden, and the United Kingdom) and outpatient departments of specialized MHC settings (France, the Netherlands, and Switzerland) [35,36]. Patients were asked by their health care professionals whether they were willing to take part in the study. The inclusion criteria were as follows: (1) must be at least 18 years of age; (2) meet the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), criteria for MDD, as confirmed by Mini International Neuropsychiatric Interview (M.I.N.I.) version 5.0 [38,39]; and (3) report mild-to-severe depressive symptoms (score of 5) on the Patient Health Questionnaire-9 (PHQ-9) [40,41]. The exclusion criteria were as follows: (1) already receiving psychological treatment for depression in a primary or specialized MHC setting; (2) be at high risk for suicide or have a DSM-IV diagnosis of substance dependence, bipolar disorder, psychotic illness, or obsessive compulsive disorder, as confirmed by M.I.N.I. version 5.0 [38,39]; (3) not able to comprehend the spoken and written language of their country of residence; (4) not have access to a computer with a fast internet connection; and (5) not have a smartphone compatible with the Android operating system or be unwilling to carry a smartphone provided by the research team. For more in-depth information about the specifics of both country and setting recruitment procedures, please see elsewhere [35,36].

Patients who met the inclusion criteria (N=943) were randomly allocated to receive either bCBT (n=476) or TAU (n=467). For the purposes of this study, only patients who were randomized to receive bCBT were initially selected, since patients who were allocated to the TAU group were not invited to complete the smartphone-based EMA measures. Of the 476 bCBT patients, 152 did not receive treatment (never attended the first f-t-f session, dropped out after the first f-t-f session, never logged...
onto the platform) or did not provide any weekly EMA reports. Of the remaining 324 patients, all patients reported on their mood, but 84 of them failed to complete reports on their levels of activities or pleasure. This led to an analytic sample of 240 patients who reported on all 3 variables of interest (activities, pleasure, and mood) in the weekly EMA reports. Potential selection bias was examined by analyzing potential differences in terms of demographic and clinical characteristics between the E-COM-PARED patients who were randomly allocated to receive bCBT but did not meet the study’s inclusion criteria (n = 476 – 240 = 226) and patients who were included in this study (N=240). The results of these analyses are presented in the Result section.

Measures

Demographic and Clinical Characteristics

At baseline, information about demographic and clinical characteristics was gathered. The basic demographics included age, gender, and educational level. This information was obtained through a web-based questionnaire. The clinical characteristics included current MDD diagnosis and other (comorbid) psychiatric diagnoses, severity of depression, and use of antidepressant medication. The presence of current MDD and current comorbid psychiatric disorders (dysthymia, panic disorder with or without agoraphobia, agoraphobia, social phobia, generalized anxiety disorder, posttraumatic stress disorder) was defined according to DSM-IV criteria [39] and established using M.I.N.I. version 5.0 [38]. Patients reported on the severity of their depression by completing a web-based version of the PHQ-9 [40-42]. This questionnaire contains 9 items, each of which covers 1 DSM-IV criterion of MDD [39]. Questions are answered on a scale from 0 (not at all) to 3 (nearly every day), as experienced during the prior 2-week period. Sum scores indicate both the presence and the severity of depressive symptoms: none (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), and severe depressive (20-27) symptoms [40,41]. The last item of the PHQ-9 evaluates suicidal ideation (ie, passive thoughts of death or self-injury). The researchers of E-COM-PARED did not actively monitor or respond to reports of suicidal ideation, as this was not a stand-alone online treatment service. The MHC professional providing the therapy was considered well qualified and trained to identify and address suicide risk in their patients.

Smartphone-Based EMA of Pleasant Activities, Pleasure, and Mood

Information about activities, that is, the level of engagement in pleasant activities, on the day of reporting was gathered through the following question: “To what extent did you accomplish pleasant activities today?” The question was answered on a visual analogue scale (VAS) that ranged from 1 to 10, with 1 precision digit after the decimal point and higher scores indicating more engagement in pleasant activities. Pleasure, that is, the subjective appraisal of the pleasure experienced through these activities, on the day of reporting was measured through the question “How much did you enjoy activities today?” This question was answered on a VAS scale that ranged from 1 to 10, with 1 precision digit after the decimal point and higher scores indicating greater pleasure experienced. Lastly, information pertaining to the patients’ current mood was collected through the following question: “How is your mood right now?” This question was answered on a VAS scale that ranged from 1 (worst) to 10 (best), with 1 precision digit after the decimal point. Higher scores thus indicated more engagement in pleasant activities, greater pleasure experienced, and better mood on the day of reporting.

The EMA protocol varied over the course of the treatment. During both the first and the last 7 days of treatment, patients were prompted to rate their mood on 3 separate occasions each day (around 10:00 AM, 8:00 PM, and a random time between 10:00 AM and 10:00 PM). During these specific weeks, at the 8:00 PM prompt, patients were also invited to report on their level of pleasant activities and experienced pleasure. From the second week until the last week of treatment, patients were prompted to rate their mood once a day at a random time between 10:00 AM and 10:00 PM. Moreover, on 1 random evening (8:00 PM) each week, patients were also invited to rate their engagement in pleasant activities, experienced pleasure, and mood. Although patients were instructed to complete the questions as quickly as possible, they were given a time frame of 60 min. Additionally, patients were also free to report their mood at any time other than the fixed prompts. The EMA protocol varied over the course of treatment, as the EMA component was used for supportive means in the treatment. The first week was for patients to get used to the EMA application, but it was considered unrealistic to expect from patients in a clinical setting to complete a full diary every day throughout the course of treatment [35,36].

For this study, weekly averages of the EMA reports were calculated in order to ensure that all patients had an equal number of measurement points. The weekly averages of the 3 questions were calculated over a 3-month period, which resulted in 12 weekly EMA reports of activity, pleasure, and mood for each patient, as 3 months was deemed an appropriate timespan for examining the process of change, given the average length of bCBT protocols [36].

Statistical Analysis

Descriptive statistics were calculated for both baseline demographics and clinical characteristics. To answer the main research questions, linear mixed model (LMM) and random-intercept cross-lagged panel model (RI-CLPM) analyses were conducted. First, we performed multiple imputation (MI, m=100) to impute the missing EMA weekly reports. In the data set, 18%, 54%, and 54% of the 12-week reports were missing for mood, pleasure, and activity, respectively. Full information maximum likelihood (FIML) and MI are 2 types of techniques that are considered best for handling missing data [43,44]. When conducting an RI-CLPM in RStudio, the default setting to handle missing observations is FIML [45]. We, however, chose to apply MI since this technique allows for a more convenient way to incorporate auxiliary variables in the model when running an RI-CLPM in RStudio. Auxiliary variables are additional covariates that are included in the model next to the variables ultimately analyzed in the final analysis. It is argued that adding auxiliary variables can substantially improve the handling of missing data [46].
We performed MI using the Amelia II-R-package (version 1.7.6) [47] as this allows for MI of time series data. The package uses a bootstrap-based expectation-maximization bootstrapping algorithm to impute missing observations. It uses all of the information present in the data set, allows for previously known information to be incorporated into the imputation model, and provides diagnostics of the model [47]. In this study, the patient ID was included as a fixed effect. Time was considered by including leads (previous measurement \([t-1]\)) and lags (next measurement \([t+1]\)) into the imputation model. Previously known information was included by setting a logical bound between 1 and 10, as this was the answer range for the EMA questions. Auxiliary variables included gender, age, educational level, comorbid DSM-IV diagnoses at baseline, PHQ-9 at baseline, PHQ-9 after 3 months, and antidepressant usage at baseline. Diagnostics of the imputation model were checked by examining overimputation diagnostic plots. Please see Multimedia Appendix 1 [48-54] for more information about both missing data and the MI procedure.

Next, the development of engaging in activities, pleasure experienced, and mood state over the duration of the treatment was examined with 3 separate LMMs. Weekly averages of the EMA reports were added as dependent variables. To test our main research questions, unconstrained RI-CLPMs were estimated. Again, the weekly averages of the EMA reports were analyzed. The RI-CLPM, as proposed by Hamaker, Kuiper, and Grasman [55], is an extension of the traditional CLPM [56]. The CLPM is an expedient method for describing cross-lagged associations between variables [56]. However, 1 key drawback of the traditional CLPM is that within-person effects cannot be extracted; this is problematic, given that these effects reflect the intrapersonal processes that are needed in order to be able to draw conclusions about how changes over time in one variable are linked to changes over time in another variable, with respect to the same person. The RI-CLPM decomposes the between- and within-person effects. Figure 2 provides a visual representation of an RI-CLPM.

**Figure 2.** RI-CLPM for 4 measurement points. \(\alpha\) and \(\zeta\) are autoregressive regression coefficients; \(\gamma\) and \(\delta\) are same-week (residual) covariances, \(\beta\) and \(\epsilon\) are cross-lagged regression coefficients, and \(\eta\) is between-person correlation. Based on Hamaker, Kuiper, and Grasman [55]. RI: random intercept; RI-CLPM: random-intercept cross-lagged panel model.

The RI-CLPM involves:

- Autoregression coefficients (\(\alpha\) and \(\zeta\)), which represent the carry-over effect (eg, \(X_t\) on \(X_{t+1}\)). A negative coefficient indicates that if the score for \(X\) in one week is above the overall mean, then the score for \(X\) in the following week is likely to be below the overall mean, and vice versa. Conversely, a positive coefficient indicates that a higher or lower score for \(X\) in one week corresponds to a higher or lower score for \(X\) in the following week.
- The cross-lagged coefficients (\(\beta\) and \(\epsilon\)) indicate the extent to which 2 variables influence each other. The coefficients show the extent to which any deviation in variable \(X\) in one week is related to any deviation in variable \(Y\) in the following week, when controlled for the autoregression of \(Y\).
- The covariance (\(\gamma\)) indicates the association between \(X\) and \(Y\) in the first week, while the same-week residual covariances (\(\delta\)) indicate the covariant change, that is, the extent to which a within-person change in \(X\) is associated with a within-person change in \(Y\) in the same week.
- The association between the random intercepts (RIs; \(\eta\)), which reflects the between-person effects over the course of the treatment.

The model fit of the RI-CLPMs was evaluated with (1) the \(P\) value of the \(\chi^2\) test statistic, (2) the standardized root-mean-square residual (SRMR), (3) the standardized...
Results

Sample Characteristics

Table 2 shows the baseline demographics and clinical characteristics of the analytic sample. The sample comprised 240 participants, 66% (158/240) of which were female. The mean age was 37.3 years (SD 13.2), while 9% (21/240), 34% (80/240), and 58% (139/240) of the patients studied at an elementary, secondary, and higher educational level, respectively. One or more comorbid DSM-IV diagnoses were reported by 59% (142/240) of the patients, while 30% (71/240) were currently using antidepressant medication. Finally, 13% (31/240) of the patients reported mild, 35% (84/240) reported moderate, 30% (72/240) reported moderately severe, and 22% (53/240) reported severe depressive symptoms at baseline.

The analyses that were conducted to examine potential selection bias demonstrated that there was no difference in terms of demographics and clinical characteristics between the E-COMPARED patients who were randomly allocated to receive bCBT but did not meet the study’s inclusion criteria (see the Methods section) (n=476–240=226) and patients who were ultimately included in the study (N=240).

Table 2. Baseline demographics and clinical characteristics of the study sample (N=240).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>158 (66)</td>
</tr>
<tr>
<td>Male</td>
<td>82 (34)</td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
</tr>
<tr>
<td>Elementary</td>
<td>21 (9)</td>
</tr>
<tr>
<td>Secondary</td>
<td>80 (33)</td>
</tr>
<tr>
<td>Higher</td>
<td>139 (58)</td>
</tr>
<tr>
<td><strong>Comorbid DSM-IV(^a) diagnoses(^b)</strong></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>98 (41)</td>
</tr>
<tr>
<td>1</td>
<td>77 (32)</td>
</tr>
<tr>
<td>2 or more</td>
<td>65 (27)</td>
</tr>
<tr>
<td><strong>Antidepressant use</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>169 (70)</td>
</tr>
<tr>
<td>Yes</td>
<td>71 (30)</td>
</tr>
<tr>
<td><strong>PHQ-9(^c)</strong></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>31 (13)</td>
</tr>
<tr>
<td>Moderate</td>
<td>84 (35)</td>
</tr>
<tr>
<td>Moderately severe</td>
<td>72 (30)</td>
</tr>
<tr>
<td>Severe</td>
<td>53 (22)</td>
</tr>
</tbody>
</table>

\(^a\)DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.

\(^b\)Current comorbid diagnoses included the DSM-IV diagnoses of dysthymia, panic disorder with or without agoraphobia, agoraphobia, social phobia, generalized anxiety disorder, and posttraumatic stress disorder.

\(^c\)PHQ-9: Patient Health Questionnaire-9.
Development of Engagement in Pleasant Activities, Experiencing Pleasure, and Mood During the Course of the Treatment

Over the course of a 12-week period, patients provided weekly EMA reports concerning their activities, pleasure experienced, and mood. Since missing data were imputed with MI techniques (see Multimedia Appendix I), 12 weekly EMA reports for all 3 variables were available for each patient. On average, engagement in activities (B=0.02, SE 0.01, \( t_{849} = 2.03, P = .04 \)), pleasure experienced (B=0.03, SE 0.01, \( t_{943} = 2.95, P = .003 \)), and mood (B=0.04, SE 0.01, \( t_{1350} = 6.2, P < .001 \)) of patients all increased slightly during the course of the treatment. Age, gender, depression severity, and antidepressant usage were not considered confounders in any of the analyses.

Longitudinal Reciprocal Associations in the BA Circle

Reciprocal Associations Between Engaging in Pleasant Activities and Experiencing Pleasure

Figure 3 shows a simplified model for the reciprocal associations between engaging in pleasant activities and experiencing pleasure. The fit indices indicate that the model fits well (\( \chi^2_{217} = 52.35, P = .99, \text{SRMR} = 0.05, \text{RMSEA} = 0.00, \text{CFI} = 1.00 \)).

Reciprocal Associations Between Experiencing Pleasure and Mood

Figure 4 shows a simplified model for the reciprocal associations between experiencing pleasure and mood. The fit indices indicate that the model fits well (\( \chi^2_{217} = 91.67, P = .99, \text{SRMR} = 0.08, \text{RMSEA} = 0.00, \text{CFI} = 1.00 \)).

At the within-person level, none of the cross-lagged coefficients were statistically significant; engagement in activities was not predictive for experiencing pleasure, nor was the opposite the case. Regarding the autoregression coefficients, only 2 autoregressive paths were significant: the autoregressive path of engaging in activities between weeks 2 and 3 (B=0.33, SE 0.12, \( P = .01 \)) and the autoregressive path of experiencing pleasure between weeks 2 and 3 (B=0.30, SE 0.12, \( P = .02 \)). The positive significant autoregressive pathway indicates that if the level of activities engaged in during week 2 was above the overall mean, then the level of activities engaged in during week 3 was also likely to be above the overall mean. This was also the case with respect to experiencing pleasure in weeks 2 and 3. Moreover, both the covariance between activity and pleasure in the first week (covariance=2.47) as well as the residual covariances from weeks 2 to 12 (range residual covariance=1.46-2.07) were statistically significant (all \( P < .001 \)).

This means that increased engagement in pleasant activities was associated with an increase in the pleasure experienced in the same week.

At the between-person level, engaging in activities and experiencing pleasure were strongly correlated (\( r = 0.88, P < .001 \)). This means that over the course of the treatment, patients who engaged more in pleasant activities also reported experiencing greater pleasure than those who engaged less in pleasant activities.
At the within-person level, none of the cross-lagged coefficients were statistically significant. The level of pleasure was not predictive for mood 1 week later, nor vice versa. With regard to the autoregression coefficients, the autoregressive path between weeks 2 and 3 was statistically significant with respect to experiencing pleasure ($B=0.26$, $SE=0.10$, $P=0.01$), while all the coefficients of mood appeared to be positive and significant ($B=0.24-0.45$, $P<0.001$). This positive significant autoregressive pathway thus indicates that if the level of experiencing pleasure (or mood) in week $t$ was above the overall mean, then the level of experiencing pleasure (or mood) in week $t+1$ was also likely to be above the overall mean. Moreover, both the covariance between experiencing pleasure and mood in the first week (covariance=1.52) as well as the residual covariances from weeks 2 to 12 (range residual covariance=0.51-1.01) were statistically significant (all $P<0.001$). This means that an increase in experienced pleasure was associated with an increase in mood in the same week.

At the between-person level, experiencing pleasure and mood were strongly correlated ($r=0.94$, $P<0.001$). This means that over the duration of the treatment, patients who experienced more pleasure also reported being in a better mood than patients who experienced less pleasure.

**Reciprocal Associations Between Mood and Engaging in Pleasant Activities**

Figure 5 shows a simplified model for the reciprocal associations between mood and engagement in pleasant activities. The fit indices indicate that the model fits well ($\chi^2_{217}=98.65$, $P=.99$, SRMR=0.08, RMSEA=0.00, CFI=1.00).

![Simplified RI-CLPM mood and engaging in pleasant activities. The between-person double-headed arrow represents a correlation. Within-person double-headed arrows represent (residual) covariances; single-headed arrows display standardized regression coefficients. Light-gray arrows represent nonsignificant covariances/coefficients. *$P<.001$, **$P=.02$. A: activity; M: mood; RI: Random Intercept; RI-CLPM: random-intercept cross-lagged panel model.](image)

At the within-person level, none of the cross-lagged coefficients were statistically significant. Mood was not predictive of engagement in activities 1 week later, nor vice versa. With regard to the autoregression coefficients concerned, autoregressive paths for mood were found to be positive and significant ($B=0.28-0.46$, $P<0.001$), while for engagement in activities, only the autoregressive path between weeks 2 and 3 ($B=0.24$, $P=0.02$) was significant. Moreover, both the covariance between mood and engagement in activities in the first week (covariance=1.43) as well as the residual covariances from weeks 2 to 12 (range residual covariance=0.50-1.00) were statistically significant (all $P<0.001$). This means that an increase in mood was associated with an increase in engagement in activities in the same week.

At the between-person level, there was a strong correlation between mood and engagement in activities ($r=0.82$, $P<0.001$). This means that over the course of the treatment, patients who experienced improved mood also reported higher levels of engagement in activities.

**Discussion**

**Principal Findings**

This study is a first attempt in examining the (temporal) associations between the 3 constructs of the theoretical framework of BA, which is grounded in Lewinsohn et al’s [14,15] theory of depression, among MDD patients during the course of bCBT. We found no evidence of a temporal relationship between the 3 variables of interest: engagement in pleasant activities, experiencing pleasure, and mood. However, the results did reveal cross-sectional positive relationships between the 3 variables. Moreover, the levels of engagement in activities, pleasure, and mood increased slightly over the course of the treatment. In addition, mood appeared to be self-predictive over time, which was not the case for either engagement in activities or pleasure. Finally, over the course of the treatment, strong positive correlations between engagement in activities, pleasure, and mood were identified at the between-patient level.

**Comparison With Previous Literature**

First, we were interested in examining the temporal dimension of the theoretical framework of BA. In this respect, our findings did not reveal any temporal relationships between engagement in activities and the subsequent pleasure and mood experienced in the following weeks. This result was somewhat surprising as it is not in accordance with Lewinsohn et al’s [14,15] theory of depression, which clearly posits a temporal relationship between engagement in activities and pleasure, pleasure and mood, and mood and activities (see Figure 1). This raises the question of whether the lack of temporal relationships in our study stems from the selected lag (weekly interval).

The selected lag was a consequence of the chosen sampling scheme in the treatment protocol. We could only use the data that were available, and the E-COMPARED study was not designed to investigate the theoretical framework of BA. To avoid false-negative or false-positive findings, it is vitally important to design future studies to include a longer follow-up period.
important to choose the right lag; however, this is difficult as the right lag cannot be standardized but, rather, is completely dependent on the research topic [68,69]. In the case of our study, it could well be that the temporal relationships would have been revealed if the time intervals between the subsequent measurements had been shorter (eg, daily rather than weekly EMA reports).

The question of whether the data were suitable for illustrating temporal relationships is further evoked by the fact that same-week relationships between the 3 examined variables were identified [68,69]. That is, in those weeks when a patient (1) engaged in more pleasant activities, they also reported an increase in pleasure; (2) experienced more pleasure, they also reported a better mood; and (3) reported a better mood, they also engaged in more pleasant activities. Although these within-patient associations are potentially in line with the theoretical framework of BA [14,15], since these same-week relationships are cross-sectional, it cannot be established whether there is causal dominance, equal reciprocal relationships, or cyclical relationships.

Moreover, the analyses highlighted between-patient effects; patients who engaged more in pleasant activities over the course of the treatment also reported experiencing more pleasure. Patients who experienced more pleasure also reported a better mood, while patients who reported a better mood also reported engaging in more activities over the course of the treatment. Although we were primarily interested in intrapatient processes and causal dominance cannot be established, the between-patient effects do complement the intrapatient effects, insofar as the positive relationship between the 3 variables of interest at the between-patient level does fit within the scope of the theoretical framework of BA [14,15]. To the best of our knowledge, this was the first (EMA) study to examine these effects over the course of treatment within a sample of adult MDD patients in routine MHC; prior studies have either focused on comparing healthy controls with depressed persons, who are often recruited from the general population (eg, [70-72]), or investigated activities or pleasure as a mediator of pre- to postdepression severity change after depression treatment [20,73].

**Limitations**

In addition to the question of whether the selected time lag was appropriate, the results should also be considered with a further limitation in mind, namely the proportion of missing weekly EMA reports. In particular, the adherence rates for the engagement in activity and pleasure reports were relatively poor (both 46%). However, we contend that we were able to mitigate this problem by carrying out MI on the missing weekly EMA reports.

**Clinical Implications and Future Research**

This study addresses a noteworthy gap in the extant literature and, as such, can be regarded as constituting an important first step toward establishing evidence for the theoretical framework of BA among MDD patients. To the best of our knowledge, this represents the first study to investigate intrapatient processes of BA during the course of (b)CBT treatment. The results lend at least some empirical support for the underlying theoretical framework of a therapy that is regarded by the American Psychological Association [74] as 1 of the recommended treatments for adult depression. A next step would be to replicate the study across a different data set, possibly with smaller time intervals between the measurements. Moreover, in our study, we focused on whether we could find associations between the 3 key constructs that are part of the theoretical framework of BA for MDD. We do know that BA starts early in treatment and remains a recurring topic in the (f-t-f) sessions throughout the entire course of treatment. However, based on our data, we could not tease apart the influence of other intervention components from the influence of BA, as BA was part of CBT. Whether BA succeeds in activating MDD patients would be an interesting question that should be explored in future work.

**Conclusions**

The results of our study are partially in accordance with the theoretical framework of BA. The analyses demonstrated statistically significant cross-sectional relationships between levels of engagement in activity, pleasure experienced as a result of these activities, and mood. However, as we did not reveal any statistically significant temporal relationships, no conclusions could be drawn concerning possible causality. A shorter measurement interval (eg, daily rather than weekly EMA reports) might be more conducive to detecting potential underlying temporal pathways. Consequently, future research should use an EMA methodology to further investigate these temporal associations, based on theory and how the treatments are presented to patients.

**Acknowledgments**

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**Conflicts of Interest**

DDE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Klinike, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is also stakeholder of the Institute for health training online (formerly GET.ON/ now HelloBetter), which aims to implement scientific findings related to digital health interventions into routine care. IT reports to have received fees for lectures/workshops in the e-mental-health context from training institutes for psychotherapists. All other authors declare that they have no conflicts of interest.
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Abbreviations

BA: behavioral activation
bCBT: blended cognitive behavioral therapy
CFI: comparative fit index
Examining the Theoretical Framework of Behavioral Activation for Major Depressive Disorder: Smartphone-Based Ecological Momentary Assessment Study

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DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
E-COMPARED: European Comparative Effectiveness Research on Internet-based Depression Treatment versus treatment-as-usual
EMA: ecological momentary assessment
FIML: full information maximum likelihood
f-t-f: face-to-face
LMM: linear mixed model
MDD: major depressive disorder
MHC: mental health care
MI: multiple imputation
PHQ-9: Patient Health Questionnaire-9
RI: random intercept
RI-CLPM: random-intercept cross-lagged panel model
RMSEA: root-mean-square error of approximation
SRMR: standardized root-mean-square residual
TAU: treatment-as-usual
VAS: visual analogue scale
Centering Lived Experience in Developing Digital Interventions for Suicide and Self-injurious Behaviors: User-Centered Design Approach

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Abstract

Background: The prevalence of self-injurious thoughts and behaviors (SITB) signals a growing public health crisis. Despite a recognized need for improved and scalable interventions, the field of SITB intervention faces several challenges: existing interventions are often time and resource intensive, most individuals with SITB do not seek formal mental health care, and efficacious treatments are characterized by small effects. Combined, these challenges indicate a need for improved SITB interventions for individuals in formal treatment and those who are not treatment engaged but are at high risk of worsening mental health and future suicide attempts.

Objective: We present a methodological approach and set of techniques that may address these challenges by centering the lived experience of individuals with SITB in the process of developing needed services: user-centered design (UCD).

Methods: We highlight the value of UCD in the context of digital interventions for SITB by describing the UCD approach and explicating how it can be leveraged to include lived experience throughout the development and evaluation process. We provide a detailed case example highlighting 3 phases of the early development process that can be used to design an intervention that is engaging and meets end-user needs. In addition, we point to novel applications of UCD to complement new directions in SITB research.

Results: In this paper, we offer a 2-pronged approach to meet these challenges. First, in terms of addressing access to effective interventions, digital interventions hold promise to extend the reach of evidence-based treatments outside of brick-and-mortar health care settings. Second, to address challenges related to treatment targets and engagement, we propose involving individuals with lived experience in the design and research process.

Conclusions: UCD offers a well-developed and systematic process to center the unique needs, preferences, and perceived barriers of individuals with lived SITB experience in the development and evaluation of digital interventions.

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KEYWORDS
user-centered design; intervention; suicide; nonsuicidal self-injury; lived experience; technology-enabled services; digital intervention; engagement; mobile phone
**Introduction**

**Background**

Suicide is a leading cause of death globally [1], and international rates of nonsuicidal self-injury (NSSI) are also high, with community (nonclinical) prevalence of 17.2% for adolescents, 13.4% for young adults, and 5.5% for those beyond young adulthood [2]. Lifetime prevalence of suicidal ideation is estimated to be between 22.3% and 32.7%, with 12-month prevalence of 10.6% in young adults [3,4]. Upward trends in these rates signal a growing public health crisis.

Despite significant advances in our understanding of the epidemiology and phenomenology of self-injurious thoughts and behaviors (SITB), including suicide and NSSI, several key challenges exist for the field of SITB intervention. First, existing SITB interventions are often time and resource intensive, making them inaccessible to many, and difficult to scale to meet the large and growing need. Second, most individuals with SITB are hesitant to disclose their struggles and do not seek formal mental health care [5-7]. These challenges reflect a need to improve interventions for individuals who make contact with formal treatment settings as well as for those individuals who are not, and do not wish to be, treatment engaged.

Digital mental health interventions (DMHIs) are a promising and viable option to address these challenges because they are efficacious, scalable, and flexible enough to be used within, as an adjunct to, or independent of, formal mental health services. DMHIs typically refer to technology-based interventions that are patient-facing. However, how DMHIs are deployed can vary significantly [8]. For example, DMHIs include stand-alone tools that are self-contained and used by patients for self-management as well as adjunctive tools meant to augment patients’ engagement in face-to-face treatments. DMHIs also vary along a spectrum of human support from fully automated or self-guided tools to those that incorporate digital coaching or lightweight human support to ensure effective use, reduce barriers, fortify points of disconnection [9], and ensure stronger adherence to the tool.

A recent systematic review of DMHIs for SITB found 22 eligible trials: 12 randomized controlled trials (RCTs), 9 single-arm trials, and 1 crossover counterbalanced controlled design [10]. The outcomes included suicidal ideation (n=14), suicide attempt (n=3), NSSI (n=4), and self-injurious behaviors not otherwise specified (n=2). Because of small sample sizes for most outcomes, a meta-analysis was only conducted for suicidal ideation, and the effect size was small (g=−0.12, 95% CI −0.29 to 0.05) for DMHI conditions compared with control conditions. This is similar to trials of standard face-to-face treatments, which have also produced small effects for suicidal ideation (g=−0.09, 95% CI −0.15 to −0.02) and SITB outcomes combined (g=−0.17, 95% CI −0.22 to −0.12) [11]. As most DMHIs are based on these evidence-based treatment models with small effects, this likely limits the potential effectiveness of DMHIs for SITB. Although incorporating user-centered design (UCD) into DMHIs for SITB alone is unlikely to sufficiently address the issue of universally small effect sizes among interventions for SITB, UCD provides a set of methodologies to refine and identify new targets and ensure that interventions are designed to meet end-user needs. Improved alignment between intervention targets and clinical needs and delivery of clinical interventions in forms more acceptable to users can lead to improved engagement—an important potential driver of clinical change [12].

Although studies of DMHIs for SITB have described good patient-reported acceptability and initial engagement with these tools, a rapid decline in engagement is common. This may suggest that although people were interested in receiving help through DMHIs, their experience with these products did not meet their expectations or preferences. Engagement with DMHIs has been a challenge across the field of digital mental health [13,14].

**Stakeholder Input**

To address the challenges of declining DMHI engagement and the stalled effectiveness of existing NSSI and suicide prevention interventions, we suggest including stakeholder input, particularly from individuals with lived experience, in the SITB DMHI design and evaluation process. This will ensure that we are designing highly engaging and effective interventions that focus on broadly applicable treatment targets. Given the sensitivity of working with a population at heightened risk of suicide, there is a need for rigorous ethical review of all study and risk management protocols [15]. Although there has been growing interest in research that incorporates the voices and needs of individuals with lived SITB experience [16,17], there has been little guidance on how best to do so.

In this paper, we describe UCD methodologies as a means to incorporate lived experience in the research process to develop interventions that are highly attuned to the needs of the individuals they are meant to support. Our aims are to (1) describe the UCD approach, (2) show how it can be leveraged to include lived experience throughout the development and evaluation process through a case example, and (3) point to promising opportunities to integrate lived experiences in research processes for SITB interventions.

**Methods**

**Procedures**

In this paper, we illustrate the process of using UCD with individuals with lived experience of SITB. This work was guided by a review of selected works on the design and development of DMHIs for SITB in the existing literature. For simplicity, we chose to illustrate the UCD process in the context of the development of a single DMHI targeting SITB. To select an appropriate case example, multiple coauthors reviewed the literature on DMHI for SITB and considered innovative methods, intervention elements, UCD technique examples, and attention to safety and ethics. The Brite app, a suicide prevention smartphone app that was developed and tested through an RCT at the University of Pittsburgh and University of Texas Southwestern Medical Center, was ultimately chosen as our case example given the aforementioned criteria [18,19]. In the next sections, we discuss the UCD process and prior use of
UCD for SITB interventions; subsequently, we present a detailed case example through the development and evaluation of Brite.

**What Is UCD?**

UCD is an approach that grounds the development of new DMHIs in the specific needs, challenges, and preferences of stakeholders and end users. In the context of DMHIs for SITB, stakeholders may include policy makers, clinicians, caretakers, and friends of individuals with SITB. End users are defined as the individuals whom the intervention is intended to serve and support, for example, individuals with SITB, for patient-facing DMHIs and clinicians or coaches for adjunctive tools. This inclusion of various stakeholders and end users in the design process is characteristic of UCD and has been used to improve the efficacy and acceptability of services.

The key aims of UCD are to increase the usability (ease of use) and usefulness (the extent to which it assists users in achieving their goals) of a technology [20]. UCD also seeks to improve satisfaction with a technology by making it acceptable and more engaging to end users. Although UCD methods are often applied to technology-based products for use in traditional work environments, they have recently been applied to many different contexts and for novel nontechnology purposes, including improving psychotherapy [21], medical care [22], and implementation strategies [23,24]. In the context of DMHIs, UCD has been leveraged to develop tools that closely align with users’ needs, ensure inclusion of the types of content and functionality that users expect, and ensure that the intervention is delivered in an appealing and usable format to seamlessly fit into their lives [25-27].

**A UCD Process**

As a methodological approach, UCD typically includes several iterative phases (Figure 1) that are either formative or summative [20]. Formative UCD processes, including elicitation and design activities, produce an initial version of the intervention, whereas summative processes evaluate the usability of the intervention. Within each phase, different objectives are met using UCD techniques (Table 1). The *elicitation phase* is focused on understanding the specific needs, preferences, limitations, and requirements of end users by directly engaging them in elicitation activities such as interviews, focus groups, or observational techniques. This phase aims to identify, and brainstorm possible solutions to, needs or challenges in direct collaboration with the population of interest. At the end of the elicitation phase, researchers compile the needs and requirements of end users in a design document, which can be used to develop prototypes for presentation to users again in design-focused activities.

The *design phase* begins the development of the DMHI and involves a set of iterative design feedback activities with end users, often involving prototypes—tools that enable feature and service ideation and initial formative evaluation of the proposed technology’s functions and features. Prototypes approximate a feature or several features of an intervention and can range from paper depictions of an app interface to a wireframe or low-fidelity (ie, alpha) version of the app itself. After each design feedback session, improvements are made to the prototype so that it gets progressively closer to meeting end users’ needs in its most acceptable form.

Finally, *usability testing* focuses on verifying that the final (ie, beta) version of the DMHI meets the requirements of the end users through single-session or longitudinal usability testing. Ideally, this phase includes both qualitative and quantitative data collection, as well as testing the intervention in the field. Data from this phase will inform intervention refinements before it is ready for initial pilot, feasibility, or clinical outcomes testing.

Table 1 lists examples of common UCD techniques used in formative and summative evaluation. Any single technique can be used for different purposes. For example, although we list focus groups under elicitation-focused techniques, for its use in identifying user needs and preferences, it can also be used in the design phase to ideate or identify usability issues. Techniques can also be combined.

**Figure 1.** User-centered design process for a self-injurious thoughts and behaviors intervention for adolescents after hospital discharge. RCT: randomized controlled trial; SITB: self-injurious thoughts and behaviors.
Table 1. User-centered design techniques.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Brief description</th>
<th>Example for SITB research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formative evaluation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elicitation-focused techniques</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Card sorting</td>
<td>Sort a set of cards with constructs relevant to the intervention into groups that make sense to the end user</td>
<td>Individuals with lived SITB experience sort emotion regulation features in terms of the most to least important for SITB management</td>
</tr>
<tr>
<td>Concept mapping</td>
<td>Create an illustration mapping the relationship between the research question and related concepts</td>
<td>Individuals with lived SITB experience create a pen-and-paper map of emotions, thoughts, and contexts and how these factors relate to certain coping strategies</td>
</tr>
<tr>
<td>Diary or EMA&lt;sup&gt;b&lt;/sup&gt; studies</td>
<td>Prompt end users to share relevant details about their perception or experience at scheduled or random intervals over time</td>
<td>Individuals with lived SITB experience are prompted 3 times daily to understand contexts or environments associated with heightened suicidal or self-injurious thoughts</td>
</tr>
<tr>
<td>Focus groups</td>
<td>Stakeholders meet for a moderated discussion related to the research question</td>
<td>Clinicians, parents, and young people with SITB are gathered to discuss day-to-day needs</td>
</tr>
<tr>
<td>Interviews</td>
<td>End users meet with the researcher for a structured or semistructured interview</td>
<td>Interviewing individuals with current SITB to understand how they conceptualize and engage in SITB self-management and identify needs [28]</td>
</tr>
<tr>
<td>Personal inventories</td>
<td>End users describe and share artifacts that are personally valuable or relevant in their life</td>
<td>Individuals with lived SITB experience are asked to bring to an interview session the personal items that provide them hope or comfort when times are difficult</td>
</tr>
<tr>
<td>Task analysis</td>
<td>Identify steps that the end user takes to complete a task</td>
<td>Individuals with lived SITB experience are asked to access and practice coping tools in an app</td>
</tr>
<tr>
<td><strong>Design-focused techniques</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-design workshops</td>
<td>Designers, end users, and stakeholders meet to collaborate on the design of an intervention</td>
<td>Individuals with lived experience of SITB and clinicians meet with the purpose of ideating and designing prototypes that will help end users when they experience urges to self-injure [29]</td>
</tr>
<tr>
<td>Passive storyboards</td>
<td>End users are presented with scenarios—or narratives describing a set of contexts and actions—and probed for how they would engage or navigate the scenario</td>
<td>In the presence of qualified practitioners, individuals with lived SITB experience are asked to reflect on a situation when they experienced an urge to self-injure and asked how they managed the urge and what resources they would usually use</td>
</tr>
<tr>
<td>Interactive storyboards</td>
<td>End users are presented with a narrative of the intervention in a series of panels and participate in the narrative while being probed on whether the product or solution meets requirements</td>
<td>Individuals with lived SITB experience are provided a visual narrative of a proposed intervention that aims to intervene in moments when suicidal distress occurs and are asked to consider its acceptability through each interaction</td>
</tr>
<tr>
<td>Blue sky prototyping</td>
<td>Considering designs that were previously ignored because of feasibility (eg, cost, risk, or complexity) to encourage radical innovation and creativity</td>
<td>Through a focus group, clinicians are provided with an implementation plan for a suicide prevention intervention that they believed had liability concerns. Rather than disregarding it, they brainstormed implementation strategies to mitigate their concerns</td>
</tr>
<tr>
<td>Parallel prototyping</td>
<td>Multiple design concepts are embodied and compared concurrently. Parallel prototyping can help provide critical feedback for concept selection</td>
<td>Individuals with lived SITB experience are provided with similar variants of prototypes that differ by look and feel and are asked to describe their perceived acceptability in moments of suicidal crisis</td>
</tr>
<tr>
<td>Wizard of Oz-ing</td>
<td>A prototype to simulate the full functionality of the intervention with a human operating behind the scenes so that all interactions seem to be computer-driven</td>
<td>Individuals with lived SITB experience are provided with an app prototype and are asked to interact with the app while a researcher navigates display behind the scenes</td>
</tr>
<tr>
<td><strong>Summative evaluation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Usability testing techniques</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive walkthrough</td>
<td>End users are presented with an intervention design and asked to show how they would use it based on design features and prompts within the intervention</td>
<td>Individuals with lived SITB experience are presented with screenshots from a web-based program designed to teach distress tolerance and are asked to describe how they would navigate the screen based on prompts</td>
</tr>
</tbody>
</table>
We note that there are ethical considerations with applying some of these techniques in populations with lived experience of SITB. Although infrequent, some participants may experience distress in relaying information about their lived experience. However, researchers should take measures to mitigate this risk, including following existing guidance on working with populations at elevated risk of suicide [33], guidance on mitigating risk in studies using ecological momentary assessment (EMA) or real-time monitoring [34,35], and guidance on collaborating with institutional review boards to develop protocols that appropriately account for beneficence and well-being [15]. This should first include attention to informed consent and enrollment processes that ensure that participants have the capacity to safely participate in research and that participants are informed of their right to discontinue study participation at any time or skip over questions that they do not wish to answer. During the conduct of research, detailed safety protocols are essential, including procedures for assessing and managing suicidal risk. When conducting UCD work with this population, we recommend that a qualified and adequately trained mental health professional be accessible to participants during all focus groups, interviews, and workshops and be available for consultation in emergent situations. In addition, all participants should be provided with readily accessible emergency contact information throughout the study period in the event that they feel unsafe or have a psychiatric emergency. If a study lasts longer than one session, it is advisable to remind participants of their rights to withdraw from the study and to converse with a qualified professional. In addition, research should be conducted within an environment where people with lived experience feel comfortable and safe sharing their stories. This might involve reviewing rules for confidentiality within focus groups and training research staff to use nonstigmatizing language in the discussion and reporting of SITB (eg, the American Association of Suicidology has a set of guidelines on appropriate language [36]).

**Applications of UCD for a Digital Mental Health and SITB Intervention**

Although UCD techniques have been used in the design of DMHIs for SITB, rarely is the full UCD process, including the 3 phases and elements of formative and summative evaluations, used. Practical constraints and a lack of understanding of how to integrate UCD throughout the full design to implementation process are possible factors for the underuse of UCD in clinical intervention design. A main deterrent is the time investment and additional considerations necessary for safely and ethically including stakeholders. Although UCD requires an upfront investment, this formative research should result in a better product that is acceptable to, and engaging for, end users [37]. This formative work can also elicit critical information about the barriers to use and use contexts, which can improve design and implementation.

Some of the more robust examples of UCD for DMHIs for SITB have resulted in well-accepted and usable products. For example, Dimeff et al [30] designed the *Dr Dave* avatar system—which includes patient- and provider-facing components—to reduce hospitalization after emergency department visits. In the patient-facing tool, *Dr Dave* administers the Virtual Collaborative Assessment and Management of Suicidality and asks clarifying questions in a conversational format. For the provider-facing tool, the avatar system summarizes the assessment results for emergency department physicians and is meant to complement standard clinical interviews to optimize patients’ clinical outcomes. Formative elicitation work, focused on understanding workflows and end-user needs, was conducted with hospital administrators, peer specialists, medical providers, and adolescents with suicidal thoughts or behaviors. The findings were then used to develop and iteratively refine prototypes in consultation with stakeholders. Usability and feasibility tests found the final prototype to be acceptable and easy to use.

Czyz et al [38] similarly engaged in iterative development of a text-based intervention to encourage safety plan adherence after hospitalization. Messages were developed through theory and expert opinion, after which adolescents with SITB provided
feedback to revise content and language in person and through a longitudinal field study. The intervention was perceived to be acceptable, and a follow-up pilot trial supported its benefit in combination with motivational interviewing–enhanced safety planning [39].

In sum, although UCD techniques have been applied in research on suicide prevention, their application has been limited, and there are no easy-to-follow, comprehensive works that provide guidance on how to incorporate UCD for SITB intervention development. As research teams using UCD often publish different phases of the process across multiple manuscripts, it is often difficult to understand the entire UCD process for any particular digital intervention. In the next section, we provide a comprehensive and detailed example of this process.

Results

An Example: Development of a Smartphone App for Adolescents With Suicidal Thoughts or Behaviors

We now elucidate what a robust application of UCD in the development of an SITB intervention could look like through a brief description of the aims of each stage and a detailed case example. The example is based on the development of a suicide prevention intervention featuring an emotion regulation and safety planning smartphone app, Brite, designed for adolescents aged 12-17 years who were hospitalized for suicidal ideation and behavior [18,19]. The intervention aims to reduce suicidal risk during the transition from inpatient to outpatient care, a critical high-risk period for suicidal behavior. The following example includes descriptions of the UCD processes used, augmented by hypothetical elements to demonstrate the wide range of UCD techniques available.

Phase 1: Elicitation

Overview

The aims of the elicitation phase are 2-fold: (1) identify user needs, preferences, and goals and (2) ideate possible solutions. Researchers work with individuals with lived SITB experience to understand their needs and preferences. This might include understanding both how they manage SITB symptoms and salient aspects of their experience, as well as exploring the types of technologies that are acceptable and the services (eg, intervention components) needed or desired as well as those that are unwanted. Questions or interactions for this phase are often informed by existing theory and empiricism on the topic but are not constrained by them. Researcher reflexivity—which entails examining and holding an awareness of one’s own beliefs and biases resulting from one’s individual experiences, training, and positionality as a researcher situated in an institution with a unique set of ideologies and biases—is critical. This includes being aware of assumptions about what the intervention could or should look like and what should help the end user, as well as being open to alternatives. Although reflexivity is important throughout all phases of the research project, it is essential during the formative work that ultimately shapes the data collected. The openness of UCD during this phase may allow for the identification of new, highly attuned treatment targets.

Once the research team has a good understanding of end-user needs, attention can be directed to ideating solutions. Ideating in this context means considering how individuals want their needs to be addressed. The transition from needs to ideating solutions can occur in the context of a single session through the pairing of UCD techniques (eg, interviews and scenarios), but it can also occur sequentially in a series of ≥2 sessions, depending on how much investigation is needed.

Example

The research team, which comprised clinical psychologists, psychiatrists, and clinical social workers, was interested in developing a service to support adolescents with suicidal thoughts or behaviors in their transition from inpatient to outpatient care. The first step was to elicit feedback from key stakeholders. Individual interviews were chosen to protect confidentiality, maximize comfort discussing SITB experiences, and alleviate concerns around youths’ susceptibility to effects of social desirability in group settings such as focus groups.

A total of 30 semistructured interviews were conducted with adolescents with lived experience with psychiatric hospitalization for suicidal ideation or behavior (10/30, 33%), their parents or guardians (10/30, 33%), and inpatient and outpatient care providers specializing in this population (10/30, 33%). The interviews included confirmatory and exploratory probes focused on stakeholders’ experiences with the transition between inpatient and outpatient care and impressions on how technology may support this transition for adolescents with SITB. The exploratory questions aimed to better understand the adolescents’ needs and preferences for timing, scope, and delivery of a smartphone app to support their care transition. The confirmatory questions probed the perceived importance of, and elicited contextual information on, core evidence-based treatment targets common to suicide prevention interventions [40-45].

Key findings across all stakeholder interviews included the need to focus on safety planning to smoothen the transitions in care. The perceived barriers to safety plan uptake during care transitions included lack of accessibility of paper-based safety plans, potential for adolescents to be too distressed to deploy the resources on their safety plan, and challenges with motivation to engage in treatment. The stakeholders viewed a smartphone app as an acceptable means to improve the accessibility of safety plans. Brief skills to reduce momentary experiences of distress that can act as a barrier to safety planning were considered essential, as were elements of motivational interviewing to bolster treatment adherence.

Phase 2: Design

Overview

After the research team has a working understanding of the needs and preferences of end users and has worked with them to ideate possible solutions, the design feedback phase begins. The aim of this phase is to develop initial prototypes to share with end users to elicit information about acceptability and needs and further understand requirements of the intervention. This phase involves iterative prototype development and design activities with end users. Iteration is critical to allow for the
gradual achievement of requirements through exploring options, pursuing new concepts, and refining prototypes. Studies show that research teams using design iteration outperform those with no iteration by producing better products that meet pre-established design requirements [46,47]. Qualitative feedback is analyzed and integrated into a progressively high-fidelity (or functional) prototype to be subjected to further feedback and evaluation. This phase usually concludes when the prototype seems to address the significant needs expressed by the participants.

**Example**

The research team aimed to create a smartphone app with safety planning and distress tolerance components that would be acceptable to adolescents with suicidal thoughts or behaviors based on the findings from the elicitation phase. They partnered with a private company with user interface expertise to draft a wish list for the desired app components. Next, the research team, user interface experts, and adolescent stakeholders with lived SITB experiences engaged in iterative development of app prototypes.

The research team decided to collect feedback in individual and group settings because the content was less sensitive (eg, focusing on the app services rather than SITB experiences) and a group format would better facilitate consensus on design aspects. Efforts were made to optimize the adolescents’ experiences in design sessions. To reduce burden, the design sessions were held in the building where the adolescents were treated after hospitalization. To increase engagement, the adolescents were recognized as experts on their own experiences and co-designers of the app.

The adolescent stakeholders met to provide feedback on app prototypes at 3 time points, with 5-8 adolescents participating at each time point. This process began with low-fidelity wireframes (paper-based prototypes) that provided an initial flow through the app and ended with a high-quality prototype (working digital product). Storyboarding, which involves a visual narrative to convey the function and purpose of the app, was used to obtain stakeholder feedback. The adolescents were asked to consider the acceptability of anticipated app components (eg, mood-monitoring content, activities, function, and flow) during moments of distress. Parallel prototyping, wherein the adolescents were provided with similar variants of prototypes that differed by look and feel as well as conceptual elements, was also used to solidify color choices, design schema, and the app name. The researchers summarized the feedback and incorporated it into the design of the improved prototype at the end of each of the 3 iterations. The prototype was considered final when, through consensus, the research team determined that the themes from qualitative feedback and the scores from quantitative usability questionnaires (eg, Usefulness, Satisfaction, and Ease of Use Scale [48]) indicated a sufficient level of satisfaction [48]. The app was assessed to be safe for evaluative testing by the research team because it met best practice standards for safety planning and incorporated brief evidence-based interventions for youths with SITB (eg, distress tolerance skills).

Key findings from this phase included the importance of considering every aspect of design (eg, cognitive burden, availability and number of coping resources, and inclusion of appropriate crisis resources) from the mindset of an adolescent actively experiencing distress. The adolescents had low tolerance for app functions that were confusing or ambiguous, and they acknowledged that this could make them prematurely stop app use. They reported that the look and feel of the app could influence their mood. Some preferred light colors, which were perceived as hopeful and uplifting; others preferred darker colors that felt more authentic to their mood. Personalization was seen as critical to engagement. As such, the final design included safety plan content (eg, internal and external coping resources, reasons to live, and crisis contacts) that was personalized and interactive as well as a combination of dark and light colors to meet users’ esthetic preferences. Coping activities on the app included a combination of existing web-based content identified by the adolescents and clinicians who treat adolescents with suicidal thoughts or behaviors and the option for adolescents to add their own photos, videos, and websites.

**Phase 3: Usability Testing**

**Overview**

The purpose of usability testing is to understand whether the product is usable and functional, as well as to identify additional refinements needed before the intervention is moved to the clinical trial phase. This phase, similar to the design phase, should involve iteration so that participant feedback can be integrated into the intervention before additional evaluations. A variety of approaches can be used during this phase, including in-laboratory testing and longitudinal field testing. In addition, this phase allows for mixed methods analysis of qualitative data from participant and researcher interactions, as well as quantitative data from standard usability scales. At the conclusion of this phase, the research team should have a usable and highly engaging intervention that meets end users’ needs.

**Example**

App usability was examined through individual sessions with 10 hospitalized adolescents before discharge as well as longitudinal field testing with 5 adolescents through an open pilot trial to ensure that they were able to navigate the app independently and to detect any remaining bugs. Specifically, the adolescents were asked to think aloud as they performed tasks such as composing their safety plan or accessing distress tolerance techniques. At the end of the session, the adolescents completed a quantitative assessment of usability. Usability metrics were good, and the adolescents had not identified major design issues; therefore, the app was ready for longitudinal testing. For the open trial, the adolescents received an orientation to the app while they were hospitalized, and they downloaded and used the app upon hospital discharge or shortly thereafter. They then used the app naturally during their transition to outpatient care. Brief telephone check-ins were conducted with the adolescents at 4 and 12 weeks after discharge. These interviews provided an opportunity for the adolescents to describe their use of the app, including contexts when the app was, and was not, helpful. This field testing revealed the need for additional changes to the app to improve technical function.

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(page number not for citation purposes)
and engagement. Modifications were made before the launch of the RCT.

Next Steps: Moving From Usability to Formal Evaluation of Treatment Targets

Overview

Once researchers have evidence of the acceptability and usability of the intervention, the final DMHI is ready to be tested in a pilot or fully powered clinical trial examining key clinical targets. During this phase, UCD methods are not often used, but they can be useful for further optimization and refinement based on problems encountered as an intervention is scaled up. This can be done in several ways, most often through including usability measures as secondary outcomes in RCTs and conducting interviews to get feedback after treatment. Another method for incorporating lived experience to adapt and refine the intervention through the trial process is suggested in the Accelerated Creation-to-Sustainment model [49]. Hybrid trials that account for the ever-evolving nature of technology can offer a more flexible and iterative approach to trial procedures and focus on optimization, effectiveness, and implementation in real-world settings [49,50]. These trials have the potential to significantly address the research-to-practice gap by producing high-quality digital interventions in a timely manner.

Example

In addition to an analysis of primary and secondary treatment outcomes (e.g., suicidal ideation and behavior), the RCT included an evaluation of app usability through exit interviews as well as usability and satisfaction questionnaires. The exit interviews probed about use of the app and its components and included questions to evaluate the extent to which the app addressed key barriers identified during the qualitative interviews, such as ability to reduce distress in the moment, use of core components of the safety plan, and motivation to engage with the app.

The findings from this RCT included overall app use rates of approximately 70% and good usability and satisfaction scores on the Computer System Usability Questionnaire [51] over the 6-month follow-up period after hospitalization. The exit interviews revealed that the end users felt that the app was effective in aiding their use of key safety plan components, including seeking social support, reaching out to crisis support hotlines, and reducing momentary distress through practicing skills. The exit interviews also revealed when adolescents opted not to use the app; their decision was often influenced by motivational factors that were sometimes external to their experience with using the app. For some, the app was viewed as part of the treatment they were receiving more broadly: when motivation to engage with treatment waned, so did interest in using the app. On the basis of this finding, some further adjustments were made in the research team’s subsequent trial (currently underway) to extend the use of motivational interviewing strategies within the app and through a coached onboarding process to augment adolescents’ motivation for engagement with the app.

Discussion

Considerations and Future Directions

The aforementioned case example demonstrates how lived experience perspectives can be engaged in elicitation, design, and initial usability testing of a new DMHI for SITB. In addition to explaining the UCD process and providing a working example of what this process can look like in designing a DMHI product, we conclude by outlining promising opportunities to integrate lived experiences in research processes that run parallel to intervention development and in emerging areas of SITB research focus. We discuss the use of UCD in (1) establishing procedures related to participant safety and comfort, (2) developing data privacy protocols for just-in-time adaptive interventions, (3) reaching and engaging individuals who are not treatment seeking, and (4) developing protocols for implementation and sustainability.

Establishing Procedures Related to Participant Safety and Comfort

UCD enables researchers to develop products as well as procedures and policies that align with end-user needs, concerns, and desires from the ground up. A promising extension of UCD for an SITB intervention is the development of protocols that ensure participant safety and comfort. This includes considerations related to risk management: (1) risks related to discomfort and privacy in the research process and (2) designing for safety. Researchers must be mindful of the burden that research activities may place on participants and be proactive in efforts to reduce burden. This includes explicitly addressing, and probing for, potential concerns around privacy, stigma, and unintended or unwanted disclosure. As topics relevant to SITB lived experience can be sensitive, researchers must plan for activities to be held at a time and place that is comfortable for participants and plan for distress management. This may include accommodations such as having at least two researchers present to conduct focus groups, with a nearby private room available for breaks or one-on-one engagement. Furthermore, staff members must have appropriate training and experience with suicide risk assessment and management.

Risk management also extends to considerations of the final intervention design itself. Effective risk management can influence whether users feel comfortable engaging with a tool or service; yet, risks are often considered without input from end users. The Trans Lifeline is a good example of a technology-enabled resource that adapted its services based on feedback from target users. The Trans Lifeline elected not to engage in nonconsensual active rescues after feedback from a 2015 survey with 800 transgender individuals [52]. Fear of such rescues, harm from encounters with law enforcement, and involuntary psychiatric hospitalization were identified as key barriers to crisis hotline use. Although crisis services can provide highly effective coping skills and emotion regulation tools that reduce the risk of a suicide attempt [53], certain interventions such as deploying police to respond to mental health crises may be harmful and reduce engagement and efficacy. Understanding the needs of constituents and the responses that communities find most beneficial and least harmful enables the tailoring of
services, protocols, and systems that effectively manage suicide risk in alignment with the goals, values, rights, and dignity of the end users.

**Developing Data Privacy Protocols for Just-in-Time Adaptive Interventions**

There are unique privacy considerations when collecting data from vulnerable populations such as individuals with SITB. As interest in the field has turned to personalized, adaptive, and in-the-moment interventions for suicide prevention and NSSI reduction [54], this necessitates the use of sophisticated passive sensing and self-report methods (eg, EMA). Given the granularity of such data, it becomes ever more important to consider privacy protocols that are aligned with end-user needs and ethics.

Discussions on how to engage individuals more meaningfully in the process of collecting and using such granular data already exist in the privacy literature and can be useful in SITB intervention. For example, Shilton [55] describes a “participatory sensing” approach where “participants are not just subjects of data collection, but take the role of investigators (when they collect data to participate in self-analytic applications) or co-investigators (when they contribute their data to larger research initiatives).” This means that individuals with lived SITB experience would have input into how, and what types of, data are collected. Participants might express comfort with certain types of data being collected passively, without their knowledge, if it could inform in-the-moment interventions. There may also be contingencies around collection—perhaps passive data collection is acceptable if users or their clinicians (if an augmentative service) get meaningful feedback [56]. There may also be contingencies around collection—perhaps passive data collection is acceptable if users or their clinicians (if an augmentative service) receive useful feedback. End-user insights should also inform how the data are processed and used by researchers and clinicians.

Although just-in-time interventions hold significant promise for SITB, there are also ethical concerns around managing participant safety and participant burden [54]. This work also tends to focus on individuals with lived experience as research subjects (eg, producers of data), rather than as collaborative informants or experts. We see UCD techniques as a useful complement for mitigating some challenges associated with EMA and passive data approaches. For example, a chief concern with EMA is that it may increase participant distress and burden.

By conducting formative work, including surveys among individuals with lived experience and feasibility studies with different EMA timetables, researchers can identify appropriate intervention schedules that are comfortable for participants and meet their needs. For an example of formative work exploring the feasibility of a particular method of elicitation (web-based focus groups) among young people with suicidal thoughts, see the study by Han et al [57]. In this work, the authors examine participants’ comfort with, and desire to use, a web-conferencing technology for future research on suicide prevention. Incorporating lived experience in the development, testing, and implementation of just-in-time interventions and related study procedures such as data privacy protocols can reduce the likelihood of disengagement resulting from the intervention being burdensome and ensure that the intervention fits into participants’ lives and that data management processes are acceptable to participants or users.

In sum, when designing interventions that collect increasingly nuanced and granular health and mental health data, it is critical to consider the risks and how individuals perceive these risks, as well as proactively consider and address ethical concerns that may arise [58].

**Reaching and Engaging Individuals Who Are Not Treatment Seeking**

UCD methods may be particularly valuable in the development of DMHIs for individuals not currently engaged in, or unlikely to engage in, formal mental health services. These individuals are not only underserved in the sense that they are not receiving services, but also their needs and goals are not well understood. Existing interventions available to this population may be inaccessible; may have been ineffective, leading to a discontinuation of services; or may not be aligned with their unique goals. Low rates of SITB or NSSI disclosure, often on account of fears of stigma or hostile risk management [5,59-61], complicate efforts to design resources for this group. A promising method for engaging a subset of this population is through web-based forums and social media sites where discussions of SITB occur regularly. Web-based activity is high among this population, in part because of the relative anonymity it affords [62-64], and UCD methods are flexible enough to meet and engage individuals in spaces where they are most comfortable. For example, recruitment can take place entirely on the web, such as through web-based forums [65], and remote UCD techniques can be used for all phases of the UCD process. Elicitation interviews can be conducted through telephone or texting, design feedback activities can occur through asynchronous anonymous focus groups, and usability testing can similarly be conducted through synchronous feedback sessions.

In sum, the potential to develop tools that meet the needs of individuals not currently treatment engaged is promising because it affords the possibility for individuals who are not interested in, or comfortable with, disclosing SITB to professionals to get support and services, and UCD provides a set of techniques to do so.

**Developing Protocols for Implementation and Sustainability**

The value of UCD can also be extended to the development of protocols for implementation and sustainability. For DMHIs that are meant to augment, or work in conjunction with, formal treatment and service settings, researchers must engage clinicians and staff early on because the DMHI must fit into their workflows. For stand-alone DMHIs, a detailed plan for disseminating and advertising the product as well as a plan for any needed maintenance through periodic usability tests are needed. Early engagement of key stakeholders can ensure that the plan or protocol will meet their needs and is feasible given their resources and constraints. For a review and example of

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how UCD can be leveraged to improve implementation, see the studies by Lyon et al. [37] and Dopp et al. [66].

Conclusions

UCD foregrounds key stakeholders with lived experience in DMHI design and in doing so may increase acceptability and engagement of interventions and illuminate intervention targets that are not readily apparent in existing theoretical frameworks or risk models. Early elicitation can increase researchers’ understandings of needs, preferences, and circumstances surrounding when and how stakeholders want to interact with interventions, digital devices, and care systems. Design activities facilitate ideation on desired DMHI components and ensure that stakeholders’ expertise and experience are incorporated into the final DMHI. Usability testing ensures that the final DMHI is perceived to be usable, useful, and acceptable to the population it will ultimately serve. UCD consists of a well-developed set of methods that have been broadly applied to address problems in many fields. We argue that this set of methods can help researchers address specific challenges to SITB interventions by providing a systematic process for invoking the lived experience of end users in research on the design, development, and evaluation of new interventions.

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Conflicts of Interest

TG receives royalties from Guilford Press. DCM has accepted honoraria and consulting fees from Otsuka Pharmaceuticals, Optum Behavioral Health, and the One Mind Foundation, and royalties from Oxford Press and has an ownership interest in Adaptive Health, Inc.

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Abbreviations

DMHI: digital mental health intervention
EMA: ecological momentary assessment
NSSI: nonsuicidal self-injury
RCT: randomized controlled trial
SITB: self-injurious thoughts and behaviors
UCD: user-centered design
complete bibliographic information, a link to the original publication on https://mental.jmir.org/, as well as this copyright and license information must be included.
Review

The Application of e-Mental Health in Response to COVID-19: Scoping Review and Bibliometric Analysis

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Abstract

Background: The COVID-19 pandemic and its mitigation measures and impacts, such as shelter-in-place orders, social isolation, restrictions on freedoms, unemployment, financial insecurity, and disrupted routines, have led to declines in mental health worldwide and concomitant escalating demands for mental health services. Under the circumstances, electronic mental health (e-mental health) programs and services have rapidly become the "new normal.”

Objective: The aim of this study was to assess key characteristics and evidence gaps in the e-mental health literature published in relation to the COVID-19 pandemic via a scoping review and bibliometric analysis.

Methods: We conducted a search of four academic databases (ie, MEDLINE, Embase, PsycInfo, and CINAHL) for documents published from December 31, 2019, to March 31, 2021, using keywords for e-mental health and COVID-19. Article information was extracted that was relevant to the review objective, including journal, type of article, keywords, focus, and corresponding author. Information was synthesized by coding these attributes and was then summarized through descriptive statistics and narrative techniques. Article influence was examined from Altmetric and CiteScore data, and a network analysis was conducted on article keywords.

Results: A total of 356 publications were included in the review. Articles on e-mental health quickly thrived early in the pandemic, with most articles being nonempirical, chiefly commentaries or opinions (n=225, 63.2%). Empirical publications emerged later and became more frequent as the pandemic progressed. The United States contributed the most articles (n=160, 44.9%), though a notable number came from middle-income countries (n=59, 16.6%). Articles were spread across 165 journals and had above-average influence (ie, almost half of the articles were in the top 25% of output scores by Altmetric, and the average CiteScore across articles was 4.22). The network analysis of author-supplied keywords identified key topic areas, including specific mental disorders, eHealth modalities, issues and challenges, and populations of interest. These were further explored via full-text analysis. Applications of e-mental health during the pandemic overcame, or were influenced by, system, service, technology, provider, and patient factors.

Conclusions: COVID-19 has accelerated applications of e-mental health. Further research is needed to support the implementation of e-mental health across system and service infrastructures, alongside evidence of the relative effectiveness of e-mental health in comparison to traditional modes of care.

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KEYWORDS

e-mental health; mental health; COVID-19; bibliometrics; health systems
Introduction

Mental illness is widespread worldwide. Depression and anxiety are the two most common mental health conditions, affecting 4.4% and 3.6% of the world’s adult population, respectively [1]. These disorders lead to considerable losses in health and functioning, with depressive disorders ranked as the single largest contributor to nonfatal health loss globally [1]. At its worst, depression can lead to suicide; more than 80,000 people die by suicide every year along with many more attempts [1,2].

COVID-19 was first reported in Wuhan, China, on December 31, 2019, and on March 11, 2020, the World Health Organization declared the disease a global pandemic [3,4]. By April 2020, most countries worldwide had introduced stay-at-home lockdown and quarantine measures to contain the disease [5]. The pandemic and the public health measures implemented to slow the spread of COVID-19 heightened risk factors associated with poor mental health, including financial insecurity, unemployment, and fear. During this time, access to protective mental health factors, such as social connection, employment, access to physical exercise, and access to health services, fell considerably [6,7].

Mental health data suggest that COVID-19 has exacerbated the mental health crisis [8], with the situation being described by some as a global mental health “catastrophe” [9]. The strictly implemented stay-at-home lockdown and quarantine measures are reported to have exacerbated stress and anger, substance abuse, online gaming, and gambling, and has led to a rise in rates of domestic violence and sexual abuse in the general population [7]. In Australia, one study identified that the population prevalence of poor mental health more than doubled from 20% [10] to around 45% in the first year of the pandemic [11], with similar increases being reported in other countries internationally [12,13]. Latest figures suggest that the groups most affected include young people, those living alone, those with lower socioeconomic status, and those who became unemployed as a result of the pandemic [8]. Although the uptake of COVID-19 vaccines is expected to reduce the likelihood of further restrictions and lockdowns, thereby alleviating some immediate stressors, much of the additional mental health burden is expected to persist due to the economic impacts and trauma resulting directly and indirectly from the pandemic.

As the COVID-19 pandemic continues, electronic mental health (e-mental health) is rapidly becoming the “new normal” [14]. The opportunities afforded by programs and services that aim to treat and manage mental health problems have been recognized for over two decades [15,16]. E-mental health is broadly defined as “mental health services and information delivered or enhanced through the internet and related technologies. It includes all technology-enabled therapies, including internet-based programs, mobile phone applications, telehealth and informational websites” (page 475 of Stone and Waldron) [17]. As a result of rapid technological developments over the past decade, the growing field of e-mental health covers far more than telehealth, with the field now ranging from online support groups and resources to digital assessment and treatment programs and, more recently, to therapeutic gaming and virtual reality (Figure 1) [18]. Telehealth and the associated terms telemedicine and telecare [19-21] historically focused on service provision via telephone, yet the technological advancement that has enabled telehealth to be delivered via communication software, including videoconferencing, has blurred the boundaries between eHealth, mobile health (mHealth), and telehealth. For the purposes of this review, we, therefore, use the phrase e-mental health as an umbrella term to capture eHealth, mHealth, and telehealth [22].

With the onset of COVID-19, the potential benefits of the use of e-mental health programs have been greatly reinforced by the need for mental health services to adapt to social distancing and stay-at-home measures. This has propelled e-mental health into widespread use in developed countries in favor of face-to-face therapies. By mid-2020, more than 80% of high-income countries had shifted to e-mental health technologies to replace or supplement in-person mental health consultations [8]. For example, by the end of 2020, Kaiser Permanente, the largest managed care organization in the United States with 12 million members, was delivering 90% of its psychiatric care virtually [23,24]. For the most part, governments in charge of publicly funded care systems have been responsive in ensuring the availability of e-mental health to the population, in some cases by adding new entitlements to services [9]. For example, in the United States, on March 17, 2020, the Centers for Medicare & Medicaid Services relaxed several requirements for the provision of and payment for telehealth services to Medicare patients [25]. Various countries have also introduced new legal and practice guidelines to assure patient privacy and quality of care [26,27]. In India, the Medical Council released the Telemedicine practice guidelines in May 2020 to help remove some of the administrative and legal concerns present in practicing virtual care [27-29]. The COVID-19 pandemic has also pushed some governments to make online or digital mental health resources widely available to the general population. As another example, the Government of Canada launched a new portal for mental health resources, Wellness Together Canada, which offers a no-cost wellness self-assessment, tracking and support resources, and counseling by text or telephone [30].
In this study, e-mental health evidence has accelerated since the onset of the COVID-19 pandemic, as indicated by the sharp increase in the number of publications in “telepsychiatry” in 2020 (Figure 2). With this burgeoning field, there is a need to identify key emerging issues in light of COVID-19 and to examine developing consensus, gaps in knowledge, as well as pertinent areas for future research. This study involved a combined scoping review and bibliometric analysis of the e-mental health literature since the beginning of the COVID-19 pandemic, exploring characteristics, key topics, and the influence of publications. Our specific objectives were as follows:

1. Investigate the key characteristics of publications in the e-mental health literature since the start of the COVID-19 pandemic (ie, from 2020 onward).
2. Identify the key topics covered by this body of literature in order to determine potential evidence gaps.
3. Analyze characteristics in the most influential publications, as indicated by Altmetric and CiteScore data.
4. Examine the future directions for research and practice in the e-mental health field, both during the COVID-19 pandemic and beyond.

Figure 1. Electronic mental health (e-mental health) technologies [18].

Figure 2. Increase in publications during 2020 (blue) and trendline (dotted blue), based on publications in MEDLINE using the search term “telepsychiatry” in titles or abstracts.
Methods

Overview

The review followed a predetermined protocol, developed in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [31,32] and the Joanna Briggs Institute Methodology for Scoping Reviews [33]. A scoping review method was used to examine the extent, range, and nature of work on this topic; identify gaps; and provide suggestions to improve future directions for research and practice on e-mental health [34]. Quality assessments were not undertaken, as the aim was to examine the full breadth of the literature, consistent with the general aims and methodology of scoping reviews [35].

Search Strategy

Four academic databases (ie, MEDLINE, Embase, PsycInfo, and CINAHL) were searched from December 31, 2019, to March 31, 2021. The search strategy consisted of terms pertaining to eHealth (eg, “eHealth” and “telehealth”), more specific terms related to e-mental health (eg, “m-mental health”), common mental disorders (eg, “anxiety” and “depression”), and COVID-19. The search strategy was adapted for each database as necessary (see Multimedia Appendix 1 for the complete search strategy, using Ovid MEDLINE as an example). The search strategy was developed in consultation with an academic research librarian and was reviewed by all authors prior to execution.

Inclusion and Exclusion Criteria

Articles were included if they were (1) in the English language, (2) peer-reviewed journal articles, (3) discussed the application of e-mental health (theoretical or applied), and (4) were published following the onset of COVID-19 (from December 31, 2019). No restrictions were placed on the target population or setting. Studies were excluded if they did not focus on e-mental health, they were book chapters or conference proceedings, or the full text was not in English.

Citation Screening

Reference details, including abstracts, were downloaded into the reference management software EndNote X9 (Clarivate), exported to Microsoft Excel, and divided among the research team for title and abstract screening. Two reviewers (IM and LAE) independently reviewed 5% of the titles and abstracts; interrater reliability between the two reviewers was high (κ=0.95, 95% CI 0.77-1.00; P<.001). Full-text screening was conducted by four independent reviewers (LAE, IM, KC, and Tamasha Jayawardena). A total of 5% of full texts were reviewed by four reviewers, with the interrater reliability assessed to be sufficiently high (κ≥0.80) [36].

Data Extraction

A customized data extraction workbook was developed in Microsoft Excel. The workbook was piloted by each of the four reviewers with a subset of papers (n=10). Issues in consistency of data entry and usability of the template were then discussed, and modifications were made accordingly. Key information extracted included the following: article characteristics (ie, authors, date of publication, country of residence of the corresponding author, and journal name); article keywords, as supplied by the authors of the paper; and article type (ie, empirical, nonempirical, protocol, or review). For empirical studies (ie, studies that present an analysis of primary or secondary data in their results), information on study design (ie, quantitative, qualitative, or mixed methods) and methods (eg, surveys and interviews) were also extracted. In addition, article titles, abstracts, and keywords were searched for terms to identify papers with specific subpopulations of interest (eg, children, adolescents, veterans, and the elderly) and specific mental disorders (eg, depression, anxiety, posttraumatic stress disorder [PTSD], and substance abuse), as well as articles with a focus on issues or challenges related to the use or uptake of e-mental health in the context of COVID-19 (eg, barriers, privacy, and ethics).

Altmetric data were selected as the most appropriate measure of an article’s impact or influence because of the recency of this literature [37]; while citations have a lag effect, the real-time update of social media metrics makes Altmetric events around research outputs visible within a short amount of time (eg, hours or days). The Altmetric Attention Score, a composite score of social interest that includes mentions in newsfeeds, Twitter, Facebook, and Google, among other sources, was collected for each included study, where available, from Altmetric Explorer in June 2021. In addition, we recorded the CiteScore for the journal in which each article was published, taken from the Scopus database in June 2021. CiteScore metrics were used rather than the Journal Impact Factor, as CiteScore values give “a more comprehensive, transparent, and current view of a journal’s impact” (page 941 of Roldan-Valadez et al) [38], and they are provided for many more journals than the Journal Impact Factor. Although previous research indicates that an article’s Altmetric score within its first year of publication reliably predicts its future citation count, we followed the recommended optimal approach of using both Altmetric scores and CiteScore values as an indicator of article impact [39].

Data Synthesis and Analysis

Articles were grouped together based on common attributes in the data (eg, article type). The country of the corresponding author was coded by income classification based on the World Bank’s definitions of gross national income per capita per year. The three categories were low (<US $1045), middle (US $1046-$12,695), and high income (>US $12,696) [40].

Key topic areas were identified through an analysis of article keywords. These were extracted by the research team and were then cleaned and checked for consistency. Derivative terms (eg, “health care” and “healthcare”) were amalgamated. Each keyword was reviewed and inductively classified by two authors (LAE and IM) into key topic and subtopic areas using the structure and definitions outlined in Multimedia Appendix 2. The keyword data were analyzed for frequency and co-occurrence and were graphically presented using Gephi (version 0.9.2) [41]. Our presentation of keyword data and discussion of key topic areas focused on the most influential papers as representatives of salient topic areas. To select these papers, we used a combination of Altmetric and CiteScore data,
including publications with journal CiteScore values of ≥5, representing the top one-third of journals in our included articles, and/or Altmetric Attention Score values in the top 25% of all publications scored by Altmetric.

Results

Overview

The search retrieved a total of 2418 publications. After removing duplicates, 1506 remained for title and/or abstract review. Following title and/or abstract screening, 1023 publications were discarded as they did not meet the inclusion criteria. Based on the full-text assessment, a further 127 publications did not meet the inclusion criteria, resulting in 356 publications included in this review (see Multimedia Appendix 3 for included articles). Figure 3 demonstrates the inclusion and exclusion of papers at each stage of the screening process.

Figure 3. Search and review strategy.

Summary Characteristics and Bibliometric Properties of the Included Publications

A summary of the key characteristics of the included articles is presented in Table 1. Of the 356 articles, most were nonempirical commentaries or opinions (n=225, 63.2%), around one-quarter were empirical publications (n=99, 27.8%), 20 were literature reviews (5.6%), and 12 were protocols (3.4%). Figure 4 shows the trends in article types published during the pandemic, with nonempirical publications peaking in June 2020 and empirical publications emerging later and becoming more frequent as the pandemic progressed.
Table 1. Summary of key characteristics of included publications.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Papers (N=356), n (%)^a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country of corresponding author</strong></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>160 (44.9)</td>
</tr>
<tr>
<td>Australia</td>
<td>28 (7.9)</td>
</tr>
<tr>
<td>India</td>
<td>27 (7.6)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>20 (5.6)</td>
</tr>
<tr>
<td>Canada</td>
<td>17 (4.8)</td>
</tr>
<tr>
<td>Other</td>
<td>104 (29.2)</td>
</tr>
<tr>
<td><strong>Country income classification of corresponding author</strong></td>
<td></td>
</tr>
<tr>
<td>High income (&gt;US $12,696)</td>
<td>297 (83.4)</td>
</tr>
<tr>
<td>Middle income (US $1046-$12,695)</td>
<td>59 (16.6)</td>
</tr>
<tr>
<td>Low income (&lt;US $1045)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Publication type and study methods</strong></td>
<td></td>
</tr>
<tr>
<td>Nonempirical</td>
<td>225 (63.2)</td>
</tr>
<tr>
<td>Empirical</td>
<td>99 (27.8)</td>
</tr>
<tr>
<td>Review</td>
<td>20 (5.6)</td>
</tr>
<tr>
<td>Protocol</td>
<td>12 (3.4)</td>
</tr>
<tr>
<td><strong>Empirical study methods</strong></td>
<td></td>
</tr>
<tr>
<td>Quantitative methods</td>
<td>68 (68.7)</td>
</tr>
<tr>
<td>Mixed methods</td>
<td>21 (21.2)</td>
</tr>
<tr>
<td>Qualitative methods</td>
<td>10 (10.1)</td>
</tr>
<tr>
<td><strong>Mental disorder of focus</strong></td>
<td></td>
</tr>
<tr>
<td>Anxiety (including posttraumatic stress disorder)</td>
<td>71 (19.9)</td>
</tr>
<tr>
<td>Depression</td>
<td>48 (13.5)</td>
</tr>
<tr>
<td>Substance abuse disorders (including addiction)</td>
<td>17 (4.8)</td>
</tr>
<tr>
<td>Psychotic disorders (including schizophrenia)</td>
<td>16 (4.5)</td>
</tr>
<tr>
<td>Suicide</td>
<td>13 (3.7)</td>
</tr>
<tr>
<td>Eating disorders</td>
<td>11 (3.1)</td>
</tr>
<tr>
<td><strong>Specific population of focus</strong></td>
<td></td>
</tr>
<tr>
<td>Children and/or adolescents</td>
<td>90 (25.3)</td>
</tr>
<tr>
<td>Older adults and/or the elderly</td>
<td>20 (5.6)</td>
</tr>
<tr>
<td>Veterans</td>
<td>17 (4.8)</td>
</tr>
<tr>
<td>Health professionals</td>
<td>15 (4.2)</td>
</tr>
<tr>
<td><strong>Modality of focus</strong></td>
<td></td>
</tr>
<tr>
<td>Telephone or videoconferencing</td>
<td>142 (39.9)</td>
</tr>
<tr>
<td>Smartphone apps</td>
<td>43 (12.1)</td>
</tr>
<tr>
<td>Support groups</td>
<td>6 (1.7)</td>
</tr>
</tbody>
</table>

^aColumns may not equal 356 due to missing values and overlap in some categories.
Publication Types and Study Methods

Of the 225 nonempirical publications, most were commentaries or opinion pieces (n=106, 47.1%), with a further 49 (21.8%) classified as descriptive case studies, 36 (16.0%) as letters to the editor, 22 (9.8%) as unstructured reviews, 10 (4.4%) as editorials, and 2 (0.9%) as unstructured protocols (Table 1). Of the 99 empirical publications, the majority used quantitative methods (n=68, 69%), 21 (21%) used a mixed methods design, and 10 (10%) employed qualitative methods alone. Most of the quantitative and mixed methods studies (n=89, 39.6%) were cross-sectional (n=60, 67%), with only 4 (4%) randomized controlled trials [42-45] and 3 (3%) nonrandomized controlled trials identified [46-48].

Overall, the empirical studies focused on the uptake and effectiveness of e-mental health initiatives in providing mental health care during COVID-19. The nonempirical descriptive case studies outlined the processes and challenges of the rapid conversion to telehealth for a particular mental health service, while nonempirical commentary or opinion pieces more broadly outlined policy changes, issues, and challenges to e-mental health and offered guidance to clinicians (see Table 2 [49-52] for exemplar papers for each category).

Corresponding authors were predominantly from high-income countries, with almost half of the 356 included outputs coming from the United States (n=160, 44.9%), followed by Australia (n=28, 7.9%), the United Kingdom (n=20, 5.6%), and Canada (n=17, 4.8%). Notably, our study identified a number of publications from middle-income countries (n=59, 16.6%), with most of these being from India (n=29, 7.6%) and China (n=9, 2.5%) (Figure 5).

Table 2. Examples of included studies.

<table>
<thead>
<tr>
<th>Authors (year)</th>
<th>Country</th>
<th>Article type</th>
<th>Article classification</th>
<th>Specific populations</th>
<th>Specific disorders</th>
<th>Article aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pierce et al</td>
<td>United States</td>
<td>Empirical</td>
<td>Quantitative survey of 2691 psychologists</td>
<td>Veterans</td>
<td>Anxiety</td>
<td>To examine the amount of psychologists’ telespsychology use before the COVID-19 pandemic, during the pandemic, and anticipated use after the pandemic, as well as the demographic, training, policy, and clinical practice predictors of these changes</td>
</tr>
<tr>
<td>Steinberg et al</td>
<td>United States</td>
<td>Empirical</td>
<td>Quantitative and qualitative survey of 51 pediatric psychologists</td>
<td>Children and adolescents</td>
<td>General</td>
<td>To examine the uptake of transitioning pediatric psychology services to meet mental health needs in response to a worldwide public health crisis, and to call attention to psychologists’ perceived benefits and challenges related to providing pediatric mental health services during the pandemic</td>
</tr>
<tr>
<td>Patel et al</td>
<td>Ireland</td>
<td>Nonempirical</td>
<td>Descriptive case study</td>
<td>The elderly</td>
<td>General</td>
<td>To discuss the transition and challenges faced in rapidly implementing telehealth in a rural psychiatry-of-old-age service in the northwest of Ireland</td>
</tr>
<tr>
<td>Haque (2020)</td>
<td>United States</td>
<td>Nonempirical</td>
<td>Perspective</td>
<td>Mental health professionals</td>
<td>General</td>
<td>To discuss policy changes due to the COVID-19 pandemic and to highlight what mental health providers should consider for future delivery and implementation of telehealth programs</td>
</tr>
</tbody>
</table>
Publication Data

The 356 included articles were spread across 165 different journals, which were primarily focused on mental health, but varied in scope. Most of the journals had a reported CiteScore in Scopus (n=138, 83.6%), with scores ranging from 0.3 (Psychiatric Times) to 25.2 (The Lancet Psychiatry). A total of 3 articles (1.8%) were published in The Lancet Psychiatry [53-55], of which 2 were from middle-income countries [53,54]. The largest number of included articles were published in JMIR Mental Health (n=19, 11.5%; CiteScore=1.3), followed by the Asian Journal of Psychiatry (n=14, 8.4%; CiteScore=4.7) and the Indian Journal of Psychological Medicine (n=13, 7.9%; CiteScore=1.8), with one-quarter of articles (n=40, 24.2%) being published across the JMIR suite of journals (mean CiteScore 3.37). The mean CiteScore value across articles (ie, CiteScore for each article based on its journal CiteScore and then averaged across articles) was 4.22 (SD 3.53); however, CiteScore values varied by article type, with protocol papers having a lower average CiteScore (mean 2.1, SD 1.55) than empirical studies (mean 3.8, SD 2.06), nonempirical articles (mean 4.6, SD 4.16), and reviews (mean 4.4, SD 1.91).

Of the 242 publications with reported Altmetric data, almost half were ranked in the top 25% of all outputs scored by Altmetric (n=118, 48.8%). Altmetric Attention Score values ranged from 1 to 282 (mean 13.33, SD 30.04); though similar to CiteScore values, there was variation in Altmetric metrics by article type, with empirical studies (mean 14.10, SD 29.22), nonempirical articles (mean 13.6, SD 32.77), and reviews (mean 11.9, SD 14.11) having higher Altmetric scores than protocol papers (mean 5.4, 4.39). The publication with the highest Altmetric score was a nonempirical contribution by Kozloff et al, which outlined the adverse mental health consequences and virtual mental health service delivery options for people with schizophrenia during COVID-19, with an Altmetric Attention Score of 282, placing it in the 98th percentile of outputs of the same age [56]. The top five articles with the highest Altmetric Attention Score values are shown in Table 3 [24,42,55-57].

Table 3. The most influential publications based on Altmetric data.

<table>
<thead>
<tr>
<th>Authors (year)</th>
<th>Country</th>
<th>Title</th>
<th>Journal</th>
<th>Altmetric Attention Scorea</th>
<th>CiteScoreb</th>
<th>Article type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torous et al (2020)</td>
<td>United States</td>
<td>Digital mental health and COVID-19: Using technology today to accelerate the curve on access and quality tomorrow</td>
<td>JMIR Mental Health</td>
<td>197</td>
<td>1.3</td>
<td>Nonempirical</td>
</tr>
<tr>
<td>Rahman et al (2020)</td>
<td>United Kingdom</td>
<td>The NIMH global mental health research community and COVID-19</td>
<td>The Lancet Psychiatry</td>
<td>124</td>
<td>25.2</td>
<td>Nonempirical</td>
</tr>
</tbody>
</table>

aAltmetric data from Altmetric Explorer as of June 2021. All scores were in the top 5%.
bCiteScore in Scopus as of June 2021.
cNIMH: National Institute of Mental Health.
High-Impact Publications and Keyword Analysis

The topmost influential publications—defined as those with Altmetric Attention Score values in the top 25% of all research scored by Altmetric, and/or CiteScore values of ≥5—were identified. Based on this definition, close to half of our 356 included publications were classified as influential (n=165, 46.3%). The 165 influential articles were broadly reflective of the countries and country incomes previously reported (high-income countries defined here: n=143, 86.7%).

Among the 165 most influential publications, 124 had author-contributed keywords, with a total of 273 unique keywords in this subset of papers. The frequency with which these keywords were used together on a publication is visually depicted in the network of co-occurring keywords (Figure 6). In this network, each circle (node) represents a keyword, and each line (edge) indicates co-occurrence on a publication. The most common keywords (highest in-degree score), as reflected in size in the figure, were as follows: COVID-19 (n=90), mental health (n=37), telehealth (n=32), telemedicine (n=30), and telepsychiatry (n=17). The sociogram includes 124 papers (grey nodes), 50 keywords (colored nodes), and 390 edges. The size of each node is filtered by the in-degree score, where bigger nodes would have larger in-degree scores (ie, the number of edges directed to the node). Our inductive analysis of keywords identified a number of key topic and subtopic areas: (1) COVID-19 pandemic; (2) mental health, including specific mental disorders; (3) e-mental health, including specific eHealth modalities and issues or challenges; (4) specific populations of interest; and (5) study field (eg, cancer and pediatrics). These are colorized separately in the figure to indicate their relation to one another.

Figure 6. Network of co-occurring keywords in 165 of the publications with Altmetric values in the top 25% or CiteScore values of ≥5. Each circle (node) is a keyword, and each line (edge) represents co-occurrence. The size of each node indicates the number of times a keyword was used. Colors represent different topic areas. CBT: cognitive behavioral therapy; mHealth: mobile health; PTSD: posttraumatic stress disorder.

Mental Disorders of Focus

Although many of the 356 articles focused on mental health broadly, describing concerns relating to the effect of the pandemic on stress (n=78, 21.9%), loneliness or isolation (n=34, 9.6%), and general well-being (n=23, 6.5%), other studies focused their attention on specific mental disorders. A total of 71 of the 356 included articles (19.9%) were concerned with anxiety disorders (see Table 3 for examples), including the use of e-mental health to treat PTSD during the pandemic. A total of 48 articles were concerned with depression (13.5%). Other disorders of specific focus identified were addiction and substance abuse disorders (n=17, 4.8%), psychotic disorders (n=16, 4.5%), suicide (n=13, 3.7%), and eating disorders (n=11, 3.1%).
eHealth Modalities

A large proportion of the 356 included articles described the application of e-mental health via telephone and/or videoconferencing during COVID-19 (n=142, 39.9%), as well as the use of smartphone apps (n=43, 12.1%) and support groups (n=6, 1.7%) in assisting people during times of need. For example, the review by Strudwick et al identified 31 smartphone apps and 114 web-based resources, including telephone support, virtual peer support groups, and discussion forums, that could be used to support the mental health of the Canadian public [58]. A smaller number of studies empirically tested the efficacy of specific e-mental health modalities during COVID-19. For example, a trial from Canada tested the efficacy of delivering videoconferencing psychotherapy for people with panic disorder and agoraphobia, demonstrating that cognitive behavioral therapy delivered via videoconferencing is no less effective than face-to-face delivery on all outcome measures, and provides important information to guide the delivery of e-mental health services during and after the COVID-19 crisis [47]. Less mentioned were virtual reality, wearables, and artificial intelligence, though these modalities were noted by Vadlamani et al as being the “future of telepsychiatry” [27].

Specific Populations of Focus

A number of articles identified particular at-risk populations who would require greater care and/or more resources to overcome barriers to access e-mental health during the pandemic. A total of 90 articles out of 356 were focused on children and/or adolescents (25.3%) (see Table 3 for examples), and 39 articles focused on older adults or the elderly (5.6%) and veterans (4.8%) as at-risk populations. There appears to be a general consensus in the literature that younger children and older adults, who may be less familiar with technology, may find it more difficult to access the benefits of e-mental health [59]. However, the flexible and remote nature of e-mental health may offer a more viable option to certain populations who may have historically fallen through the cracks or struggled to engage with traditional psychology service provision, for example, marginalized populations, such as those identifying as LGBTQ+ (lesbian, gay, bisexual, transgender, queer, questioning) [60], and young adults who prefer to seek help anonymously and at a time that suits them via smartphone apps [61].

A further 15 articles (4.2%) were specifically concerned with the mental health impact of COVID-19 on health professionals themselves. For example, Cheng et al outlined a peer support project offering support from mental health professionals overseas to frontline health care workers in Wuhan, China, via a popular smartphone app [62].

Issues and Challenges

Overview

A total of 68 papers out of 356 (19.1%) identified issues and challenges associated with e-mental health in the context of COVID-19. An inductive thematic analysis identified that many issues and challenges were highlighted, with complexities present at the patient, clinician, technological, treatment, ethical, organization or service, and broader system levels (see Figure 7 for a summary of the issues identified).

Privacy and Security Issues

At the technological level, included articles discussed how the rise in videoconferencing during COVID-19 has raised security concerns, as some platforms can be easily hacked or viewed by others [63,64]. Although some platforms, such as BlueJeans, have been developed with higher security measures in place (eg, offer end-to-end encryption), privacy cannot be guaranteed in its entirety. As a result of the COVID-19 pandemic, some governments issued emergency waivers suspending the requirement to comply with information protection laws in order to facilitate access to videoconferencing services [65]. However,
patient confidentiality and privacy remains a compelling issue [27,64], encompassing informed consent procedures [66-68], risks associated with the blurring of professional boundaries [59], and concerns about family members listening in on sessions [64].

**User Perspectives and Uptake**

A mixed methods study on the perspectives and experiences of mental health professionals reported on their need for robust, secure, user-friendly technology and better logistical and technical support [69]. Issues have also been noted for clinicians who were insufficiently trained or had limited experience with technology [27]. An unstructured review article identified that rapid uptake of e-mental health technology has been facilitated by clinics providing clinician training as well as already having online storage, remote access to records, and videoconferencing technologies available in their workplace [70]. Larger clinics providing substantial services to the community reported the need to transition rapidly to ensure continuity of care, whereas smaller clinics were able to temporarily pause services or refer their clients elsewhere [70]. Articles also pointed to mental health professionals identifying concerns around the impact on the treatment relationship itself, noting the potential for inferior patient-clinician interactions [71,72] and therapeutic alliance [64,73,74]. They highlighted particular issues around the identification of nonverbal cues [59,66], transference processes [73,74], disturbances or interruptions to the session [27], and difficulties in assessing and responding appropriately to high-risk situations [59], particularly for children [75,76].

**Access and Suitability**

Despite most people now having internet access, the “digital divide” was still viewed as an issue in some articles for certain patient and consumer groups, such as the elderly, veterans, those of lower socioeconomic status, those with cognitive impairments or vision or hearing difficulties, and those still having access issues and poorer digital competence [27,63,64,72,77]. Concerns were also raised in some publications of patients with certain conditions not being suitable for e-mental health solutions, such as patients with psychosis, in acute crisis, or at risk of self-harm [63,64]. As identified by Naik et al, a “‘one-size-fits-all’ approach will not suit the needs of all patients,” with the need to refine e-mental health services to meet patient-specific needs (page 6) [74].

**Policy and Regulation**

At the broader system level, several articles pointed to changes in regulation and reimbursements that have enabled clinicians practicing in a wide range of settings to quickly adopt e-mental health solutions for both existing and new patients struggling with the pandemic’s impact [29-31,52,67]. Patel et al identified a number of local and national collaborative approaches to care that have been developed since COVID-19, such as “Webinars for Nursing Homes” that have linked palliative care, geriatrics, and psychiatric old-age services in Ireland through Project ECHO AIIHPC (Extension for Community Healthcare Outcomes, All Ireland Institute of Hospice and Palliative Care) to help nursing home staff improve their knowledge of e-mental health tools [51]. Patel et al further argued that a national repository of common e-mental health services could support collaboration between organizations.

**Discussion**

**Principal Findings**

Although it has been only 18 months since the start of the pandemic, this review identified that the total number of articles on e-mental health quickly thrived, with nonempirical articles peaking in June 2020 and empirical articles emerging later and becoming more common as the pandemic progressed. The location of articles was predominantly in high-income countries (ie, the United States, Australia, the United Kingdom, and Canada), reflecting general trends previously identified in the e-mental health literature [78,79]. However, a higher number of articles from medium-income countries were identified in this review in comparison to previous e-mental health reviews [78], with most of these articles coming from India and China. Increased outputs from China may be attributed to having the earliest outbreak of COVID-19, and for other middle-income countries, such as India, this could be reflective of the particular concerns and urgent solutions needed for people living in these countries [80].

Our bibliometric analysis indicated that the e-mental health literature during COVID-19 has had above-average influence, with almost half of the articles being ranked in the top 25% of all output scores by Altmetric and having an average CiteScore across articles of 4.22. Nonempirical articles (eg, commentaries or opinion pieces) received a notable amount of attention; articles of this type surged early in the pandemic, so elevated influence may reflect researchers and clinicians searching for new information on e-mental health, guidelines, evidence-based practice, and other relevant developments at an uncertain time and when empirical studies were limited.

The network analysis of author-supplied keywords identified key topic areas, which were explored further via our full-text analysis. Many articles focused broadly on mental health and well-being, with specific attention being paid to anxiety disorders, depression, substance abuse disorders, and psychosis. Children and adolescents were the most frequently identified in articles focused on specific populations, with other identified at-risk populations, including the elderly, veterans, and health professionals themselves. It was noted that younger children and older adults, who may be less familiar with technology, may find it more difficult to access the benefits of e-mental health. Frontline workers directly involved in the care of patients with COVID-19 have been identified as being at particularly high risk for mental health issues as a result of excessive workloads and work hours, insufficient protective equipment, feeling inadequately supported, as well as the high infection rate among medical staff [81]. Studies from past pandemics (eg, SARS) suggest that those in emergency departments, intensive care units, and infectious disease wards are at highest risk of developing adverse mental health outcomes [81].

Modalities of e-mental health largely focused on the application of “telehealth” via telephone or videoconferencing. However, there were also a number of articles reporting on the adoption...
of smartphone apps [82-85] and virtual support groups [62,86-88]. Self-directed treatment apps may be particularly helpful for those preferring to seek help anonymously and seeking flexibility or for those who have historically struggled to engage with traditional psychology service provision. Less mentioned were virtual reality, wearables, and artificial intelligence, though these modalities are widely believed as becoming more important in the future [27].

Since the start of the pandemic, both clinicians and patients have been required to gain both the skills and experience to adopt e-mental health solutions out of necessity, with a number of descriptive case studies being identified that inform the rapid conversion to e-mental health to continue to deliver care [89,90].

Various included articles articulated the main issues and challenges to this rapid conversion, as well as highlighting the fast-tracking of more relaxed regulations and supported reimbursements to overcome some of the barriers related to practicing virtual care. Included articles suggested that the experience has been largely valuable for patients and health care professionals alike; however, a number of concerns remain, with complexities identified at the levels of the patient, clinician, technology, treatment, ethics, organization or service, and broader system. A “one-size-fits-all” approach will not suit the needs of all patients, clinicians, or services [74]. Future research and interventions in e-mental health should investigate how to overcome or improve upon these barriers.

**Future Directions**

After any subsequent waves of COVID-19 subside, the key question is whether we are likely to remain in the “new normal,” in which telehealth remains a prominent vehicle for mainstream mental health treatment delivery [66]. The ability of health care systems to continue to provide telehealth depends on the continuation of relaxed regulations and supported reimbursements to incentivize the use of telehealth [66].

It is unclear what rationale the regulatory bodies and insurers will employ to decide which prior limitations, if any, should be reinstated [66]. At the same time, given the large scale at which these tools are now being used, there is renewed urgency to assess and address ethical issues associated with e-mental health tools, such as maintaining privacy and patient data protection, and whether the privacy and safety regulations that have been relaxed need to be tightened to increase accountability [14].

Despite the swift adoption of the multitude of e-mental health apps and platforms that emerged during the pandemic, little is known about their immediate-, medium-, or long-term clinical value or the barriers to, and facilitators of, their uptake [18]. Given that many of the digital tools used in e-mental health have been developed outside of the health care system [91,92], there is also little understanding of how to optimize their integration into existing health care models and their various governance, funding, planning, and accountability frameworks.

To date, there continues to be little translational research (ie, the implementation of e-mental health clinical trial research into practice settings) [93], limited use of quality evaluation measures [94], as well as little or no long-term follow-up [95]. This research-to-practice gap suggests there is much to learn about how e-mental health can be best incorporated into real-world settings to reap its benefits [96], with the current rapid uptake of e-mental health solutions providing a stimulus to addressing this gap.

Some key research questions identified in the literature include the need to compare specific outcomes for in-person versus remote care related to specific mental health conditions, such as those with paranoia or other psychotic disorders and substance use disorders. Such conditions may pose unique challenges to management via e-mental health programs and services [97,98], conditions that could also benefit from the greater flexibility of this modality [66,99]. Other questions have also emerged in the current literature: What types of patients respond particularly well to virtual rather than in-person visits? [14,72]; Are there differences in quality of care by socioeconomic status, health literacy, technology literacy, and other individual factors outside of psychiatric conditions?; What are the impacts of telehealth on the therapeutic relationship and on clinicians themselves?; and What are the financial implications of widespread adoption of telehealth? [14].

Now is the time to accelerate e-mental health research to ensure the continued success of virtual modes of care beyond the pandemic.

**Strengths and Limitations**

The strengths of this review are the inclusion of a broad range of articles, including nonempirical articles, reviews, and protocols. In addition to looking at the countries of origin, we also examined article influence and provided a novel keyword analysis with inductive thematic coding to identify key topic areas. Our thorough analysis of the key issues and challenges identified gaps in research to guide the next wave of research on e-mental health. The limitations of this review are primarily methodological. We chose to use CiteScore data because almost 85% of the identified journals had CiteScore information and almost 70% had reported Altmetric data, but not all journals have CiteScore data, nor do all articles have Altmetric Attention Score values available. Similarly, the keyword analysis could only be conducted on journal articles that provided keywords. To supplement this, we undertook an analysis of specific subpopulations, mental disorders, and issues or challenges within titles and abstracts for all publications. Although we included a broad range of journal articles (eg, commentaries, reviews, letters to the editor, and protocols), we did not include a grey literature search, which may have broadened our understanding of the e-mental health field since the pandemic began. Although we identified a relatively high proportion of articles from medium-income countries, our restriction to records in English and published works may have underestimated the true amount of literature emerging from low- and middle-income countries. Although, the inclusion of non-English studies can add substantially to the resources required to complete a review, we believe it could be important to include them in an updated search of the literature in this field in the future. The inclusion of conference abstracts in the updated search would also be beneficial, given the rapidly emerging nature of the topic.

**Conclusions**

Arguably, the COVID-19 pandemic is the defining moment for e-mental health adoption, with virtual care being likely to remain a prominent vehicle for mainstream mental health service
delivery postpandemic. This review identified that many of the emerging e-mental health studies focused on the application of "telehealth" via telephone or videoconferencing, with notable interest in, and concern for, vulnerable populations, such as children, veterans, and health professionals as well as those with pre-existing mental health conditions, including anxiety disorders, depression, substance abuse disorders, and psychosis. The rapid expansion of e-mental health services during the pandemic has been enabled by existing technology and swiftly implemented policies but has been challenged by numerous issues at the patient or clinician level and at the technology or treatment level, or due to factors at the ethical, organization or service, and broader system levels. Ensuring that the field advances beyond simply the sharp increase in publications documenting the use of e-mental health—and the concomitant interest by readers—to further accelerate access and quality of care beyond the pandemic will be the next big challenge.

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Authors' Contributions
This study was originally designed by LAE, IM, CP, and KC. Data extraction and screening was conducted by LAE, IM, and KC, with research assistance from SH. The first draft of the Results section was written by LAE, IM, KC, and CP. All authors provided critical feedback and helped shape the final manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Database search strategy using Ovid MEDLINE.
[DOCX File, 14 KB - mental_v8i12e32948_app1.docx ]

Multimedia Appendix 2
Coding structure and definitions for keyword classification.
[DOCX File, 16 KB - mental_v8i12e32948_app2.docx ]

Multimedia Appendix 3
Articles included in this study.
[XLSX File (Microsoft Excel File), 5553 KB - mental_v8i12e32948_app3.xlsx ]

References


Abbreviations

- **ECHO AIIHPC**: Extension for Community Healthcare Outcomes, All Ireland Institute of Hospice and Palliative Care
- **e-mental health**: electronic mental health
- **LGBTQ+**: lesbian, gay, bisexual, transgender, queer, questioning
- **mHealth**: mobile health
- **PRISMA-ScR**: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
- **PTSD**: posttraumatic stress disorder

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Abstract

Background: Cancer survivors often experience disorders from the depressive spectrum that remain largely unrecognized and overlooked. Even though screening for depression is recognized as essential, several barriers prevent its successful implementation. It is possible that better screening options can be developed. New possibilities have been opening up with advances in artificial intelligence and increasing knowledge on the connection of observable cues and psychological states.

Objective: The aim of this scoping meta-review was to identify observable features of depression that can be intercepted using artificial intelligence in order to provide a stepping stone toward better recognition of depression among cancer survivors.

Methods: We followed a methodological framework for scoping reviews. We searched SCOPUS and Web of Science for relevant papers on the topic, and data were extracted from the papers that met inclusion criteria. We used thematic analysis within 3 predefined categories of depression cues (ie, language, speech, and facial expression cues) to analyze the papers.

Results: The search yielded 1023 papers, of which 9 met the inclusion criteria. Analysis of their findings resulted in several well-supported cues of depression in language, speech, and facial expression domains, which provides a comprehensive list of observable features that are potentially suited to be intercepted by artificial intelligence for early detection of depression.

Conclusions: This review provides a synthesis of behavioral features of depression while translating this knowledge into the context of artificial intelligence–supported screening for depression in cancer survivors.

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KEYWORDS

artificial intelligence; cancer; depression; facial expression; language; oncology; review; screening; speech; symptom

Introduction

While cancer incidence is increasing worldwide [1], so are 5-year survival rates, from 49% in the 1970s to 69% in 2017 [2,3]. After having cancer, individuals can be faced with a wide array of challenges, such as fatigue, pain, impaired cognitive functions, and fear of cancer recurrence [1]. Among these challenges, depressive spectrum and mood-related disorders are among the most common psychological conditions [4]; it is estimated that in the first 2 years after diagnosis, 12% to 20% of cancer survivors meet diagnostic criteria for major depression disorder [1,5,6]. This is even more pronounced in cancer survivors with other comorbid chronic diseases [7] and breast cancer survivors [8]. At any point during survivorship, a dysphoric mood, anxiety, appetite changes, insomnia, or irritability can present and last weeks or even months [9];
however, these conditions frequently remain underrecognized and overlooked in clinical practice [10] because the signs and symptoms of depression in patients with cancer are heterogeneous [11]. Many survivors are also more likely to report somatic complaints rather than an overtly depressed mood. Moreover, only a minority of posttreatment survivors report experiencing clinically significant psychological distress during the treatment phase of their disease [12]. Although cancer distress screening has been recognized as an important tool, health care systems struggle to implement these tools in practice [13]. Lack of staff, difficulty in differentiating between mental health distress and symptoms of the disease, time constraints, accessibility restrictions, and availability of services represent the major barriers to regular screening [14].

Patient-gathered health data and patient-reported outcomes, in particular, have become a valuable tool in understanding the symptomatology of cancer patients and survivors [15]. Patient-reported outcomes give voice to the patient’s perspective and can inform decision-making by providing insight into the quality of life that is complementary to clinician-rated adverse events [16]. Digital interventions that collect patient-reported outcomes have been recognized as feasible and acceptable by clinicians and patients alike [17]. However, self-reporting often involves reporting bias, which may result in erroneous judgments such as the reconstruction of memories and excessive reliance on cognitive heuristics [18]. Retrospective self-reports of negative mood states experienced in the past (eg, the most recent 2 weeks) tend to be exaggerated in a negative direction [19]. Reporting and interpretation biases are even more pronounced for people suffering from symptoms of depression [20,21]. Moreover, inattentive responding and social desirability may distort the quality of results even further [22,23]. Currently, big data and artificial intelligence offer new opportunities for the screening and prediction of mental health problems. Specifically, there is a growing interest in examining relationships between observable cues, such as language use, speech, and facial expressions, and the psychological characteristics of the communicator [24]. These observable cues are generated spontaneously, are less impacted by cognitive and other biases related to desirability and crassness, and can contribute to improving the objectivity of psychiatric assessments [25]. The main motivation of this scoping review was to identify the observable features of depressive symptoms that are expressed during conversation (often without awareness), and that can be intercepted using artificial intelligence to be developed in the project Patient-Centered Survivorship Care Plan After Cancer Treatments Based on Big Data and Artificial Intelligence Technologies (PERSIST [26]).

To our knowledge, past reviews (eg, [25,27-29]) mainly focused on specific modalities (ie, text, language, vocal features, or facial expressions). None, however, has focused on integration and the analysis of the complementary role of these modalities when expressed concurrently during a conversation; therefore, in this scoping meta-review, we integrated information from systematic reviews and meta-analyses on specific modalities and observable features of depression that are capable of being exploited by artificial intelligence.

Methods

Overview

We followed the methodological framework outlined by Arksey and O’Malley [30] and Levac and colleagues [31]. The framework proposes 6 stages: (1) identifying the research questions; (2) identifying relevant studies; (3) study selection; (4) charting the data; (5) collating, summarizing, and reporting results; and (6) consultation exercises. To ensure the process of this scoping review was systematic, transparent, and complete, we followed PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews [32]) guidelines.

Identifying the Research Questions

We first established the purpose of the review and developed specific research questions to guide our scoping review (eg, search terms, eligibility criteria)—which (1) text-related cues, (2) speech-related cues, and (3) facial expressions offer a valid insight into individuals’ depression?

Identifying Relevant Studies

Two large and commonly used databases, SCOPUS and Web of Science, which complement each other well [33,34], were used to identify the relevant papers. After a preliminary search in both databases, which helped us to refine the search strategy and ensure that the databases provide adequate coverage of the research topic, we conducted the main search on March 16, 2021.

Our search strategy combined terms related to depression (depression, “major depressive disorder,” “depressive episode,” depressivity, depressed), cues (feature*, indicator*, marker*, sign, signs, signal, signals, cue*, symbol*, pattern*, style*, clue*, manifestation*, expression*), behavior (language, linguistic, speech, acoustic, “facial expression”), and reviews (review, meta-analysis, “state of the art,” state-of-the-art). It should be noted that the last group of keywords (ie, those pertaining to reviews) was added in the process of search strategy refinement, as the number of papers was otherwise too high and not feasible for a scoping review. As such, the present scoping review is a scoping meta-review, which uses high-level evidence to answer research questions and policy dilemmas [35]. Additionally, the search strategy included keywords related to different disorders that affect behavior and display of emotions (dementia, “Parkinson’s disease,” autism, schizophrenia, Alzheimer’s, “neurological disorder,” stroke, “Huntington’s disease,” paralysis, mutism, “multiple sclerosis,” “cerebral palsy,” “Down syndrome”). Since comorbidity of depression and these disorders could skew our conclusions, such papers were already excluded in the first step. These groups of keywords were later combined into a nested format using Boolean operators (AND, OR, NOT), and titles, abstracts, and keywords were searched. The exact search string for SCOPUS was “TITLE-ABS-KEY ( ( depression OR “major depressive disorder” OR “depressive episode” OR depressivity OR depressed ) AND ( sign OR signs OR signal OR signals OR cue* OR symbol* OR pattern* OR style* OR clue* OR manifestation* OR expression* OR feature* OR indicator* OR
marker* ) AND ( speech OR “facial expression” OR language OR linguisric OR acoustic ) AND ( review OR meta-analysis OR “state of the art” OR state-of-the-art ) AND NOT ( dementia OR “Parkinson’s disease” OR autism OR schizophrenia OR “Alzheimer’s disease” OR “neurological disorder*” OR stroke OR “Huntington’s disease” OR paralysis OR mutism OR “multiple sclerosis” OR “cerebral palsy” OR “Down syndrome”) .” In order to identify potential additional papers, different combinations of search terms were used in Google Scholar, because this database can lead to the identification of additional unique entries [36].

The inclusion criteria were derived from the research questions guiding this scoping review and were set a priori. In order to be considered for inclusion in the scoping review, studies had to (1) be available in English and (2) published (ie, preprints and other unpublished papers were not considered). Studies were then excluded if (1) they were not based on empirical primary studies (ie, no quantitative evidence, obtained by collecting data on human participants), (2) they included human participants who suffered from other disorders that affect behavior and display of emotions, (3) they did not focus on adults, and (4) they did not offer evidence on the observable features (ie, text, speech, or facial expression) of depression. Since we aimed to provide a complete overview of all the research activity related to our research questions, we did not treat the methodological quality of reviews and primary studies as a reason for exclusion [30,37].

Study Selection

All citations identified in the electronic databases were exported to Excel spreadsheets (Microsoft Inc). Database searches yielded a total of 1203 papers, and 1 additional paper was identified through other sources (Figure 1). After duplicates were removed, 1023 titles and abstracts were screened in 2 stages. In the first stage, the authors (IM, NP, and US) individually excluded highly irrelevant papers. In the second stage, 2 reviewers (NP and US) independently reviewed the titles and abstracts of the remaining citations and settled disagreements through discussion. After this step, 18 papers underwent a thorough full-text review independently by 2 authors. Disagreements in this phase were settled through discussion and adjudication by a third reviewer (IM). In the end, 9 papers fulfilled the predetermined criteria and were included in the scoping review.
Figure 1. Flowchart of search and study selection.

Charting the Data

We developed a spreadsheet form based on research questions to determine variables to be extracted from the reviewed papers. Two authors (NP and US) then extracted the following data from each paper: (1) authors, (2) year of publication, (3) type of paper, (4) number of primary studies included, (5) inclusion criteria, and (6) important results or information relevant to our research questions. During this process, results were categorized into the following categories: (1) text cues, (2) speech cues, and (3) facial expression cues. Data extraction and categorization of results were refined and updated in an iterative process as the papers were reviewed. The resulting chart was used for analysis.

Collating, Summarizing, and Reporting Results

We did not follow a well-structured meta-analytic approach in comparing and summarizing the results given the aim and nature of a scoping review. Since the aim of a scoping review includes mapping the existing findings on a topic and providing their descriptive overview [30,37], the results were analyzed by 2 authors (NP and US) using thematic analysis [38] within 3 predefined categories of cues of depression (text, speech, and facial expression cues). To maintain rigor in collating and summarizing results, this process was reviewed by 2 authors (IM and SL).

Consulting With Stakeholders

We developed a review protocol that ensured psychological (BM, NP, and US), medical/oncological (SL), technological (IM), and methodological (NP, US) expertise were included. Health-care professionals involved in PERSIST were consulted to develop relevant inclusion and exclusion criteria (eg, specific conditions that could impact the expression of depression).

Results

Characteristics of Reviewed Studies

The final selection of papers in this review (Table 1) included 2 meta-analyses (22%), 2 systematic reviews (22%), 2 literature reviews (22%), 1 scoping review (11%), and 2 empirical studies
(22%) that were included because their state-of-the-art met the criteria of this scoping review. Papers were published from 1997 to 2021, with most (7/9, 78%) published after 2013. Papers included from 8 to 60 primary studies on the topics in line with this review, and most focused on more than 1 category of depression cues.

### Table 1. An overview of the characteristics of the papers reviewed.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Type of paper</th>
<th>Primary studies, n&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Depression cue categories addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cummins et al [28]</td>
<td>Literature review</td>
<td>60</td>
<td>Facial expression, speech, other&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dwyer et al [40]</td>
<td>Scoping review</td>
<td>22</td>
<td>Language use</td>
</tr>
<tr>
<td>Edwards and Holtzman [41]</td>
<td>Meta-analysis</td>
<td>21</td>
<td>Language use, speech</td>
</tr>
<tr>
<td>Kim et al [27]</td>
<td>Systematic review</td>
<td>15</td>
<td>Language use</td>
</tr>
<tr>
<td>Pampouchidou et al [29]</td>
<td>Systematic review</td>
<td>43</td>
<td>Facial expression, other</td>
</tr>
<tr>
<td>Scherer et al [42]</td>
<td>Review within empirical study&lt;sup&gt;c&lt;/sup&gt;</td>
<td>8</td>
<td>Facial expression, speech, other</td>
</tr>
<tr>
<td>Shan et al [43]</td>
<td>Review within empirical study&lt;sup&gt;c&lt;/sup&gt;</td>
<td>13</td>
<td>Facial expression, speech, other</td>
</tr>
<tr>
<td>Sobin and Sackeim [44]</td>
<td>Literature review</td>
<td>10</td>
<td>Facial expression, speech, other</td>
</tr>
</tbody>
</table>

<sup>a</sup>The number of primary studies that provided information on depression cues in 1 of 3 categories of interest.

<sup>b</sup>Other represents depression cues that are outside of the scope of this review.

<sup>c</sup>These papers include a comprehensive review and an empirical study.

### Features Related to Language Use

All 3 studies that focused on features related to language use [27,40,41] report that people with depression tend to focus on themselves, which is manifested in increased use of first-person singular pronouns, such as “I,” “my,” and “me.” While the relationship between using such words and depression is relatively weak, findings of the relationship are ubiquitous and well replicated: based on their meta-analysis [41], Edwards and Holtzman suggest that it is equally present in different subsamples (eg, age, gender, clinical or nonclinical samples) and contexts (eg, written or spoken text, private or public language).

Depression can also be inferred from other linguistic features, particularly those that—either directly or indirectly—express depressive symptoms. Analyses of text-based communication have revealed that depressed individuals tend to use more negative-valence words (eg, words related to pain, expressions of sadness and anger, aggressive emotions, and rumination) and fewer positive emotion words than their nondepressed counterparts. For example, some of the specific language markers of depression include words such as “hurt,” “tears,” “alone,” “hate,” “sleep,” and “worry” [27,40]. Depression can also be inferred from explicit mentions of the treatment of depression (words such as “side effects” and “therapy”) [40].

Reviews [27,40] also suggest the existence of other linguistic features of depression. Patients with mental health issues, including those with depression, use more absolutist words (eg, “always,” “never”) [40] and tend to be focused on the past (eg, “learned,” “remember”) [27]. Furthermore, for example, depressed users on Twitter were found to generally have fewer words per Tweet, while other studies show that people with depression in general also exhibit lower complexity of language (ie, use fewer complex sentences) [27]. Reviews have highlighted that depressed individuals tend to avoid complex sentences containing adverbial clauses, which is a type of dependent clause that functions as an adverb (eg, “as soon as,” “even though”) [40].

### Features Related to Speech

To some extent, features related to speech overlap with features related to language use and written communication. As mentioned above, increased usage of first-person singular pronouns has been identified in spoken language [41]. Moreover, similarly to written text, depressed individuals tend to engage less in verbal communication and speak in shorter phrases [42,43]. However, spoken language is generally an even richer source of information than written text—the information that it contains includes not only the message but also the manner in which the words are spoken.

Prosody, which describes the properties of intonation, stress, and rhythm (among others), is an additional source of information that has been well studied. Reviews and studies [28,42-44] indicate that the most promising prosodic feature of depression is related to speech rate. Depressed individuals speak at a slower rate than controls (particularly at the phoneme—the smallest unit of sound in speech—level) and exhibit longer pauses when answering questions, during the conversation, and at speech initiation [28,42-44]. The speech pause time is not only a good discriminator between depressed individuals and controls but also between depressed individuals and individuals with other mental health diagnoses, including bipolar disorder [44]. Although some authors report that there are conflicting results on the effect of depression on loudness and variation in loudness [28], others emphasize that especially reduced variation in loudness seems to be a common feature of depression [42,43]. Another variable that is often studied in the context of depression is fundamental frequency (also known as pitch or F0). All papers included in our scoping review concluded that depressed individuals exhibit lower pitch variability (also known

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(page number not for citation purposes)
as change of pitch) compared to controls, although some authors acknowledge that there was heterogeneity in primary studies [28,42-44]. The combination of lower variation in loudness as well as lower variation in pitch can result in monotonous speech among depressed individuals [42,43]. Similarly, depression has also been linked to a lack of linguistic stress (ie, relative emphasis given to a certain syllable or word), reduced intonation [28], repetitious pitch inflections and stress patterns [43], as well as poorer articulation (specifically, in terms of diphthong production, which refers to a sound made by combining 2 vowels) [44]. Fewer papers have studied other speech-related sources of information. Studies on source features (ie, features related to the source of voice production) have primarily focused on voice quality, with results showing that depression is linked to decreased voice quality (eg, aspiration, jitter, shimmer, and breathy phonation) and that the voices of depressed individuals are generally harsher [28,42]. Several studies have focused on comparisons of the glottal spectrum and flow parameters between depressed patients and controls. For example, depressed individuals exhibit higher energy in the upper frequency bands of the glottal spectrum [28]. Depression has also been linked to increased tension in the vocal tract and the vocal folds, with differences in parameters capturing glottal flow between moderate to severe depression and speakers without depression. Differences can specifically be found in their Normalized Amplitude Quotient, which is an amplitude-based measure of the glottal flow and glottal flow derivative, and their Quasi-Open-Quotient, which refers to an amplitude-based measure of the glottal flow pulse that offers important insight into the open period of the vocal folds [28,42]. Some studies also suggest that depressed individuals differ from their nondepressed counterparts in terms of the formant (information on acoustic resonances of the vocal tract) and spectral features (information on the speech spectrum). First, depressed speech is associated with decreased formant frequencies, particularly in the second formant location (phoneme/a1), although studies also show that the first 3 formant frequencies and bandwidths, grouped together, are significantly different between depressed patients and controls [28]. Second, while spectral analysis seems to have limited usefulness in classification systems, some studies have reported a relative shift in energy from lower to higher frequency bands, while others report a reduction in subband energy variability among depressed individuals [28].

Features Related to Facial Expression

Bylsma and colleagues [39] suggest that observing the behavioral indicators, there is reduced positive emotional reactivity in depressed patients and people with major depressive disorder compared to controls but found no differences in negative emotional response in comparison to controls. Their review also found “more pronounced blunting of positive emotional reactivity compared to negative emotional reactivity” [39]. Pampouchidou and colleagues [29] suggest that depression is associated with the variability and intensity of facial expressions (eg, reduced or decreased emotional facial expressivity [28,29,42]) with fewer animated facial expressions [43] and generally decreased facial mobility [28]. Links between depression and more frowns [29,42] and the occurrence of sad, negative, and neutral expressions [29] were also suggested.

Differences between people with depression and nondepressed individuals have been observed in eyebrow activity [29], through generally reduced eyebrow movements [28] and lower frequency and duration movements [44]. Differences can be observed in the region of the Veraguth fold (skin fold on the upper eyelid and between the eyebrows) and in the extended activity on the corrugator muscle (in the medial extremity of the eyebrow) [29].

Depression is associated with reduced saccadic eye movements [28,29], reduced horizontal pursuit [28], and increased visual fixation [28,29]. People with depression generally tend to engage less in mutual gazes [42] and limit eye contact [29]. Eye contact tends to be shorter in duration compared to normal controls [29,44] and people with schizophrenia [44] and occurs less frequently than in controls [44]. Depression tends to be associated with avoiding eye contact [43], low frequency and duration of glances [29], more gaze aversion, more downward gaze, and more nonspecific gaze [42]. Additionally, association with depression was observed in pupil dilation responses and bias, pupillary response, iris movement, and eyelid activity (eg, openings, blinking) [29].

Differences between people with depression and nondepressed individuals tend to be observed in mouth animation [29]. Specifically, they tend to present fewer mouth movements [42], more frequent lip pressures, down-angled mouth corners, and reduced activity on the zygomaticus muscle (which moves the mouth angle in producing a smile) [29]. Depression is generally associated with less smiling [28] (ie, smiling less often [29,42,44] and shorter duration smiles [29,44]) and can be observed in smile intensity [29]. People with depression tend to exhibit more smile controls [42] and listening smiles (smiles presented when not speaking) [29]. Associations between depression and head pose (ie, orientation and movement) [29] were also suggested. People with depression tended to turn the head away [42] and were more likely to hold their head in a downward position [43] than nondepressed individuals. People with depression, in comparison to those with schizophrenia, tended to exhibit more large head movements and a higher occurrence and duration of small head movements [44].

Discussion

General

Even though cancer survivors often find themselves experiencing disorders from the depressive spectrum, these conditions frequently remain underrecognized and overlooked [4,10]. Screening for psychological distress in this population is recognized as essential, but several barriers for its successful implementation persist [13,14]. For instance, the most used method of self-reporting of symptoms can result in significant bias in reporting experiences, which is even more pronounced in people with depression [18-23]. Therefore, a better way to detect psychological disorders in cancer survivors is needed.
Big data and artificial intelligence, together with a growing body of knowledge on the connection between observable cues and psychological states of a person, offer new opportunities to better detect psychological disorders in cancer survivors. As Low and colleagues [25] suggest, spontaneously generated cues of psychological states and their recognition by artificial intelligence could result in improved screening for psychological disorders.

In this scoping review, we reviewed 9 meta-analyses, systematic and literature reviews, and similar papers to conduct a meta-review of observable cues of depression. The findings of our meta-review revealed several observable characteristics of depression in each of the 3 categories. In language use, people with depression tend to show increased use of first-person singular pronouns, use more negatively valenced words, and less positive emotion words than nondepressed individuals. Additionally, the use of absolutist words, the use of words focusing on the past, and low language complexity are often present. In speech, people with depression engage in less verbal communication and speak in shorter phrases; lower speech rate, longer speech pauses, and potentially lower variation in loudness are exhibited. Some authors [42,43] also suggest lower pitch variability and change rate in people with depression, resulting in generally monotonous speech. Reduced intonation, repetitious pitch inflections and stress patterns, poorer articulation, decreased voice quality, generally harsher voice, and higher vocal tension also tend to be present. In the category of facial expressions, people with depression in comparison to nondepressed individuals show reduced positive emotional reactivity and emotional facial expressivity. Generally, they produce fewer animated facial expressions and facial mobility and exhibit more frowns and more sad, negative, and neutral expressions. There is less movement in the eyebrow region, and eyes exhibit reduced saccadic eye movements, reduced horizontal pursuit, and increased visual fixation. People with depression tend to engage in less mutual gaze, avoid or limit their eye contact, show more gaze aversion, and show more downward and nonspecific gaze. Fewer mouth movements, more lip presses, and down-angled mouth corners also proved to be evident in people with depression. Additionally, decreased smiling can be observed, together with more smile controls and listening smiles. They also turn their head away more often and hold their head in a downward position.

The diagnosis of cancer and subsequent treatments can have a large impact on patients’ psychological well-being. Along with the physical remnants of treatment, cancer survivors often continue to grapple with anxiety and depression. Almost one-third of cancer patients suffer from a comorbid mental health condition [45]. Although professional support is available after diagnosis and during treatment, the symptoms are still often overlooked in patients and long-term survivors [46], partially due to significant overlap between symptoms of emotional distress and late effects of cancer or side effects of treatment, but mainly due to depression’s complexity and subjective nature. Namely, as symptoms of depression may be normal for some, the that are symptoms present may impose significant psychological strain on other patients [47]. The difficulty in diagnosing depression in cancer patients has led to the development of several diagnostic approaches [48]. However, since screening is mostly based on self-reports during 6-month or 1-year follow-up, symptoms can remain unnoticed for a long period of time or can even be completely overlooked. The technological advances and reliability of machine learning–supported feature extraction classification methods may allow new, less intrusive, and more reliable ways to detect symptoms of depression. As highlighted in this scoping review, completely unrelated spoken or even written interactions, as well as visual cues, may reveal early warning signs that should trigger further clinical assessment.

While the technological advances may be of great benefit in recognizing these cues and signs, it is particularly important to note that many existing studies tend to exploit only 1 modality, such as text analysis [49], though it may be combined with other aspects of users’ writing (eg, the time gap between 2 consecutive writings; [50]), for artificial intelligence–based recognition of depression and other mental health issues. These approaches can be informative and helpful in the early detection of depression but tend to perform suboptimally due to their relatively narrow focus [51]. Our review shows that depression is likely expressed through all 3 forms of communication simultaneously; therefore, the prevailing unimodal approaches to artificial intelligence recognition of depression (eg, [43]) may be inadequate. Trimodal approaches are especially important in improving the accuracy of predictive models and reducing the chance of false classification of individuals as those presenting or not presenting signs of depression. For example, when using unimodal speech analysis models, an error could occur in the instance of nonnative speakers who often use first-person singular pronouns, which could be recognized as a meaningful feature of depression, whereas the result might be different when the other 2 modes are also examined. In PERSIST [26], we intend to exploit findings of this review to deliver an explainable artificial intelligence capable of sensing, detecting, and interpreting the affective states spontaneously expressed through language, speech, and mimicry during interaction (ie, diary recordings).

Study Limitations

While this scoping meta-review offers a valuable synthesis of research on the observable cues of depression and translates this knowledge into the context of screening cancer survivors’ depression with artificial intelligence, it does not offer an all-encompassing picture of the current state of research on the behavioral features of depression. First, the papers included in our scoping review highlight that depression is also associated with cues, such as body movement (including gestures, fidgeting) and posture, that are outside of the scope of this meta-review. As these features could explain the variance in depression expressions above and beyond the features described in our review (and hence improve the accuracy of depression detection algorithms), we argue that attempts to synthesize research on these additional cues would be highly beneficial. Second, the findings of our meta-review represent the features of depression that are characteristic of the average person with depression. Future research should take into consideration potential moderators that determine whether features are present and to what extent. In other words, future research should...
explore which cues are relevant in which cases, to allow the development of algorithms that are robust to individuals’ characteristics. Third, because we focused only on English-language papers, based on studies that were largely conducted on Anglophone participants in industrialized countries, our conclusions may be culturally biased. Further research is thus needed to understand whether our findings can be generalized. Lastly, since we included reviews instead of original empirical papers, it is possible that we overlooked more recent papers related to this topic that have not yet been included in any reviews.

**Clinical Implications**

This review provides valuable theoretical background and ideas for technological implementation that could facilitate the development of improved artificial intelligence solutions to detecting cancer survivors’ depression. We argue that such solutions may benefit clinicians as well as cancer survivors. For clinicians, these solutions may be more cost-effective and efficient for recognizing distress in patients after cancer than existing methods. As such, artificial intelligence could replace some elements of current screening procedures and supplement others. Additionally, such solutions may be used for ecological momentary assessments (and over longer periods of time), which is not possible with traditional clinical assessment and self-report instruments. For cancer survivors, on the other hand, artificial intelligence may be an accessible and nonobtrusive way of monitoring their mental health that does not require any conscious effort.

**Conclusions**

Evidence from 9 reviews (based on more than 200 primary empirical studies) show that there is a robust association between depression and a wide array of specific observable cues. Such associations are an excellent theoretical underpinning for the development of artificial intelligence algorithms; therefore, it is time to move from the question of whether artificial intelligence can support the process of detecting cancer survivors’ depression to the question of how this can be done.

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**Conflicts of Interest**

None declared.

**References**


Abbreviations

**PERSIST:** Patient-Centered Survivorship Care Plan After Cancer Treatments Based on Big Data and Artificial Intelligence Technologies

**PRISMA-ScR:** Preferred Reporting Items for Systematic Reviews and Meta-analyses Extension for Scoping Reviews

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Effectiveness and Feasibility of Internet-Based Interventions for Grief After Bereavement: Systematic Review and Meta-analysis

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Abstract

Background: Although grief and its symptoms constitute a normal reaction to experiences of loss, some of those affected still report elevated levels of distress after an extended period, often termed complicated grief. Beneficial treatment effects of face-to-face therapies, for example, grief counseling or cognitive behavioral therapy against complicated grief, have been reported. Evaluations of internet- and mobile-based interventions targeting symptoms of grief in bereaved individuals with regard to objective quality criteria are currently lacking.

Objective: We aim to conduct a systematic review and meta-analysis on the effectiveness and feasibility of internet- and mobile-based interventions against symptoms of grief after bereavement.

Methods: We conducted systematic literature searches of randomized controlled trials or feasibility studies published before January 9, 2020, following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, in PubMed, PsycINFO, Web of Science Core Collection, and the Cochrane Library. The quality of evidence was assessed using the Grading of Recommendations, Assessment, Development, and Evaluations system. We further assessed aspects of feasibility and rated quality of interventions using criteria suggested by an expert panel on mental health care (German Association for Psychiatry, Psychotherapy, and Psychosomatics). A random-effects meta-analysis was conducted to assess between-group effect sizes.

Results: In total, 9 trials (N=1349) were included. Of these, 7 studies were analyzed meta-analytically. Significant effects were found for symptoms of grief ($g=0.54$, 95% CI 0.32-0.77), depression ($g=0.44$, 95% CI 0.20-0.68), and posttraumatic stress ($g=0.82$, 95% CI 0.63-1.01). Heterogeneity was moderate for grief and depression ($I^2=48.75\%$ and $55.19\%$, respectively) and low for posttraumatic stress symptoms ($I^2=0\%$). The overall quality of evidence was graded low (grief and depression) to moderate (posttraumatic stress). User satisfaction with the interventions was high, as was the quality of the interventions assessed using objective quality criteria.

Conclusions: Internet- or mobile-based interventions might constitute an effective treatment approach against symptoms of grief in bereaved adults. However, the small sample sizes and limited number of studies included in the review warrant further investigation.

Trial Registration: International Prospective Register of Systematic Reviews (PROSPERO) CRD42012002100; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=131428

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KEYWORDS

grief; systematic review; meta-analysis; internet-based; online therapy
Introduction

Background
Owing to the increasing use of the internet, internet- and mobile-based interventions (IMIs) offer valuable treatment options for a broad range of mental health diagnoses and syndromes available to sections of the society [1]. The effectiveness of IMIs has already been proven for mild to moderate depression [2-4], anxiety [5,6], posttraumatic stress disorder [7-9], and other mental health diagnoses [10]. Reviews have reported effect sizes comparable with those observed in face-to-face therapies [11]. Compared with face-to-face contact and traditional therapies, IMIs offer several advantages, including low-threshold accessibility, flexible use independent of time and location, and high levels of anonymity and privacy, which might be especially useful for people with fear of stigmatization as a result of mental illness [12-15]. For these and other reasons, IMIs provide a feasible approach to reach underserved populations, such as older citizens or people living in rural areas with possibly difficult access to mental health care services.

Grief and its symptoms have long been recognized as a normal reaction to the loss of a significant other [16,17]. Although most bereaved individuals are eventually able to accept the loss and cope with their grief after a certain amount of time, some still report elevated levels of distress, such as posttraumatic stress, depressive symptoms, and persistent symptoms of grief after an extended period (ie, ≥6 months after the loss or longer) [18,19]. It is estimated that these persisting symptoms of loss-related grief, often termed complicated or prolonged grief, are present in 6%-10% of those experiencing bereavement [20]. Previous reviews and meta-analyses have reported beneficial treatment effects of face-to-face interventions, for example, grief counseling or cognitive behavioral therapy (CBT) against complicated grief [19,21,22]. However, a treatment gap for bereaved individuals has been suspected [23-25], further stressing the potential of IMIs as a safe and effective treatment option.

Objectives
So far, interventions targeting symptoms of grief in bereaved individuals have not been evaluated with regard to objective quality criteria. Assessing the quality of IMIs targeting symptoms of grief after bereavement could therefore help establish IMIs as a feasible treatment option in the health care sector.

Against this background, this review aims to do the following:

1. Provide evidence on the effectiveness of IMIs in targeting symptoms of grief after bereavement. The rationale for the review and meta-analysis was determined in advance in a published review protocol [26].
2. Critically assess the quality of available evidence using a well-established standardized tool for methodological quality assessment, the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system [27].
3. Assess the quality of applied interventions using objective quality criteria proposed by an expert panel on mental health care, namely, the Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde (DGPPN; German Association for Psychiatry, Psychotherapy, and Psychosomatics) [1], thereby allowing for statements on clinical implications and the potential of IMIs for individuals experiencing grief after bereavement.
4. Provide information on feasibility of treatment and satisfaction of trial participants. This will provide valuable information on the potential of IMIs for both clinicians and decision makers in mental health care as well as for individuals experiencing grief after bereavement.

Methods

Registration, Protocol, and Guidelines
The review methods, eligibility criteria, and strategy for data analyses are outlined in the study protocol [26]. The systematic review was registered with PROSPERO (CRD42012002100). We followed the recommendations of PRISMA (Preferred Reporting items for Systematic Reviews and Meta-Analyses) guidelines [28].

Eligibility Criteria
We searched for randomized controlled trials (RCTs) and feasibility studies published before January 9, 2020, including adults (≥18 years) in bereavement. Measures of the effectiveness and feasibility of IMIs were included. IMIs were defined as any psychological intervention targeting bereavement provided in a web-based or mobile setting, defined as online-, internet-, web-, or mobile-based. Studies were excluded if the intervention was an online self-help support group, forum, or chat or an internet- or mobile-based lifestyle intervention, that is, interventions aimed at increasing quality of life or overall well-being but not targeting symptoms of specific mental health conditions. The respective IMIs had to be compared with another IMI or to one of the following control conditions: no psychological treatment, attention or psychological placebo, waiting list, and active or no IMI treatment.

To be eligible for the review, original studies had to be targeted at individuals who experienced bereavement, whereas grief or grief-related symptoms were required as outcomes.

Search Strategy and Study Selection
A database search was conducted using a comprehensive search strategy for MEDLINE (PubMed interface), Cochrane Central Register of Controlled Trials, PsycINFO, and Web of Science (Web of Science interface). Studies published in English or German were considered. A combination of the following search terms was used: bereavement or widowhood or grief AND online or web or computer or mobile or e-health or internet AND intervention or psychotherapy or cognitive behavioral therapy or cbt. If feasible, Medical Subject Headings were used as search terms. The finalized MEDLINE search strategy was adapted to the syntax and subject heading specifications of the other databases. The search details for MEDLINE are available in Multimedia Appendix 1.
First, titles and abstracts were screened for all database returns by 2 researchers independently (M Luppa and CS). Second, studies were checked according to the following eligibility criteria by full-text analysis: (1) published in English or German, (2) participants aged ≥18 years, (3) participants experienced bereavement, (4) an IMI designed specifically for bereavement was evaluated (ie, effectiveness or feasibility), and (5) the study was an RCT or a feasibility study.

Data Extraction
Data from each included study were extracted and collected independently by 2 investigators (M Luppa and CS). A standardized data extraction form was applied. The reliability of data abstraction was tested using a random sample. Discrepancies at each stage of the selection process were resolved by discussion with the inclusion of a third researcher (SGRH). The data extracted were study characteristics: author, year of publication, country, study design, sample sizes, response rates, and recruitment; participant characteristics: age and gender; methodological aspects: diagnostic approach, diagnostic criteria, inclusion and exclusion criteria, and measurements (effectiveness and feasibility); and intervention characteristics: name, description, duration, guidance, and focus. In addition, if necessary, the authors were contacted for further information.

Quality Assessment
The risk of bias of the included studies was assessed by M Luppa and AEZ independently using the Cochrane Collaboration tool for assessing risk of bias [29]. The tool covers 6 domains of potential bias (eg, random assignment of participants to interventions, allocation concealment, and handling of missing data), with each domain labeled as high, low, or unclear for each study. The overall quality of evidence was assessed using the GRADE system [27].

A set of quality criteria suggested for IMIs by the DGPPN [1] was applied to assess the quality of the interventions described in the included studies. Quality criteria included information on therapeutic quality requirement, patient safety, information on mode of delivery (eg, guided or unguided), and data protection. These criteria were based on the Model for Assessment of Telemedicine Applications [30]. As these recommendations are aimed at already disseminated IMIs, the criteria were adapted slightly to be applicable to RCTs.

Effect Sizes and Meta-Analytic Procedures
For all studies, effect sizes of changes in outcomes targeting symptoms of grief after bereavement between baseline or preintervention and postintervention (ie, treatment effect) were obtained from sample sizes, means, and SDs in the experimental and control groups of the trials. Effect sizes were included as between-group effect sizes per outcome using data from intention-to-treat analyses or per-protocol analyses in cases where intention-to-treat data were not available. Standardized mean group differences within the studies and a pooled overall effect size of a given outcome across studies were estimated using the Hedges method to adjust for heterogeneity in sample sizes [31]. This estimator can be interpreted similarly to Cohen $d$, whereby effect sizes <0.5 are considered small, 0.5-0.8 indicate a moderate effect size, and >0.8 indicate a strong effect size [32]. Heterogeneity was further inspected by applying $Q$ and $I^2$ statistics and forest plots. To account for diversity in trial outcomes focusing on grief treatment, stratified meta-analyses were run for the respective outcomes considered in the original studies. Funnel plots and Egger tests were applied to assess potential publication bias and small study effects. In addition, to identify potential determinants on the pooled estimates, meta-regression analyses were conducted including the variables dropout rate (intervention and control group), feedback from the therapist (binary variable, yes or no), number of sessions or assignments, time since loss, and age of participants. All analyses were conducted using Stata 16.0 (standard edition, StataCorp).

Results
Study Selection
Of 275 studies identified through a literature search, 93 (33.8%) were duplicates and were therefore removed. After screening the titles and abstracts or reading the full text of the remaining articles, 4.9% (9/182) studies met the eligibility criteria and were included in the review. The selection process is illustrated in Figure 1. Most studies were excluded because the participants did not experience grief after bereavement or because the intervention did not address grief after bereavement (n=125).
Description of Selected Articles

An overview of the characteristics of the study samples is provided in Multimedia Appendix 2 [33-41]. In total, 2 studies applied the same intervention [33,34,42] in different samples, whereas 1 study [35] tested 2 interventions (exposure and behavioral activation) against the same control group. Therefore, the number of interventions differed slightly from the number of included studies. The investigations of Wagner et al [36] and Wagner and Maercker [37] were based on the same population but reported data from different time points (posttreatment and 3-month follow-up and 1.5-year follow-up, respectively) and therefore were both included in the review.

All studies except 2 [34,37] were RCTs. In these studies, a simple randomization strategy [33,35-39] or a stratified block design [40,41] was used for randomization. The pilot study of Kersting et al [34] was nevertheless included because the results were compared with those of a randomized control group. Therefore, the study design can be regarded as an RCT. At baseline, there were no significant differences between the intervention and control groups in the 6 studies [34,36-40]. In 2 articles, there were significant differences between at most 2 measured scales [33,35]. In all, 1 study did not report differences between the intervention and control groups [41].

Most studies were implemented in German-speaking [33,34,36,37,41] or English-speaking [38-40] countries; 1 study [35] was conducted in the Netherlands. The sample sizes ranged from 25 [41] to 757 [39]. The samples mostly included women (range 67.9%-100%) and middle-aged adults (mean range 34.2-63.4, SD 5.2-7.8 years). Overall, the level of education was rather high in all included studies, as indicated by the large proportion of participants with a high level of education or a university or college degree.

Participants mainly reported the loss of a parent [38], relatives other than their partner (ie, child, sibling, or parent) [35], a child during pregnancy [33,34], a spouse [40,41], or a child [36,37,39]. Certain trials were designed for specific types of death (eg, expected loss as a result of natural death [38] and prenatal loss of a child [33,34,42]), whereas the remaining trials were not restricted in this regard. However, it must be noted again that the intervention applied in the study by Kersting et al [34] was the same as in the study by Kersting et al [33], whereas the study by Wagner and Maercker [37] displayed the follow-up data from the study by Wagner et al [36]. The time since loss varied considerably among the trials, ranging from 1 to 6 months [38] to several years [36,39].

A description of the study characteristics is provided in Multimedia Appendix 3 [33-41]. All interventions were web-based and delivered as individual therapy. No study tested a mobile-based program. Most studies focused on complicated grief [33,34,36,37], whereas others focused on normal grief [38], complicated grief and rumination [35], prolonged grief [40,41], and bereavement [39]. For reasons of simplicity and because of similar eligibility criteria of the included articles, these terms are summarized as grief. Furthermore, 6 studies assessed posttraumatic stress symptoms (PTSS) [33-37,40] and 8 studies assessed depressive symptoms [33-37,39-41].

The duration of treatment ranged from 2 days [38] to 3 months [39], whereas most interventions lasted 5 weeks [33,34,36,37].
In total, 8 studies used a wait-list control group design. In another RCT, the researchers applied a treatment-as-usual control group [38]. Attrition rates ranged from 0% [38] to 59% [39].

Descriptions of the interventions are presented in Table 1. Except for Making Sense of Grief [38], which is a psychoeducational self-help tool based on social cognitive theory, all interventions were based on elements of CBT. With the exception of the study by Van der Houwen et al [39], all CBT-based interventions included distinct modules on exposure and cognitive reappraisal. In total, 2 interventions [35,40] included elements of behavioral activation.

### Table 1. Description of the interventions.

<table>
<thead>
<tr>
<th>Study</th>
<th>Therapeutic approach</th>
<th>Intervention components</th>
<th>Exposure</th>
<th>Cognitive reappraisal</th>
<th>Behavioral activation</th>
<th>Therapist feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brodbeck et al [41]</td>
<td>CBT</td>
<td>Text-based modules including writing assignments, covering the areas psychoeducation, assessment of current situation, fostering positive thoughts and emotions, finding comfort, self-care, and accepting memories</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Dominick et al [38]</td>
<td>Social cognitive theory</td>
<td>3 intervention modules (“My grieving style”; “Who am I?”; and “How am I doing?”), including interactive exercises supplemented by video testimonials; type-in responses and check lists; additional models: “Grief experience” and “Resources” offering text articles and websites or books covering grief-related topics</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Eisma et al [35]</td>
<td>CBT</td>
<td>Email-based homework assignments; exposure condition: writing assignments, imaginal or in vivo exposure exercises; behavioral activation condition: 7-day activity diary, identification of pleasurable and meaningful activities, identification of personal core values, development of new meaningful and pleasurable activities based on these values</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Van der Houwen et al [39]</td>
<td>CBT</td>
<td>Email-based writing assignments; exposure: describing the most distressing aspects of the loss (2 assignments); cognitive reappraisal: information on and identification of dysfunctional grief cognitions, letter to hypothetical bereaved friend (2 assignments); integration or restoration: letter to the deceased (1 assignment)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Litz et al [40]</td>
<td>CBT</td>
<td>Internet-based psychoeducation (18 sessions); education about loss and grief, instruction on stress management and other coping skills, behavioral activation: assignments on self-care and social re-engagement, accommodation of loss by establishing and working toward a personalized goal, and relapse prevention</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kersting et al [34]</td>
<td>CBT</td>
<td>Email-based writing assignments; self-confrontation: describing the circumstances of the loss (4 assignments); cognitive restructuring: supportive letter to hypothetical bereaved friend (4 assignments); social sharing: symbolic farewell letter to oneself, a loved one, or a person connected to the loss (2 assignments)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Kersting et al [33]</td>
<td>CBT</td>
<td>Similar intervention components as Kersting et al [34]</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Wagner et al [36]</td>
<td>CBT</td>
<td>Email-based writing assignments; exposure: describing the circumstances of the loss, specifically distressing loss-related thoughts (4 assignments); cognitive reappraisal: letter to hypothetical bereaved friend, identification of new role or identity after the loss and possible rituals to remember the deceased by, activation of social resources and competencies (4 assignments); integration and restoration: outlining important memories about the loss; reflecting on therapeutic process and grieving style; letter to oneself, a significant person, or a person related to the loss</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Wagner and Maercker [37]</td>
<td>CBT</td>
<td>Similar intervention components as Wagner et al [36]</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

aCBT: cognitive behavioral therapy.
An unguided internet-based treatment was applied in 2 studies [38,39]. All other interventions were guided via email [33-36,41] or telephone [40]. Guidance involved individual written feedback [33,34,36,37,42], technical information on how to use the intervention [35,39], or technical assistance via email or telephone and short reminders for participants with longer periods of inactivity [40]. Most interventions included writing assignments dealing with specific aspects of the loss [35,41] and exposure condition [33,34,36,37,39,42].

**Effect Sizes**

The forest plots of between-group effect sizes at the postintervention assessment for grief, PTSS, and depression across the studies are shown in Figure 2. Effect sizes ranged from moderate (grief: g=0.54, 95% CI 0.32-0.77; depression: g=0.44, 95% CI 0.20-0.68) to large (PTSS: g=0.82, 95% CI 0.63-1.01), whereas heterogeneity was low for PTSS (I²=0%) and moderate for grief (I²=48.75%) and depression (I²=55.19%). In total, 2 studies were excluded from the meta-analysis because they covered outcomes other than grief, depression, or PTSS [38] or follow-up data from included samples [37]. The results of the meta-regression analyses for grief and depression revealed that none of the considered determinants was associated with the respective pooled effect sizes. The Egger test revealed no indication of small study bias for grief (P=0.16), PTSS (P=0.62), or depression (P=0.62). Funnel plots indicated the presence of publication bias for grief and depression. Meta-regression results and contour-enhanced funnel plots are provided in Multimedia Appendix 4.

**Figure 2.** Effect sizes of interventions for grief, posttraumatic stress symptoms, and depression [33,34,36,37,40-42]. PTSS: posttraumatic stress symptoms.
Feasibility

Satisfaction with the internet-based intervention or other aspects of feasibility was measured in 5 studies [35,36,38,40,41], and their respective measures and results are provided in Table 2. Dominick et al [38] assessed acceptability and usability using items derived from web evaluation instruments, whereas Brodbeck et al [41] assessed satisfaction with self-constructed items derived from a validated questionnaire on patient satisfaction [43]. The trial by Litz et al [40] relied on the Post-Study System Usability Questionnaire and a protocol evaluation questionnaire, whereas Eisma et al [35] used a standardized questionnaire derived from earlier interventions for bereavement [44].

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome assessment</th>
<th>Rating&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brodbeck et al [41]</td>
<td>11 items measuring satisfaction; 4-point scale (1=not at all to 4=very much)</td>
<td>3.36 (0.32)</td>
</tr>
<tr>
<td>Dominick et al [38]</td>
<td>4 items measuring satisfaction (usefulness, helpfulness, satisfaction with the intervention, and recommendation to friends); 7-point Likert scale, 1=not at all to 7=extremely); 6 items measuring usability and acceptability (6-point Likert scale, 1=strongly disagree to 6=strongly agree); open question on possibilities to improve intervention</td>
<td></td>
</tr>
<tr>
<td>Eisma et al [35]</td>
<td>6 items measuring feasibility (comprehensibility of instructions and homework, feeling understood by the therapist, general feasibility, usefulness of treatment, and satisfaction with treatment), 5-point scale (1=completely disagree to 5=completely agree)</td>
<td></td>
</tr>
<tr>
<td>Litz et al [40]</td>
<td>Acceptability or usability (PSSUQ&lt;sup&gt;b&lt;/sup&gt;); 13-item 7-point scale, 1=strongly agree to 7=strongly disagree); system usefulness: ease, simplicity, efficiency of learning to use the website and using the intervention; information quality: is the information on the use of the website clear, easy to understand, and effective for helping with completion of the tasks?; protocol evaluation questionnaire: personal relevance and meaningfulness of intervention modules, accessibility of information, and general reactions to the intervention and its web-based format; qualitative feedback on intervention</td>
<td></td>
</tr>
<tr>
<td>Wagner et al [36]</td>
<td>4 items measuring treatment experience: contact with therapist (personal, impersonal, or do not know), experience of therapist contact via email (unpleasant, pleasant, or do not know), missing face-to-face contact with therapist (no, yes, or I do not know), and assumed effectiveness of intervention to reduce complaints (no, a little, quite a bit, or very strongly)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Results reported as mean (SD) or percentage.

<sup>b</sup>PSSUQ: Post-Study System Usability Questionnaire.

Methodological Quality

Risk of Bias

The risk of bias was assessed using the Cochrane Collaboration tool for assessing risk of bias [29], indicating low or high risk of bias for each study across 6 domains (Figure 3). Risk in a specific domain was labeled unclear if sufficient information was not available. As blinding of participants is not feasible in intervention trials requiring active participation and most trials included at least some kind of feedback from therapists or other study personnel, the domain blinding of participants and personnel was labeled not applicable for all trials. The risk of bias assessment for the individual studies is provided in Multimedia Appendix 5 [33-41].
Overall Quality of Evidence

The quality of evidence, assessed using the GRADE criteria, was considered low for depression and moderate for grief and PTSS. The domains of quality assessment for the 3 outcomes are presented in Table 3.

### Table 3. Quality of evidence across studies (Grading of Recommendations, Assessment, Development, and Evaluations [27]; n=8).

<table>
<thead>
<tr>
<th>Quality assessment</th>
<th>Outcome measure</th>
<th>Depression (n=8)</th>
<th>Grief (n=8)</th>
<th>PTSS(^a) (n=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Downgrade in quality of evidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of bias</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Inconsistency</td>
<td>No(^b)</td>
<td>No(^b)</td>
<td>No(^b)</td>
<td></td>
</tr>
<tr>
<td>Indirectness</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Imprecision</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Publication bias</td>
<td>Suspected(^c)</td>
<td>Suspected(^c)</td>
<td>Suspected</td>
<td></td>
</tr>
<tr>
<td>Upgrade in quality of evidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large effect</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Possible confounding would change effect</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Dose-response effect</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Effect (95% CI)</td>
<td>0.54 (0.32-0.77)</td>
<td>0.44 (0.20-0.68)</td>
<td>0.82 (0.63-1.01)</td>
<td></td>
</tr>
<tr>
<td>Overall quality of evidence</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)PTSS: posttraumatic stress symptoms.
\(^b\)\(I^2\)<60%.
\(^c\)As indicated by funnel plots.

Quality Criteria for IMIs

In addition to the methodological quality of the studies, we assessed the quality of the interventions described in the included studies based on recommendations by the DGPPN adapted for RCTs. The results are presented in Table 4. We also included an item covering information on potential funding sources and their role in the conduction of the study. If information on the intended purpose of the intervention was not available on the web and could not be obtained from the corresponding study authors, the criterion was marked as unclear. The overall quality varied across the interventions, whereas 2 interventions met all 12 criteria [34,41]. The quality of other interventions ranged from 5 [38] to 10 points [40].
Table 4. Quality assessment of internet- and mobile-based interventions.

<table>
<thead>
<tr>
<th>Item</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td></td>
</tr>
<tr>
<td>Is the intended purpose of the intervention clearly stated (which psychological symptoms can be alleviated by the intervention, orientation toward current version of the ICD\textsuperscript{a} and empirical evidence regarding the intervention)?</td>
<td>Yes Unclear Unclear Unclear Unclear Unclear Yes</td>
</tr>
<tr>
<td>Description of the intervention</td>
<td></td>
</tr>
<tr>
<td>Is the intervention based on evidence-based theories and techniques of psychotherapy? Are these theories and techniques clearly stated?</td>
<td>Yes Yes Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Information whether intervention is guided or unguided</td>
<td>Yes No Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>If guided, is there information on the type and content of guidance and who initiates contact?</td>
<td>Yes N/A\textsuperscript{b} Yes N/A Yes</td>
</tr>
<tr>
<td>Information on how often or how frequently the intervention should be used, possible prerequisites</td>
<td>Yes No Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Qualification</td>
<td></td>
</tr>
<tr>
<td>Was the intervention developed by registered psychotherapists or specialists in the field of psychiatry, psychotherapy, or psychosomatic medicine or affected parties? Is their possible involvement clearly stated?</td>
<td>Yes Yes Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Exclusion of participants with full-blown disorders (eg, severe depression and suicidal ideation)</td>
<td>Yes Yes Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Effectiveness</td>
<td></td>
</tr>
<tr>
<td>Use of intention-to-treat analyses to estimate effects</td>
<td>Yes No Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Between-group Cohen $d$ is reported for primary outcome (determined in advance)</td>
<td>Yes No Yes Yes Yes Yes Yes</td>
</tr>
<tr>
<td>Has the trial been registered in a clinical trial register?</td>
<td>Yes No No No Yes Yes No</td>
</tr>
<tr>
<td>Safety of patients</td>
<td></td>
</tr>
<tr>
<td>Advice on handling of crises (eg, referring to professional care with face-to-face contact); if people with full-blown disorders are included: assessment of emergencies and immediate reference to professional help</td>
<td>Yes Yes No No No Yes No</td>
</tr>
<tr>
<td>Provision of information on potential funding sources and their role in the conduction of the study</td>
<td>Yes Yes Yes No Yes Yes No</td>
</tr>
<tr>
<td>Number of criteria\textsuperscript{c} fulfilled (n=12), n (%)</td>
<td>12 (100) 5 (42) 9 (75) 7 (58) 10 (83) 12 (100) 8 (67)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}ICD: International Statistical Classification of Diseases and Related Health Problems.

\textsuperscript{b}N/A: not applicable.

\textsuperscript{c}Quality criteria based on the study by Klein et al [1].
Discussion

Principal Findings
This review systematically assessed the effectiveness of IMIs in treating symptoms of grief, depression, or PTSS after bereavement. We also provided information on the feasibility and quality of the delivered interventions based on quality criteria proposed by a professional organization in the field of mental health, namely, the DGPPN. Internet- or mobile-based interventions for grief after bereavement were found to be effective against symptoms of grief, PTSS, and depression, with the largest effect sizes observed for PTSS. These findings are in line with a recent review by Wagner et al [45] and Johannsen et al [19] covering face-to-face interventions targeting grief symptoms; however, the observed effects were lower than the effect sizes reported for IMIs targeting anxiety disorders, depression, or insomnia (for a meta-review, please see Stein et al [10]).

The observed treatment effects were smaller for depression ($g=0.44$) than for grief symptoms ($g=0.54$), which might indicate differences in symptomatology between grief and depression. Recent network analyses have found symptoms such as disturbed sleep, fatigue, anhedonia, and psychomotor agitation to be characteristic of major depressive disorders but not of persistent complex bereavement disorder [46]. It is possible that the interventions tested in the included studies are more suitable for addressing symptoms of grief than symptoms of depression. Addressing the latter in future interventions targeting bereaved individuals could further improve symptoms of depression. Most included studies relied on email-based writing assignments as part of the treatment; other IMIs specifically targeting depression included animated demonstrations or focused on increasing physical and social activity [47]. The individual intervention components should be tested in future trials.

The largest effect sizes were observed for PTSS. Regarding individual studies, however, the strongest effects for PTSS were observed in trials specifically addressing parents or women who had lost a child [33,34] or comprised samples where most participants had experienced the loss of a child [36]. Several studies reported pregnancy loss or loss of a child to be a risk factor for PTSD [48,49], and a review on face-to-face grief counseling identified parents mourning the loss of a child as high-risk mourners [50]. These factors might have led to a high proportion of traumatic loss experiences in the analyzed samples, contributing to the observed large effect size for PTSS.

Except for the study by Van der Houwen et al [39], all studies included in the meta-analysis applied guided interventions; therefore, current evidence is strongest for IMIs including a predetermined type of contact between the patient and therapist. This might point toward a useful treatment option for patients currently unwilling or unable to seek face-to-face mental health care or to discuss problems related to grief. On the other hand, IMIs could be integrated into regular care of patients experiencing grief after bereavement, and future trials are needed to provide more information on the potential of unguided interventions.

Assessment of the included interventions revealed high levels of quality, that is, instructions on how and how often to use the intervention, information on type of guidance by psychologists or other study personnel, and advice on handling of acute crises were provided. However, only a limited number of trials testing the interventions had been registered in a clinical trial register. All but 2 interventions [34,41] had no active address on the web at the time of the review or information of the presence of the intervention on the web could not be obtained retrospectively; therefore, certain aspects (eg, information on indication and purpose of the intervention provided for participants) could not be evaluated for all studies.

Furthermore, 5 (56%) out of 9 studies assessed feasibility or user satisfaction [35,36,38,40,41], revealing moderate to high levels of user satisfaction on average. Most participants regarded the interventions as both understandable and helpful. However, not all studies systematically assessed aspects of feasibility. Additional aspects could be covered in future trials, for example, time needed to complete the intervention or the intervention components on the part of the participants; certain studies included in this review reported considerable differences between scheduled and actual time needed to complete the intervention [40]. In addition, information on the amount of time devoted to feedback on assignments or inquiries from participants by psychologists or study personnel could provide useful information on the cost-effectiveness of the respective interventions [11]. The overall quality of evidence, as assessed by the GRADE criteria, was rated low for grief and depression and moderate for PTSS, particularly because of wide CIs and the possibility of publication bias.

In addition to the observed positive effects of IMIs against symptoms of grief, depression, and PTSS, future studies are needed to investigate the underlying mechanisms of the effects of these treatments (ie, what makes internet- or mobile-based approaches effective [19,34]). This should also include a more detailed feasibility assessment of the respective intervention components (eg, psychoeducation, exposure, behavioral activation, and therapist feedback) to investigate which components provide the most beneficial effect against the respective symptoms. Most included studies applied a wait-list control design; future research investigating different settings and study designs (eg, combined use of IMI and face-to-face CBT or evaluation against another mental health IMI) could yield valuable results on the effectiveness of IMIs against grief symptoms. Although the studies discussed in this review relied on self-reported data on symptoms of grief, PTSS, and depression, further investigations using clinical interviews to assess change in symptom load and symptom severity could further elucidate our knowledge on the effectiveness of IMIs. Respective analyses could yield valuable information as, in a systematic review, the effectiveness of face-to-face interventions was found to be related to symptom severity at baseline [22].

Limitations
Certain limitations need to be pointed out when interpreting our findings. Most participants in the included studies were women; therefore, we can only make limited assumptions about the effectiveness of the treatments for men. Recent reviews and
meta-analyses have reported that men and women are equally affected by prolonged grief following natural or unnatural losses [20,51], highlighting the need for interventions for both men and women. Although some interventions were specifically targeted at women (e.g., interventions aimed at grief after pregnancy loss), the effectiveness of IMIs for grief after bereavement in men remains an unsettled question. Beyond that, the level of education was comparatively high in the included studies, possibly indicating selection bias. Future trials might consider a wider variety of recruitment strategies to achieve more gender-balanced samples and a greater diversity of education levels, possibly increasing the generalizability of the results. Furthermore, this review and meta-analysis relied on a relatively small number of studies with partially very small sample sizes, stressing the need for further RCTs assessing the effectiveness of IMIs for grief after bereavement.

Conclusions
Our review provides evidence for the potential of IMIs as a safe and effective approach for treating symptoms of grief, depression, and posttraumatic stress after bereavement. Owing to the low cost and high accessibility, IMIs could benefit a large number of individuals experiencing grief after the loss of a significant other. With the inclusion of conditions such as persistent complex bereavement disorder or prolonged grief disorder in the Diagnostic and Statistical Manual of Mental Disorders and the International Statistical Classification of Diseases and Related Health Problems, awareness of the potential of IMIs targeting grief after bereavement should be raised among clinicians and decision makers in mental health care. The proof of effectiveness provided by RCTs is a central prerequisite for the implementation of new treatments in health care systems. The evidence reported in this review might therefore contribute to the advancement of IMIs for grief in bereaved individuals and their certification and implementation in routine care in the future. Further studies are warranted to deepen our knowledge on what makes IMIs successful for which populations of bereaved individuals and on the needs and preferences of users. This could contribute to improved care for and well-being of those experiencing grief after bereavement.

Acknowledgments
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Authors' Contributions
M Luppa, M Lübner, and SGRH conceptualized the study. M Luppa and CS performed the systematic literature search and identified eligible studies. M Luppa, CS, and AEZ extracted the data. AEZ and M Luppa systematically assessed the quality of the included studies, drafted and revised the manuscript, and conducted the meta-analysis and interpreted the data. M Lübner, JS, AP, and SGRH contributed to the manuscript and revised it for intellectual content. All authors read and approved the final version of the manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File, 1150 KB - mental_v8i12e29661_app1.docx]

Multimedia Appendix 2
Description of study samples.
[DOCX File, 26 KB - mental_v8i12e29661_app2.docx]

Multimedia Appendix 3
Study characteristics.
[DOCX File, 42 KB - mental_v8i12e29661_app3.docx]

Multimedia Appendix 4
Meta-regression analysis for grief, posttraumatic stress symptoms, and depression.
[DOCX File, 30 KB - mental_v8i12e29661_app4.docx]

Multimedia Appendix 5
References


Abbreviations

- CBT: cognitive behavioral therapy
- DGPPN: Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde (German Association for Psychiatry, Psychotherapy, and Psychosomatics)
- GRADE: Grading of Recommendations, Assessment, Development, and Evaluations
- IMI: internet- and mobile-based intervention
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- PTSS: posttraumatic stress symptoms
- RCT: randomized controlled trial

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Sharing Clinical Notes and Electronic Health Records With People Affected by Mental Health Conditions: Scoping Review

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Abstract

Background: Electronic health records (EHRs) are increasingly implemented internationally, whereas digital sharing of EHRs with service users (SUs) is a relatively new practice. Studies of patient-accessible EHRs (PAEHRs)—often referred to as open notes—have revealed promising results within general medicine settings. However, studies carried out in mental health care (MHC) settings highlight several ethical and practical challenges that require further exploration.

Objective: This scoping review aims to map available evidence on PAEHRs in MHC. We seek to relate findings with research from other health contexts, to compare different stakeholders’ perspectives, expectations, actual experiences with PAEHRs, and identify potential research gaps.

Methods: A systematic scoping review was performed using 6 electronic databases. Studies that focused on the digital sharing of clinical notes or EHRs with people affected by mental health conditions up to September 2021 were included. The Mixed Methods Appraisal Tool was used to assess the quality of the studies. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Extension for Scoping Reviews guided narrative synthesis and reporting of findings.

Results: Of the 1034 papers screened, 31 were included in this review. The studies used mostly qualitative methods or surveys and were predominantly published after 2018 in the United States. PAEHRs were examined in outpatient (n=29) and inpatient settings (n=11), and a third of all research was conducted in Veterans Affairs Mental Health. Narrative synthesis allowed the integration of findings according to the different stakeholders. First, SUs reported mainly positive experiences with PAEHRs, such as increased trust in their clinician, health literacy, and empowerment. Negative experiences were related to inaccurate notes, disrespectful language use, or uncovering of undiscussed diagnoses. Second, for health care professionals, concerns outweigh the benefits of sharing EHRs, including an increased clinical burden owing to more documentation efforts and possible harm triggered by reading the notes. Third, care partners gained a better understanding of their family members’ mental problems and were able to better support them when they had access to their EHR. Finally, policy stakeholders and experts addressed ethical challenges and recommended the development of guidelines and trainings to better prepare both clinicians and SUs on how to write and read notes.
Conclusions: PAEHRs in MHC may strengthen user involvement, patients’ autonomy, and shift medical treatment to a coproduced process. Acceptance issues among health care professionals align with the findings from general health settings. However, the corpus of evidence on digital sharing of EHRs with people affected by mental health conditions is limited. Above all, further research is needed to examine the clinical effectiveness, efficiency, and implementation of this sociotechnical intervention.

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KEYWORDS

Electronic health record; open notes; user involvement; patient advocacy; patient portal; patient rights; collaborative health care; participation; coproduction; system transformation; health care reform

Introduction

Background

Electronic health records (EHRs) are implemented throughout health care as important tools for documenting and coordinating care within and across health care provider organizations. In the past 2 decades, secure patient portals have provided service users (SUs) opportunities to access certain information from the EHR and interact with health care providers. Administrative functions, such as appointment booking and prescription renewals, are common, but giving SUs access to the full clinical content of the EHR has been more controversial.

Although patient-accessible EHRs (PAEHRs) contain many different types of information [1], one of the more disputed functions has been providing SUs access to clinical notes or narrative visit reports. This practice is often referred to as open notes [2,3]. Open notes can be considered an essential part of any PAEHR. In some countries, for example, in Sweden [4], Norway [5], Finland [6], and Estonia [7], nationwide PAEHR services, including open notes, are offered to most adult citizens. The legislation for giving SUs access to their EHRs is in place in many countries. In the European Union, most of the member states provide patients access to their EHRs; however, the level of access varies between member states. Legally, the SUs’ access to the EHR is usually covered by general data protection rules [8]. In the United States, since April 2021, a new federal rule mandates that all patients be offered access to their EHRs, including the narrative notes written by clinicians [9]. Notably, this rule encompasses the sharing of notes in psychiatry but excludes psychotherapy notes [10].

However, the sharing of mental health notes remains controversial. Health care professionals (HCPs) may be unclear when it is appropriate to close access or to hide aspects of documentation from patients. For example, in the United States, information blocking is permitted if doing so “will substantially reduce the risk of harm” to an SU or another person [11]. It is at the discretion of licensed HCPs to determine what constitutes a substantial risk in the context of a current or prior clinician-patient relationship. In such cases, the rules specify that risks must reach a clinical threshold well beyond the patient being upset [10]. However, as noted, these rules leave considerable latitude for interpretation, and so far, there are no clear procedures for monitoring or auditing clinicians’ decisions [12].

Moreover, beyond legal rulings, many HCPs report concern that SUs will become anxious or confused if they are offered access to their PAEHR [3,13]. HCPs also report concerns that providing access to SUs will reduce clinicians’ autonomy [14-17] and encroach on the quality of documentation [5,13-20]. Fears about additional workplace burdens [13,14,16-18,21,22], increased time spent responding to SUs’ anxieties, or misunderstandings about their clinical documentation [13,14,16,17,23] are additional concerns.

To date, between 2012 and 2021, 7 reviews have explored the effects of PAEHRs [24-30]. In 2020, a systematic review and meta-analysis found that adult patients’ access to EHRs was effective in reducing hemoglobin A1c levels and could improve patient safety. However, the authors concluded that more methodologically robust studies were necessary to increase meta-analytic power and to evaluate the effects of access in different health care domains [30]. Similarly, in 2021, a Cochrane database systematic review found that the effects of patient access compared with usual care were uncertain [25].

In mental health, sharing SUs’ health records and the use of PAEHRs are also topics for further development and research. Although the implementation of PAEHR in mental health is similar to other health care domains, the perspectives, expectations, and experience in mental health can be of different natures. For example, the fear of unexpected consequences led to a shadow record in Norway [5]. Several studies have further identified that within mental health, there are strong divergent views, expectations, and concerns based on either the SUs’ conditions or the HCPs’ professional role, with psychiatrists holding the most negative attitude toward open mental health notes [5,13,17,20]. We also observed that many studies focused on whether the use of PAEHR can be harmful to SUs; this theme will be discussed in the Special Challenges in MHC section in more detail.

Context and Scope of the Review

This is the first review to evaluate studies of PAEHR specifically among SUs affected by mental health conditions. In light of the new ruling in the United States and advances in patient access in the Nordic countries, evaluating the effects of PAEHR in mental health care (MHC) is particularly timely. As previous publications have stressed, PAEHR in MHC raises new practice dilemmas [10,31] but might also offer new opportunities to empower patients [32]. In the era of transparency, HCPs must now balance respect for patient autonomy and open and transparent information disclosures with duties to prevent patient harm. Persons with mental health conditions represent a vulnerable patient population, and there may be the potential...
to exacerbate perceptions of stigmatization or undermine the therapeutic alliance.

**Objectives**

Considering the urgent need for greater clarity regarding best practices in this domain, our goal was to initiate a scoping review to explore what is understood about the effects of PAEHR among SUs, care partners, and HCPs. The study objective was to map the available findings on sharing EHRs with SUs affected by mental health conditions. Hence, we map the key concepts underlying the research area, (ie, mental health and neighboring fields) with the available evidence. The following research question is examined in detail: What is known from the existing literature about sharing EHRs or clinical notes with people affected by a mental health condition?

**Methods**

**Scoping Review**

Compared with the systematic review method, which is guided by a strongly focused research question, a scoping review aims to open up the spectrum of the available evidence on a relatively new field of research, so that its breadth and depth become visible [33]. A systematic scoping review was considered highly appropriate because of the lack of systematic reviews on the research topic and the exploratory nature of our research question.

The methodological framework for scoping reviews proposed by Arksey and O’Malley [33], its further development by Levac et al [34], and the Johanna Briggs Institute guidance on conducting systematic scoping reviews were applied in this work [35]. Accordingly, the following steps were performed: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collating, summarizing, and reporting the results, and consultation with stakeholders on how to report and integrate the study findings. As specified by Arksey and O’Malley, at least 2 reviewers (JS, AB, and SH) were involved in the study selection and analysis. To ensure reproducibility and traceability, a scoping review was carried out and prepared according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Extension for Scoping Reviews checklist to report our results (Multimedia Appendix 1) [33,34,36].

**Information Sources and Search Strategy**

A literature search was conducted on April 16, 2021, and updated on October 2, 2021. A title and abstract search were carried out in 6 electronic literature databases: MEDLINE, Embase, Scopus, PsycINFO, Web of Science, and Google Scholar. The research question was based on three key concepts: (1) EHR, (2) sharing EHR with SUs, and (3) Mental Health, which were combined with the Boolean AND (Textbox 1). The search terms were adapted according to different databases. Subsequently, references of the found papers were scanned backward to find prior work that should be considered for the research topic [37]. This was followed by another forward search using Google Scholar to identify papers that cite the papers included in the review so far. Finally, in accordance with Haddaway et al [38], Google Scholar was used to track down gray literature.

<table>
<thead>
<tr>
<th>Textbox 1. Key concepts of the search strategy.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electronic health record search string</strong></td>
</tr>
<tr>
<td>• “open notes” OR “opennotes” OR “patient portal” OR “health record” OR “patient record” OR “psychiatric record” OR “clinical record” OR “health notes” OR “visit notes” OR “clinical notes” OR “psychotherapy notes”</td>
</tr>
<tr>
<td><strong>Sharing electronic health records with service users search string</strong></td>
</tr>
<tr>
<td>• Access OR show OR open OR share OR read OR engage OR participate OR participation</td>
</tr>
<tr>
<td><strong>Mental health search string</strong></td>
</tr>
<tr>
<td>• Mental OR psych*</td>
</tr>
</tbody>
</table>

**Eligibility Criteria**

Inclusion and exclusion criteria (Textbox 2) were informed by the review process and were applied at the study selection stage. All studies were included in the review as long as the participants were involved in the process of sharing EHRs or were affected by mental health conditions. This included not only SUs and medical staff, but also stakeholders from administration, information technology, and health policy. However, only studies that focused on the digital sharing of health records with SUs were selected. Purely paper-based sharing of medical files was set as an exclusion criterion.
Textbox 2. Inclusion and exclusion criteria.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Studies published up to September 30, 2021</td>
<td>• Gray data (Websites, tweets, and blogs)</td>
</tr>
<tr>
<td>• Studies in English</td>
<td>• Paper-based sharing of patient files</td>
</tr>
<tr>
<td>• No restrictions on the type of study</td>
<td>• Pediatric and adolescent health care settings</td>
</tr>
<tr>
<td>• Studies containing original empirical data</td>
<td></td>
</tr>
<tr>
<td>• Studies on service users affected by a mental health condition (&gt;18 years)</td>
<td></td>
</tr>
<tr>
<td>• Studies on care partners or family members of people affected by a mental health condition</td>
<td></td>
</tr>
<tr>
<td>• Studies on health care providers</td>
<td></td>
</tr>
<tr>
<td>• Studies on policy stakeholders</td>
<td></td>
</tr>
<tr>
<td>• All health care settings</td>
<td></td>
</tr>
<tr>
<td>• No location restrictions</td>
<td></td>
</tr>
</tbody>
</table>

Because people affected by mental health issues are treated at several other institutions in addition to psychiatric facilities (eg, outpatient psychotherapists and primary care by general practitioners), where sharing EHRs are also a common practice—at least in some countries—it was decided not to narrow down the search to individual medical specialties but to include all areas in which people affected by mental health conditions are treated.

All study types and designs were considered in this review. Search criteria were designed to include formally published peer-reviewed articles and selected grey literature (eg, dissertations and book chapters) as long as they contain original empirical data. Gray data such as websites, tweets, and blog posts were excluded. Studies conducted up to the end of September 2021 were eligible for inclusion.

Selection of Studies

The search results were exported from the respective search engines, merged in a Microsoft Excel table (columns: author, year, title, and abstract), and duplicate entries were removed. Study titles and abstracts were screened independently by 2 reviewers (JS and SH) using predefined eligibility criteria. To select mental health populations that were treated outside of mental health settings, all studies dealing with PAEHRs were initially selected for title screening. If mental health populations were named in the abstract, corresponding publications were included. Papers were excluded when the abstracts were not available. If it was not possible to decide on the suitability of a paper based on the abstract, the full text was assessed. The screening results were then discussed and consented to by the reviewers. As part of this iterative process, the full texts of the preselected studies were read. The decision to exclude individual studies was made at the level of the full text.

Data Extraction and Management

The research team developed a standardized template to extract and chart relevant data from the included studies [5,12-23,39-56]. The following parameters were recorded in detail: reference ID, authors, year, country, design, sample, participants, treatment setting and medical specialty, study purpose, and a summary of the results. The data were extracted by JS and AB, and checked for accuracy and completeness by CB (see Multimedia Appendix 2 [5,12-23,39-56] for more information).

Quality Assessment of Studies

The Mixed Methods Appraisal Tool (MMAT) was used to assess the quality of the included studies [57]. This tool was developed for quality assessment in systematic reviews that comprise qualitative, quantitative, and mixed method studies. It was successfully tested for reliability and efficiency in systematic reviews [58]. The evaluation of the MMAT is based on criteria that are specific to the method used and includes the following: the suitability and rigor of the methods used, control of confounding factors, minimization of selection bias, and consideration of limitations. The MMAT grading was carried out by 2 researchers (AB and JS) independently of one another and consented to their results. When no agreement could be reached regarding the assessment, a third researcher (SH) was consulted. One study was excluded from the analysis owing to a low-quality score (Results section). Because of the limited informative value, the mean value of the MMAT of all included studies was not calculated. Instead, a detailed description of the quality of the included studies is provided based on the MMAT grading results. A comprehensive presentation of the individual ratings of each criterion can be found in Multimedia Appendix 3 [5,12-23,39-56].
Qualitative Analysis and Synthesis
The results of all included studies were compiled and analyzed. The results were then analyzed independently by 2 researchers (AB and JS) using thematic analysis (Braun and Clarke [59]). In this process, the analytic material was increasingly summarized, and key themes were identified to organize the study results. The results of this synthesis process were discussed and approved by the entire research team.

SUs’ Involvement Statement
The review was neither coproduced nor carried out with the participation of SUs with lived experience of mental distress or any form of Patient and Public Involvement. However, after completion of the review, 2 researchers (LC and SM) with lived experience were invited to critically comment on the paper from an SU’s perspective. The commentaries are attached in the Multimedia Appendix 4.

Results
Study Selection
In total, 1034 records were identified—827 (79.98%) records from database searching, 207 (20.01%) through other sources (198 from Google Scholar, 9 through communication with authors and consultation with experts). After removing duplicates, 86.46% (894/1034) entries remained for title, abstract, and keyword screening. This step reduced the selection by a total of 854 to 40 records that were then subjected to a full-text eligibility check. Finally, 2.99% (31/1034) of entries that met the inclusion criteria of this review article were retained. The study selection process is shown in the PRISMA flow diagram (Figure 1) adapted from Moher et al [60].

Basic Characteristics of the Body of Evidence
These studies mainly used qualitative methods or surveys. A randomized controlled trial design was used once among the observational studies. Instead of well-established outcome measures, self-developed and unvalidated questionnaires were predominantly used in the surveys. A comprehensive overview of the basic parameters of the included studies is presented in Table 1.
Table 1. Basic characteristics of the included studies (N=31).\textsuperscript{a}

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total, n (%)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualitative</td>
<td>10 (32)</td>
<td>[12,15,16,18,21-23,39,50,51]</td>
</tr>
<tr>
<td>Survey</td>
<td>9 (29)</td>
<td>[5,13,14,17,40,43,45,48,49]</td>
</tr>
<tr>
<td>Mixed method</td>
<td>4 (13)</td>
<td>[20,46,47,55]</td>
</tr>
<tr>
<td>Descriptive</td>
<td>2 (6)</td>
<td>[53,54]</td>
</tr>
<tr>
<td>Cohort</td>
<td>2 (6)</td>
<td>[41,52]</td>
</tr>
<tr>
<td>Intervention</td>
<td>4 (13)</td>
<td>[19,42,44,56]</td>
</tr>
<tr>
<td>Randomized controlled trial</td>
<td>1 (3)</td>
<td>[44]</td>
</tr>
<tr>
<td><strong>Publication year</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012-2014</td>
<td>1 (3)</td>
<td>[44]</td>
</tr>
<tr>
<td>2015-2017</td>
<td>6 (19)</td>
<td>[13,15,19,39,47,56]</td>
</tr>
<tr>
<td>2018-2020</td>
<td>18 (58)</td>
<td>[5,14,16-18,20-22,40-43,45,46,49,52-54]</td>
</tr>
<tr>
<td>2021 and onwards</td>
<td>6 (19)</td>
<td>[12,23,48,50,51,55]</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>1 (3)</td>
<td>[21]</td>
</tr>
<tr>
<td>Canada</td>
<td>3 (10)</td>
<td>[20,45,56]</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1 (3)</td>
<td>[23]</td>
</tr>
<tr>
<td>Norway</td>
<td>3 (1)</td>
<td>[5]</td>
</tr>
<tr>
<td>Sweden</td>
<td>5 (16)</td>
<td>[14,16,17,50,55]</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>2 (6)</td>
<td>[47,51]</td>
</tr>
<tr>
<td>United States</td>
<td>8 (58)</td>
<td>[12,13,15,18,19,22,39-44,46,48,49,52-54]</td>
</tr>
<tr>
<td><strong>Study participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service users</td>
<td>17 (55)</td>
<td>[19,23,39-41,43-49,51-54,56]</td>
</tr>
<tr>
<td>Veterans</td>
<td>5 (16)</td>
<td>[39-41,43,52]</td>
</tr>
<tr>
<td>Health care professionals</td>
<td>16 (53)</td>
<td>[5,13-23,42,53-55]</td>
</tr>
<tr>
<td>Relatives</td>
<td>1 (3)</td>
<td>[45]</td>
</tr>
<tr>
<td>Policy stakeholders</td>
<td>2 (6)</td>
<td>[12,50]</td>
</tr>
<tr>
<td><strong>Treatment setting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient</td>
<td>11 (35)</td>
<td>[5,14,16,17,23,45,47,50,52,55,56]</td>
</tr>
<tr>
<td>Outpatient</td>
<td>29 (94)</td>
<td>[5,13-23,39-50,52-56]</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (3)</td>
<td>[51]</td>
</tr>
<tr>
<td><strong>Clinical field</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychotherapy</td>
<td>4 (13)</td>
<td>[18,46,53,54]</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>13 (42)</td>
<td>[5,14,16,17,19,20,23,45,47,48,50,55,56]</td>
</tr>
<tr>
<td>Veterans Affairs Mental Health</td>
<td>9 (29)</td>
<td>[13,15,22,39,43,52]</td>
</tr>
<tr>
<td>Somatic (General practitioner, Primary Care and other)</td>
<td>6 (19)</td>
<td>[5,21,44,48,49,51]</td>
</tr>
<tr>
<td>Not applicable</td>
<td>1 (3)</td>
<td>[12]</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Individual papers can be assigned to the various subparameters at the same time, which means that percentages of over 100% can be achieved.

**Search Results**
The results of the qualitative analysis and synthesis are presented thematically based on the main categories formed. The identified categories were as follows: (1) SUs’ experiences of reading mental health notes (positive and negative), (2) experiences of care partners, (3) HCPs’ experiences of sharing mental health
notes (benefits and risks), and (4) views of policy stakeholders and experts.

**SUs’ Experiences**

**Overview**

SUs’ attitudes and experiences toward OpenNotes were evaluated in about half of the papers. This included whether reading OpenNotes had any effect on SUs’ MHC, such as if the patient-clinician relationships were affected. In most papers, the participants were diagnosed with one or more mental disorders, such as posttraumatic stress disorder (PTSD) [22,39,41,43,52], bipolar disorder, psychotic spectrum disorder [22,39,41,43,48,52-54], personality disorder [40,43,44,47], substance use disorder [40,43,44,47,52], and major depressive disorder [22,39,41,43,46,53]. Other mental health issues among the participants were depression (unclear to what severity or type) [40,44,52], mild or atypical depression [46], anxiety disorder [41,43,47,52,53], military sexual trauma [52], and other mental illnesses within the International Classification of Disease-10 codes F00-F99 [48]. In 5 papers, mental health diagnoses or issues were not highlighted [19,45,49,51,56]. The most frequent care settings were outpatient and inpatient psychiatry, outpatient veterans’ mental health, outpatient psychotherapy, and primary care settings.

**Positive Experiences**

Positive experiences were reported to the greatest extent in all studies [19,22,39,40,45-47]. In one study, 94% (108/115) of all study participants reported that being able to read therapy notes on the web is a good idea [46]. In another study, most participants reported that they were extremely to moderately positive about open mental health notes [40]. SUs’ reported that they wanted to continue having web-based mental health notes available [19,46,47]. It was reported that open notes within MHC increased feelings of validation [46], SUs’ sense of control of their care 48.9% (87/178) [40,46], 82% (43/52) [19], 93% (372/400) [49], and helped SUs to understand potential side effects of medications, as well as to remember to take their medications [19,48,49,52]. One survey analysis examined SUs’ experiences with open notes by comparing persons with serious mental health diagnoses (defined as major depressive, psychotic, schizoaffective, or bipolar-related disorders), persons with other mental health diagnoses, and those with no mental health diagnoses [48]. The study found that 20% of SUs with serious mental health diagnoses, and 18% with other mental health diagnoses reported that they were more likely to adhere to their medications after reading their notes, compared with 14% of persons with no mental health diagnosis. The study also reported that among SUs with serious mental health diagnoses, the majority reported a better understanding of why medications were prescribed (67%), feeling more comfortable (65%), and more in control (67%) of their medications, and that notes helped answer questions about their medications (60%) [48].

In one self-reported web-based survey study from the United States, more than half of the study participants (total n=52) reported that open notes helped them to remember the plan for their MHC [19]. Other studies report that being able to access and read notes is extremely important for SUs to better take care of themselves [46,49]. Studies also report that open notes increased SUs’ understanding of their mental health [19,49] and awareness of their diagnosis [45]. In addition, SUs reported being better prepared for their visits [46,49], and the odds of attending their scheduled appointments increased by 67% after portal implementation [56]. A study at the Department of Veterans Affairs (VA) reported that the most frequently used features were medication refill, appointment view, secure messaging with the HCP, and Blue Button (eg, allowing the SUs to share their VA care documentation with a non-VA health care provider) [52].

Several papers have reported that open notes within MHC help SUs gain trust in their clinicians [39,40,46] and improve transparency [46]. SUs emphasized the importance of talking openly and upfront to each other [22,39]. In one of the semistructured interview studies conducted in the United States, SUs emphasized the importance of obtaining an overall picture of their mental health via the notes and of detailed notes that thoroughly summarized each visit. Notes that were written in this way reportedly increased feelings of being understood by their clinician. Notes that embraced strengths and progress in treatments also reportedly improved health and increased feelings of being valued and supported by their clinician [22].

The accuracy of the notes was also identified as a reason why SUs wanted to read their notes [19,22,45,46]. Health users desired the opportunity to ensure that no errors occurred and that the description of the visit was correct [19,45,46]. In one cross-sectional survey study conducted in the United States, 94% of the SUs (total n=108) reported that the description of the visits in the notes usually or always conformed to their visit [46]. Another survey study conducted in the United States found that SUs diagnosed with PTSD were more likely to report having read their notes [43]. A Canadian study reported improved recovery among SUs that use a patient portal according to Mental Health Recovery Measures. The study also reported an 86% decrease in the number of requests for health information among SUs [56].

Two studies have evaluated the impact of EHR use on in-session behavioral treatment with a computer screen facing the SU [53,54]. SUs reported that EHR use during their appointment did not impact communication and increased collaboration during their planning [53], and that collaborative documentation endorsed a strong therapeutic relationship [54].

In a feasibility study conducted in the United Kingdom, participants with severe mental illness monitored their health. The participants self-monitored and interactively input their health information into the EHR, which allowed them to self-monitor and become interactive with the service. The participants reported that the interactive part was most useful because they could monitor their mood over time, allowing them to better understand their illness [47]. In one cross-sectional randomized controlled trial, the hypothesis of mental health or substance use conditions as a possible barrier to engagement with web-based health information was examined. The results found that a mental health diagnosis was not a barrier to the ability to use a PAEHR [44]. The same results were reported in a mixed method study with a survey and interviews, where SUs with a severe mental health diagnosis
reported the benefits of using a PAEHR to self-monitor health outcomes, which contributed to experienced improvements in well-being over time [47]. Another study reported SUs’ positive experiences of a web-based educational program of open notes, which appeared to improve patient activation, trust in their clinician, and efficacy in health care interactions. Schizophrenia spectrum disorder, bipolar disorder, older age, and a higher number of mental health visits were common variables that were significantly associated with these improvements [41].

In one study, 43.7% (45/103) SUs reported interest in providing portal access to a care partner, and 33% (34/103) participants were concerned about privacy breaches and cybersecurity [45]. Other papers reported that SUs shared or discussed their notes with others; the most frequent sharing or discussion was with a care partner (15/108, 13.9% [46]; 9/52, 17% [19]).

**Negative Experiences**

Negative experiences have been reported in fewer papers and consistently on a smaller scale. Some SUs reported feeling judged and labeled [22,46], and 1 participant (total n=28) in a semistructured interview study described how the tone of the notes made him feel like being perceived as a complainer [22]. Some SUs felt offended by their notes (2/108, 1.8% [46]; 5/52, 9% [19]), or offended and disrespected by the tone of their notes [39]. Studies also reported that some health users experienced stress and worry when reading their mental health notes (14/178, 7.9% [40]; 9/108, 8.3% [46]; 2/52, 4% [19]; 32/400, 8% [49]), which caused some individuals to question the nature of documentation and therapy itself [19]. Feeling upset when reading mental health notes was also reported sometimes 17.9% (32/178) or often or always 7.9% (14/178), with the most frequent response “the notes make my problems seem smaller than they are” [40]. One study reported that health users found simple language to be preferable to medical terminology [22].

Studies have reported that SUs expressed feeling upset and worried when seeing inaccuracies in their notes or details with a lack of congruence between what the note said and their recollection of a visit [19,39,46]. Others felt confused and blindsided when discovering diagnoses in their notes that had not been discussed with them [22,39] and worried that errors could affect their mental health treatment [19,39]. Such incongruences in the notes contributed to strained trust in clinicians, as they experienced low transparency or lack of respect [22,39]. Some SUs also expressed concerns about privacy and confidentiality (15/108, 13.9% [46]; 9/52, 18% [19]; 164/400, 41% [49]). In addition, health SUs reported concern about who could access their mental health notes, and that medical appointment notes should be between them and their care providers [19,46]. One qualitative focus group study investigated SUs’ expectations of having access to their mental health notes. The participants emphasized the need to maintain confidentiality and expressed concerns about the security of the data systems. They wanted to have the choice to decide what information should be shared (eg, with other HCPs within the organization) and raised concerns about inaccurate notes and the need for transparency from their clinician regarding the content of the notes [51]. One self-reported cross-sectional survey study conducted at the Veterans Affairs Medical Center in the United States reported that SUs with PTSD diagnoses were more likely to experience negative emotions after reading their notes (no further explanation of why in the paper) [40].

**Experiences of Care Partners**

Only one study included care partners, such as family members and friends, as study participants in a cross-sectional survey (total n=7) [45]. Participants stated that to be able to support their family members it would be helpful and convenient to have access to the SU’s health record. They expressed an interest in accessing health records, messaging providers, receiving educational materials, appointment times, and self-assessments. Of the 7 participants, 5 (71%) expressed an interest in scheduling appointments and renewing medications.

**HCPs’ Experiences**

HCPs’ attitudes and experiences toward open notes in MHC were explored in about half of all papers. Study settings included veterans mental health (inpatient [22]; ambulatory [13]), inpatient and outpatient (1 large mental health hospital [20], 1 university hospital [15], 1 adult psychiatric clinic at a university hospital [14,16,17,55]), 2 ambulatory care settings [18,19], 1 primary health care [21], 2 health centers [53,54], and 1 MHC organization [23]. Psychiatrists, nurses, psychologists, therapists, and medical secretaries were the most common study participants.

**Experienced Benefits**

Unlike perceived risks, the HCPs’ perceived benefits of sharing mental health notes with SUs were reported in most studies to a minor extent. Mental HCPs believed that open notes contributed to better documentation [13,18,22], increased patient-clinician collaboration [13,22], and improved SU participation in care [13,15,19,23]. They also believed that open notes strengthened the patient-provider relationship [15,18,23], increased transparency [15,20], and increased feelings of trust [14,15]. A survey study from Norway reported that 2.39% (107/4477) mental HCPs believed that SUs in MHC had increased understanding of their diagnosis, treatment, and follow-up when reading their EHR [5].

One semistructured interview study with therapists, conducted in the United States, reported that the most significant impact of open notes was that it encouraged HCPs to be more sincere during visits and that it was easier to address difficult topics because communication was strengthened [18]. Transparent communication was reported to be important in maintaining patient-provider relationships and helpful when documenting potentially surprising and sensitive information such as diagnoses [15,18,22]. One self-reported survey study that evaluated the effects of a training program for mental health staff on open notes reported communication improvements, such as more frequently advising and educating SUs to access and read their notes, as well as more frequently asking SUs about questions and concerns regarding their notes [42]. One study evaluated the impact of EHR use on in-session behavioral treatment with a screen facing the SU, where HCPs confirmed the accuracy and acceptability of documentation with the SU to a large extent [54].
Notes that highlighted SUs’ strengths and treatment progress were perceived as necessary by mental HCPs [22]. These notes could help SUs gain control of their health and treatment [14,16,23], and also demonstrate that the HCPs heard and understood the SUs’ from a patient perspective [22]. Some papers reported that HCPs believed that collaborative notes could facilitate patient-centered care [15] and, in turn, that the power between care providers and SUs can be more equally distributed [15,21]. One full-population survey conducted before implementation in Sweden reported that mental HCPs believed that open notes within MHC would contribute to equal terms for all SUs, patient satisfaction would improve, and MHC would be both more efficient and safer [17]. In a full-population survey conducted after implementation in Sweden, mental HCPs believed that open notes improved SUs’ recall about their care plan better, helped them to be better prepared for visits, increased their understanding of their mental health condition, and strengthened health care SUs’ trust in them as clinicians [14].

**Experienced Risks**

Most papers reported mental HCPs’ anticipation of and experiences with open mental health notes: negative experiences and risks were reported on a larger scale, unlike positive experiences and benefits. The negative impact on SUs was a commonly expressed risk. Both before and after the experience of the practice, many HCPs believed that SUs would worry more [13,14,17], disagree with the content of their notes [13,17] or their diagnosis [13], be confused or offended [15,17,19,20], or that the assessment might be stigmatizing [15,19]. A Swedish full-population survey study reported that 25.5% (178/699) of the respondents experienced notes being more confusing than helpful for SUs [14], and that open mental health notes could make the care process less effective [16]. Other papers report respondents’ worry regarding patient disengagement from care [13,19] and increased clinical burden [13,14,16-18,20,21,23]. A Swedish full-population baseline study (total n=871) found that mental HCPs worried that visits would take significantly longer (35%), that they would spend more time addressing SUs’ questions outside of visits (40%), that they would spend more time dictating, writing, or editing notes (41.5%), and that they would be less candid in documentation (40.5%) after SUs are provided access to EHRs [17]. A survey study from Norway reported that 28.9% (1298/4477) of HCPs in psychiatric care did not report all relevant information in the EHR, and they reported spending more time writing notes (29%) [5]. In one United States survey study conducted in the Department of Veterans Health, about half of the total respondents (n=263) wanted open notes within MHC to be discontinued [13].

Many mental HCPs perceived a negative impact on the therapeutic relationship [15,18,20,22], as open notes may disconnect SUs from the in-person experience [15], and therefore, not facilitate discussions and the development of good relations during the visits [15,20]. A United States study, with semistructured interviews conducted at the Veterans Health Administration reported that HCPs’ concerns about how shifting patient-clinician power distribution affected their approach of providing care, such as how some SUs almost dictated how to write their notes and what information they should exclude [15]. Other papers report concerns about SUs’ lack of understanding of medical terminology documented in the notes, which could lead to misunderstandings and misinterpretations [14,16-19,23]. HCPs reported being less candid, less detailed [13,14,16-20,22], changing the tone of their documentation, and reported being afraid SUs’ might find errors and request changes [13,17,23]. Sharing sensitive information with SUs has been raised in some papers as a concern [19-23]. HCPs recommended excluding detailed information of traumatic experiences for privacy and safety reasons [22] and wanted to assess what to include in the notes on a case-by-case basis [19,20,22]. Issues of anonymity, privacy, and patient safety have also been raised as concerns [13,14,16-18,20,23,55], as HCPs reported not being able to protect SUs and the disclosure of third-party names [14,16,17,23]. One study evaluated the impact of EHRs on in-session behavioral treatment with a screen facing the SU, where HCPs were more likely to perceive in-session computing as more harmful to communication and computer use more disruptive than SUs [53].

In a pilot survey study conducted in the United States, mental HCPs offered SUs access to their mental health notes for 20 months. The study reported that the severity of illness, duration of treatment, and psychiatric diagnoses were critical variables in their selection, and psychotic, personality, cognitive, bipolar, and substance use disorders were excluded [19]. Another survey study conducted in Sweden found that mental HCPs experience personality disorders, psychosis, and paranoia as the most challenging SU groups to access and read their notes [14]. Studies have reported that the HCPs with the most negative attitude toward open mental health notes are psychiatrists [5,13,17,20], those working in acute care settings [20], nurse practitioners [13], psychologists [17], and medical secretaries [17].

**Views of Policy Stakeholders and Experts**

Two studies included the views of policy makers [50] and experts [12] on open notes in MHC. The first study explored Swedish national and local policy regulations regarding SUs’ access to their psychiatric notes and to what extent they were offered access. Regional policies and regulatory documents were analyzed, and key stakeholder email interviews were conducted. The study reported that out of Sweden’s 21 self-governing regions, 17 (80%) shared adult psychiatry notes with SUs, 15 (71%) regions shared pediatric and adolescent psychiatry notes, and 8 from forensic psychiatric care. Of the 6 regions that did not share notes from forensic psychiatric care, 2 (33%) planned to implement open notes, whereas 4 (67%) had decided to exclude open notes from this psychiatric care setting. All 17 regions shared psychiatry notes with both outpatients and inpatients. Immediate access to open notes was most common, followed by a 14-day respite period to provide access [50].

The latter study [12] was a web-based purposive survey of 70 experts on open notes drawn from 6 countries, including informaticians, clinicians, chief medical information officers, SUs, and patient advocates. Participants emphasized the importance of educating mental HCPs in writing notes and offering SU guidance on the risks and benefits of access. Experts...
suggested that HCPs should become more knowledgeable about patient terminology or use everyday language, and highlighted the importance of accurate, objective, and truthful notes. Experts addressed the need for guidance on how to describe sensitive and challenging topics in the notes. Recommendations included the need to train the staff on dealing with practice dilemmas specific to sharing mental health notes and dealing with possible disagreements [12].

Quality of Included Studies

We reported the grading according to the recommendations by the authors of MMAT [57]. Overall, we found that the quality of the included studies was very high or high, with some exceptions. We found the findings of these studies to be valuable and included these in our review after a discussion between the reviewers (AB, JS, and SH). In contrast, we excluded 1 paper with very low MMAT grading, as it was a design paper providing little insight into our research question. Of the 31 studies included, 16 (51%) used quantitative analyses, with majority reporting results from the surveys. The mean response rate was mostly low to moderate. Hence, there was a moderate bias in the nonresponse bias in these studies. A detailed description of the included studies and an overall MMAT grading can be found in Multimedia Appendix 3.

Discussion

Principal Findings

PAEHRs in MHC are a fairly new field, so the available evidence is limited. However, the increasing number of studies carried out in recent years has confirmed the increasing interest in applying PAEHRs in the mental health sector. It is not surprising that most of the studies were conducted in the United States and Scandinavia, given the legal initiatives there and the implementation of OpenNotes that go beyond pilot projects. The results of the included studies show a clear predominance of positive experiences among SUs, who in turn face an excessive amount of perceived burden and fears on the part of the HCPs—an aspect that requires a closer look. The results also point to several practical and ethical challenges that reveal both structural barriers and resistance on the part of the HCPs to change their usual routines and abandon the previous routines in the transparent handling of medical documentation. The extent to which these findings are specific to the MHC field can only be clarified in comparison with research from general health care settings. Therefore, we will (1) compare findings across different medical fields, (2) compare stakeholders’ expectations and experiences with PAEHRs, (3) discuss the special challenges of PAEHRs in MHC settings, and finally, (4) deduce tasks for future research on PAEHRs in MHCs.

Comparison With Non-MHC Settings

First, the corpus of evidence on PAEHRs in general health settings is significantly more extensive, which is reflected, for example, in the number of available reviews [25,27,61-63]. Although studies conducted in the mental health sector are primarily of an exploratory, qualitative, and descriptive nature, recent work from general health settings includes overall effectiveness studies often with randomized controlled designs [64]. Looking at the examined outcomes, improvements in medication adherence, disease awareness, self-management of the illness, and a decrease in office visits were demonstrated for nonmental health users [65,66]. However, there are also several qualitative findings on the experiences of veterans with PAEHRs in general health settings that are very similar to the included evidence. For example, Woods et al [67] found that the use of PAEHRs improves patient-physician communication and appointment recall and that SUs’ health literacy, understanding, and control of health issues were strengthened. Furthermore, veterans reported almost the same issues with PAEHRs as users affected by a mental health condition (eg, concerns about medicalized language in clinical notes and inconsistencies and errors in the documentation). This study is particularly comparable across medical fields, as the same access system myhealthvet was used.

Negative Expectations Versus Positive Experiences

As stated above, the present findings show an imbalance between negative and positive views of HCPs (and SUs) with PAEHRs. For instance, the assumption that SUs would often disagree, feel offended, or stigmatized with notes written by their therapist predominates the staff perspective in the existing evidence. These results contrast with the predominantly positive experiences of the users, who often describe the notes as very precise and a reflection of the visit that took place [19,22,45,46]. A closer look reveals that the focus of several of the included studies was on expectations before having used the EHR, and a significantly lower proportion of HCPs were asked about their actual experiences with the EHR. At this point, a comparison with general health settings is useful, where PAEHRs were piloted and researched much earlier than in mental health settings: a qualitative study of HCPs’ and SUs’ expectations toward PAEHR carried out in 2005 showed a similar imbalance [68]. With increasing implementation and use experiences, HCPs’ views on PAEHRs seem to have become increasingly positive [69]. Beyond that, the introduction of innovations in health care that disrupts or changes HCPs’ routines often appears to be accompanied by skepticism and discomfort [70]. This aspect seems to be more intensified when it comes to innovations that aim to expand the power or influence of SUs in the treatment process. For instance, the introduction of second opinion programs in the early 2000s—to check a physician’s recommendation of a particular surgical intervention—led to considerable skepticism and reservations among physicians, whereas this quality assurance measure has been proven to be a helpful and accepted standard in various health systems [71,72]. A sensitive way of dealing with these resistances could be shown in one of the included studies, which evaluated a web-based educational program on OpenNotes [42]. The provision of training HCPs on how to share the EHR seems to be of fundamental importance to address fears and reservations and contrast them by the overall positive evaluation results.

Special Challenges in MHC

Several of the included studies dealt with the question of whether PAEHRs could be harmful or disadvantageous for SUs with certain mental health issues or acute illness states and should therefore be limited. The findings of this study are
ambiguous. Initially, none of the included studies revealed critical events, such as self-harm, suicide attempts, or other violent behavior in connection with PAEHRs. Although isolated negative effects from reading EHRs have been described, they do not seem to be related to specific mental health conditions. Some unspecified adverse effects have been described for SUs with PTSD in Veterans Affairs Mental Health and can therefore not be easily transferred to other MHC settings [40]. The concerns expressed by clinicians toward individuals with whom it has been hard to develop trusting relationships with, or are delusional or paranoid, or who are prone to violence could not yet be confirmed by any of the included observational studies, which included SUs as participants. These concerns seem to be comprehensible from a professional point of view; however, instead of denying access to a subset of patients or not informing them about the possibility of accessing their EHR, one of the included studies recommended offering an educational program on the use of PAEHR to learn about the benefits and misuses of reading therapy notes, and to discuss possible adverse side effects with each individual SU. Discussion about restricting access to the EHR to only a subset of SUs, however, can be considered contrary to the basic idea of coproduction and may lead to epistemic injustice [73]. This might also apply to partial access restrictions, such as sharing notes only on a case-by-case basis or the release of clinical notes after an acute mental crisis has subsided [31]. PAEHR is of overriding relevance in the field of MHC, where therapeutic decisions are often guided by clinicians’ individual experiences, which are applied to the individual case instead of a small-step procedure described in guidelines, unlike other medical disciplines, such as surgery or internal medicine. Therefore, it is important to make medical decisions as comprehensible and transparent as possible. Hence, it cannot be concluded from currently available evidence that restricting PAEHRs makes sense for certain groups of SUs. Conversely, users should be able to dispose of omissions or restrictions on the release of their EHR themselves, especially when it comes to particularly sensitive information that should not be accessible to family members, for example, in the event of intimate partner violence or sexual abuse. In this regard, further research should assess the needs of SUs to be able to develop evidence-based best practices [74].

Limitations of Studies
Several important limitations arise from the studies reported in this scoping review. Most of the studies were based on surveys, and it is not known whether response biases affect findings. One-third of the included studies (8/31, 25%) were carried out in Veterans Affairs Mental Health settings, and half of these studies (4/8, 50%) selected American veterans as participants. As already discussed, this group is not necessarily comparable with the general population with regard to the distribution of psychiatric disorders and use behavior, which limits generalization.

Other studies examined PAEHR implementations in which only selected SUs were granted access to their EHR. In the Peck et al [19] study for example, treating clinicians decided for themselves which users were included or excluded from the intervention (PAEHRs). These results can also only be transferred to the population of psychiatric users to a very limited extent.

Much of the included evidence relates to OpenNotes, which is a self-described advocacy research unit that supports the dissemination of PAEHRs (note: not to be confused with VA OpenNotes, which is not connected or formally affiliated with the OpenNotes advocacy group). This implies a possible conflict of interest and increases the risk of positive bias in the results. Similarly, some authors contributed up to 10 of the 25 included studies, which increased the risk of not being able to replicate the findings [75]. However, because all included studies were subjected to a comprehensive methodological quality check in this review, the risk of these biases can be ranked as low.

Future Research
In addition to the research gaps already mentioned, the present corpus of evidence is incomplete and needs to be extended. First, the predominantly exploratory findings must be quantitatively validated. Currently, there is a lack of studies examining the effects of PAEHRs on the basis of well-established psychological outcomes such as symptom severity, social functioning, and empowerment using controlled designs and including more participants over a longer period of follow-up, as this may increase the likelihood of detecting the effects of the intervention.

Second, there is no evidence on the efficiency of PAEHRs in MHC. Therefore, the exact treatment costs of SUs having access to their EHRs should be measured and compared to demonstrate the efficiency of this intervention. Approximately 60% of psychiatrists’ working time in acute settings is not patient-related [76]; thus, it should be investigated to what extent PAEHRs may increase the time spent on documentation or whether PAEHRs can reduce treatment costs in the long term by accelerating therapeutic processes.

Third, several EHR solutions contain interactive tools to promote self-management and monitor the mood or activities of the SUs’ everyday lives. Further research should explore the role and scope of these extensions in PAEHR. To understand psychiatric treatment as a fully coproductive process, the EHR should not only be accessible but also easy to use among SUs [77]. Methods of participatory design can help study this.

Fourth, most of the existing interventional studies have excluded persons affected by severe mental illness or those being (involuntarily) treated in inpatient settings, often for safety reasons. However, there is initial evidence for a meaningful application of PAEHRs in acute psychiatry [78,79], which should be further explored. This includes a close examination of the question of whether PAEHRs can contribute to suicide attempts or other violent behaviors. In this context, the subgroup of individuals that HCPs are most concerned about should be examined; that is SUs with whom it has been very difficult to develop trusting relationships, or are delusional or paranoid, or who are prone to violence. Few studies have focused on the impact of PAEHRs on psychotherapy. In addition, little is known about the SUs’ perceptions of what clinicians have written. In this context it has to be considered more closely which type of
language is either helpful or hindering and which information should necessarily be included in the notes [31].

Fifth, further research should explore how PAEHRs affect documentation [80]. For example, it is not known whether access changes the quality of mental notes. For example, computer software programs that use validated metrics such as the Flesch-Kincaid reading scale could be employed to explore whether the length of notes changes after implementation or whether access changes readability.

Finally, as many of the included studies have mentioned concerns regarding privacy and data security [16,18,19,21,46,51], we think this theme has been covered rather superficially and the findings are sometimes contradictory. On the one hand, it was reported, for example, that SUs did not hold significant privacy concerns and worried more about data security [19], whereas in contrast privacy concerns were reported by both SUs and HCPs, which were partially reinforced after the implementation of a PAEHR [16]. Therefore, we believe that further, more rigorous, research on privacy and security is needed in the field of MHC.

Strengths and Limitations of the Scoping Review
This is the first systematic scoping review collating existing evidence about sharing EHRs or clinical notes with people being treated for mental health conditions. Several limitations should be considered when interpreting the findings. On the one hand, our search may have missed some relevant studies owing to the variety of terms used for EHR (eg, clinical note, electronic medical record, and patient portal), and the restriction on English-language and peer-reviewed publications. However, by applying a rigorous search strategy and continuously expanding the search term in the process, 1032 potential records could be identified and screened, which, considering the relative novelty of the research subject, represents a comprehensive result. In addition, the review benefited from a diversity of authors, located in 4 countries (Germany, Norway, Sweden, and the United States), who bring a variety of academic and health care backgrounds to this exploration (psychiatric practice, implementation science, philosophy of medicine, and health care ethics). Although this work was not coproduced by researchers with and without lived experience of mental distress, it was critically reviewed and commented on by 2 user researchers (SM and LC) to ensure adequate engagement of the authors (JS, AB, CB, MH, and SH) with PAEHRs from an SU perspective.

Conclusions
The corpus of evidence on sharing EHRs or clinical notes with people affected by mental health conditions is limited. Further research is needed to examine the clinical effects, costs, and implementation of PAEHRs. The user perspective on OpenNotes should be examined more closely with participatory design methodologies and involving researchers, including SUs and caregivers, with lived experience of mental distress.

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Conflicts of Interest
CB is based at OpenNotes, a research and advocacy unit that investigates patients' access to their clinical records.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) extension for Scoping Reviews Checklist.

Multimedia Appendix 2
Summary of included studies.

Multimedia Appendix 3
Mixed Methods Appraisal Tool ratings for each study.

Multimedia Appendix 4
Service user commentary.

References


Abbreviations

EHR: electronic health record
HCP: health care professional
MHC: mental health care
MMAT: Mixed Methods Appraisal Tool
PAEHR: patient-accessible electronic health record
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD: posttraumatic stress disorder
SU: service user
VA: Veterans Affairs
Understanding Engagement Strategies in Digital Interventions for Mental Health Promotion: Scoping Review

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Abstract

Background: Digital interventions offer a solution to address the high demand for mental health promotion, especially when facing physical contact restrictions or lacking accessibility. Engagement with digital interventions is critical for their effectiveness; however, retaining users’ engagement throughout the intervention is challenging. It remains unclear what strategies facilitate engagement with digital interventions that target mental health promotion.

Objective: Our aim is to conduct a scoping review to investigate user engagement strategies and methods to evaluate engagement with digital interventions that target mental health promotion in adults.

Methods: This scoping review adheres to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for scoping reviews. The search was conducted in 7 electronic databases from inception to April 2020. The inclusion criteria for studies were as follows: adult (aged ≥18 years) users of digital interventions for mental health promotion from the general population; any digital intervention for mental health promotion; and user engagement strategies described in the intervention design. We extracted the following data items: study characteristics, digital intervention (type and engagement strategy), evaluation of engagement strategy (method and result specifying whether the strategy was effective at facilitating engagement), and features of engagement (extent of use and subjective experience of users).

Results: A total of 2766 studies were identified, of which 16 (0.58%) met the inclusion criteria. The 16 studies included randomized controlled trials (6/16, 37%), studies analyzing process data (5/16, 31%), observational studies (3/16, 19%), and qualitative studies (2/16, 13%). The digital interventions for mental health promotion were either web based (12/16, 75%) or mobile app based (4/16, 25%). The engagement strategies included personalized feedback about intervention content or users’ mental health status; guidance regarding content and progress through e-coaching; social forums, and interactivity with peers; content gamification; reminders; and flexibility and ease of use. These engagement strategies were deemed effective based on qualitative user feedback or responses on questionnaires or tools (4/16, 25%), usability data (5/16, 31%), or both (7/16, 44%). Most studies identified personalized support in the form of e-coaching, peer support through a social platform, personalized feedback, or joint videoconference sessions as an engaging feature.

Conclusions: Personalized support during the intervention, access to social support, and personalized feedback seem to promote engagement with digital interventions for mental health promotion. These findings need to be interpreted with caution because the included studies were heterogeneous, had small sample sizes, and typically did not address engagement as the primary outcome. Despite the importance of user engagement for the effectiveness of digital interventions, this field has not yet received much attention. Further research is needed on the effectiveness of different strategies required to facilitate user engagement in digital interventions for mental health promotion.
Introduction

Background

Mental health promotion and well-being is a global public health challenge because of the high prevalence of mental disorders [1]. Mental health disorders are among the leading causes of global disability-adjusted life years (DALYs), with depressive disorders responsible for 1.8% of the DALYs and anxiety responsible for 1.1% of the DALYs [2]. As such, mental health disorders carry high costs not only for individuals, but also for families, communities, and societies [3]. In the European Union, the costs of mental disorders are estimated as being more than €600 billion (US $694 billion), which represents more than 4% of the gross domestic product across the European Union [3].

Mental health disorders have increased over time globally [2], highlighting the need for the prevention of mental disorders and promotion of mental well-being and mental health of the general population.

To face the challenge of the increasing burden of mental disorders and to address the demand for mental health promotion, technological approaches provide a solution [1]. Digital interventions offer the potential to overcome availability and accessibility barriers, including geographical location and time [1,4,5]. Furthermore, digital interventions for mental health are accessible to internet users who own PCs or mobile devices. Anonymous use is desired to bypass barriers because of the stigma of seeking help for mental health concerns [4,6,7]. Thus, digital interventions may reach different target groups compared with local mental health services [6].

Digital interventions for mental health are defined as interventions that are delivered through a digital platform such as the web [1,4,8], smartphone apps [4,6], SMS text messaging (on any platform) [1], and virtual reality [1,4] and target the prevention or treatment of mental health disorders. These interventions mostly implement techniques related to cognitive behavioral therapy or positive psychology [7] and, in the context of mental health, have been applied in healthy [4,8] and clinical samples [4,6,7]. The effectiveness of such interventions has been addressed by a number of systematic reviews. For example, Lattie et al [4] investigated digital interventions for college students who were either healthy or showed symptoms of psychological distress, depression, or anxiety. The authors found that some interventions, regardless of the type of digital intervention, were effective in improving mental health outcomes, including depression, anxiety, and psychological well-being in general. Furthermore, a systematic review by Weisel et al [6] examined mobile apps for adults with heightened symptom severity of several mental health disorders. Indeed, some interventions such as apps delivering cognitive behavioral therapy were found to be effective in reducing symptoms of depression but not effective in reducing symptoms of anxiety [6]. Overall, the systematic reviews suggest that an important function of digital interventions is to not only address existing clinical symptoms, but also to target the promotion of mental health; in general, enhance mental health promotion. Thus, this scoping review focuses on the application of digital interventions in studies with nonclinical samples for mental health promotion.

Engagement in digital technologies is critical for their effectiveness; however, retaining users’ engagement in digital interventions is challenging [9]. Digital interventions, in general, are prone to attrition because of their self-help and unguided nature [5]. For example, the systematic review by Lattie et al [4] revealed that many digital interventions that targeted the promotion of mental health in college students were effective, but attrition rates (ie, proportion of participants dropping out from the intervention) were high in the investigated trials. In some trials, most of the participants adhered to the first module but did not complete the subsequent modules [4]. Despite some evidence for the effectiveness and benefits of digital interventions for mental health promotion, problems are further encountered in translating the results from research studies into real-life settings [9]. Attrition is frequently reported in real-life settings when using digital interventions for general health and well-being [9] as well as prevention and treatment for specific conditions such as depression [7]. These findings highlight the need to develop strategies to effectively engage users with digital interventions for mental health promotion.

Engagement with digital interventions can be defined as “(1) the extent (e.g. amount, frequency, duration, depth) of usage and (2) a subjective experience characterized by attention, interest, and affect” [10]. The features frequency, duration, and amount refer to temporal use, with “amount” being defined as “total length of each intervention contact.” “Depth” is defined as a “variety of content used” [10]. Accordingly, engagement is described as a multidimensional construct in which users experience sustained behavioral aspects of engagement.

Objective

A synthesis of evidence on engagement strategies is required for digital interventions that address mental health promotion. Our aim is to collate such evidence using a scoping review approach to obtain a broad understanding of how user engagement is explored, measured, and evaluated in the context of digital interventions for mental health promotion. The research questions are as follows:

1. What strategies are applied to improve user engagement with digital interventions for mental health promotion?
2. What type of strategies result in better engagement with digital interventions for mental health promotion, and how is this improvement in engagement measured?

KEYWORDS
digital interventions; mental health promotion; engagement; scoping review; mobile phone
Methods

Methodological Details
This scoping review followed the Joanna Briggs Institute Scoping Review Methodology [11] and is reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines [12]. Additional methodological details are reported in the multimedia appendices. The completed PRISMA-ScR checklist is shown in Multimedia Appendix 1.

Protocol and Registration
The protocol for this review was prospectively registered at the Open Science Foundation registries [13].

Eligibility Criteria
Primary studies with any design were eligible for inclusion. The studies had to fulfill the following Population, Intervention, Control, and Outcomes characteristics:

Population: Any users of digital interventions for mental health promotion aged ≥18 years from the general population not in a clinical setting.

Intervention: Digital intervention for mental health promotion.

Control: Any comparator, such as another intervention type, or no comparator;

Outcomes:
1. Any user engagement strategy used in the design of digital interventions for mental health promotion.
2. Effectiveness of engagement strategies assessed and evaluated after the intervention.

The exclusion criteria were as follows:
1. Studies without primary data, including reviews, commentaries, letters to the editor, and study protocols.
2. Studies with clinical samples or specific subpopulations, for example, high-risk groups.
3. Studies with digital interventions for mental health treatment or health-related fields other than mental health.
4. Studies that did not report or recommend engagement strategies in the intervention design.

Information Sources
The information sources were the following electronic databases:
1. MEDLINE through Ovid
2. CINAHL through EBSCO
3. The Social Science Citation Index through Web of Science
4. The Science Citation Index through Web of Science
5. The Emerging Sources Citation Index through Web of Science
6. PsycINFO through Ovid
7. The Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews through the Cochrane Library

Search Strategy
The search strategy was developed by the team assisted by an experienced information specialist who subsequently conducted the search. Databases were searched from inception to April 2020, with no language limits applied. The search results for each database are presented in Multimedia Appendix 2. The search structure combined appropriate keywords and controlled vocabulary terms for 3 concepts: digital health interventions, engagement, and mental health. The search syntax for MEDLINE is presented in Multimedia Appendix 3.

Selection of Sources of Evidence
All results were exported to EndNote (Clarivate) reference management software for deduplication and then imported to Covidence (Veritas Health Innovation Ltd) systematic review management software for title, abstract, and full-text screening. In all, 2 authors (MS and LK) independently selected studies based on title or abstract, and any inconsistencies were resolved by consensus during discussion. A list of articles included and excluded for full-text screening are presented in Multimedia Appendix 4.

Data-Charting Process
A data-charting form was developed and calibrated by the team. The team discussed and agreed upon how data items would be selected and coded. In all, 2 authors (MS and LK) tested and calibrated self-developed data-charting forms for each study design until all relevant data were captured. The full data charting was conducted independently by 2 authors (MS and LK), and any discrepancies were discussed until consensus was reached.

Data Items
For each article, the data extracted included the following:
2. Study and participant characteristics: study design, aim of the study, sample size, age, and gender of participants.
3. Characteristics of the digital intervention: mode or type, aim, and content.
4. Engagement measures: user engagement rate for the intervention, type of tool used to measure user engagement, and features of engagement measured.
5. Engagement strategies: strategies for user engagement used in the design and effective evaluated user engagement strategy.

Study Quality
Effective engagement strategies were identified for each article based on the authors’ analysis of subjective user experience obtained through qualitative methodologies or questionnaires or, if available, based on the percentage of participants engaging with the intervention for a specific duration as determined by objective measures of intervention use.

Study Quality
Consistent with the PRISMA-ScR [12] guidelines, Joanna Briggs Institute Scoping Review Methodology guidance, and the framework proposed by Arksey and O’Malley [14], a quality appraisal was not conducted.
Data Synthesis
The data were divided into groups based on study design. The outcomes were narratively synthesized for each study design.

Results
Selection of Sources of Evidence
A total of 4585 articles were identified across all databases. Of the 4585 articles, 1819 (39.67%) duplicates were removed. On screening of the titles and abstracts of the remaining 2766 studies, 2654 (95.95%) were excluded, and the full texts of 112 (4.05%) articles were downloaded and screened against the inclusion and exclusion criteria. Of these 112 articles, 96 (85.7%) were excluded, and a total of 16 (14.3%) articles were included in this review. Figure 1 provides an overview of the selection process of the articles.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

Study Characteristics
Table 1 presents the general description of the studies. Of the 16 studies, 16 (100%) were published between 2013 and 2020 and originated from Europe (6/16, 37%), North America (6/16, 37%), and Australia (4/16, 25%). The study designs included randomized controlled trials (6/16, 37%), process data studies (5/16, 31%), observational studies (3/16, 19%), and qualitative studies (2/16, 13%). A process data study is a study conducting a secondary analysis on the primary data sets. The digital interventions for mental health promotion were mostly web based (12/16, 75%) or mobile app based (4/16, 25%).

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(page number not for citation purposes)
Table 1. General characteristics of studies (N=16).

<table>
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<th>Study design</th>
<th>Type of study</th>
<th>Intervention type (intervention name)</th>
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<tr>
<td>Lappalainen et al, 2013 [15]; Finland</td>
<td>RCT&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Feasibility</td>
<td>Web portal (P4 Well)</td>
</tr>
<tr>
<td>Todkill and Powell, 2013 [16]; United Kingdom</td>
<td>Qualitative study</td>
<td>Evaluation of design</td>
<td>Web based (MoodGym)</td>
</tr>
<tr>
<td>Morris et al, 2015 [17]; United States</td>
<td>RCT</td>
<td>Efficacy</td>
<td>Web based (Panoply)</td>
</tr>
<tr>
<td>Clarke et al, 2016 [18]; Australia</td>
<td>Process data study</td>
<td>Evaluation of usability engagement and efficacy</td>
<td>Web based (myCompass)</td>
</tr>
<tr>
<td>Laurie and Blandford, 2016 [19]; United Kingdom</td>
<td>Qualitative study</td>
<td>Gain insight into user experience</td>
<td>Mobile app (Headspace)</td>
</tr>
<tr>
<td>Zarski et al, 2016 [20]; Germany</td>
<td>Process data study</td>
<td>Evaluation of use in 3 intervention groups of RCTs</td>
<td>Web based and mobile app (GET.ON Stress)</td>
</tr>
<tr>
<td>Chou et al, 2017 [21]; United States</td>
<td>Process data study</td>
<td>Evaluation of design</td>
<td>Web based and mobile app (SuperBetter)</td>
</tr>
<tr>
<td>Dryman et al, 2017 [22]; United States</td>
<td>Process data study</td>
<td>Evaluation of use, engagement, and efficacy</td>
<td>Web based (Joyalbe)</td>
</tr>
<tr>
<td>Ly et al, 2017 [23]; Sweden</td>
<td>RCT</td>
<td>Feasibility</td>
<td>Mobile app (Shim)</td>
</tr>
<tr>
<td>Bakker et al, 2018 [24]; Australia</td>
<td>Cross-sectional</td>
<td>Evaluation of usability and feasibility</td>
<td>Mobile app (MoodMission)</td>
</tr>
<tr>
<td>Morrison et al, 2018 [25]; United Kingdom</td>
<td>Observational study</td>
<td>Efficacy</td>
<td>Web based and mobile app (Healthy Paths and Healthy Mind)</td>
</tr>
<tr>
<td>Song et al, 2018 [26]; Canada</td>
<td>Process data study</td>
<td>Evaluation of use and engagement</td>
<td>Web based (Walk Along)</td>
</tr>
<tr>
<td>Birk and Mandryk, 2019 [27]; United States</td>
<td>RCT</td>
<td>Efficacy</td>
<td>Web based (NR&lt;sup&gt;c&lt;/sup&gt;)</td>
</tr>
<tr>
<td>Carter et al, 2019 [28]; United States</td>
<td>Cross-sectional</td>
<td>Evaluation of design</td>
<td>Mobile app (NewCope)</td>
</tr>
<tr>
<td>Przybylko et al, 2019 [29]; Australia</td>
<td>RCT</td>
<td>Efficacy</td>
<td>Web based (The Lift Project)</td>
</tr>
<tr>
<td>Renfrew et al, 2020 [30]; Australia</td>
<td>RCT</td>
<td>Comparison of 3 modes of engagement strategies</td>
<td>Web based and mobile app (MyWellness)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Country of the corresponding author.
<sup>b</sup>RCT: randomized controlled trial.
<sup>c</sup>NR: not reported.

Qualitative Studies

Overview

Of the 16 included studies, 2 (13%) were qualitative studies (36 participants). Both studies reported effective engagement strategies based on user feedback.

Engagement Strategies Used in the Design

Todkill and Powel [16], conducted a qualitative study with 20 participants who used the intervention for 12 weeks. The intervention included a total of five modules that taught relaxation and meditation techniques, one module per week, web-based workbooks with 29 web-based exercises. No engagement strategy was reported.

Laurie and Blandford [19], conducted a qualitative study with 16 participants who used the intervention for 30 days. The intervention consisted of one audio file for daily guided meditation exercises for 10-15 minutes and a supplementary videos every 3-4 days. The researchers reported following engagement strategies used in intervention design (1) primary task support (audio and video content for meditation); (2) guidance (meditation guided by audio content); (3) third-party endorsement (during sign-up, users read quotes from journalists and celebrities); (4) social support (built-in buddy feature, allowing users to team up with others); (5) trust in provider.

Recommended Engagement Strategies

Both studies recommended the provision of daily challenging content and flexibility and ease of use as useful engagement strategies.

Observational and Process Data Studies

Overview

Of the 16 included studies, 3 (19%) were observational studies (592 participants) and 5 (31%) were process data studies (7000 participants). Table 2 presents the findings of these studies.
Table 2. Overview of observational and process data studies (n=8).

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of participants</th>
<th>Intervention (duration)</th>
<th>Engagement strategy in intervention design</th>
<th>Recommended engagement strategy (author conclusion based on engagement rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarke et al, 2016 [18]</td>
<td>90</td>
<td>Assessment of users’ self-reported symptoms followed by 24x7 access to a personalized intervention that includes real-time self-monitoring of moods and interactive psychotherapeutic modules (7 weeks)</td>
<td>1. Reminders to facilitate self-monitoring by SMS text messaging or email as scheduled by the user; 2. Graphical feedback about self-monitoring</td>
<td>1. Personalized feedback incorporating program content; 2. Alerts and reminders; 3. Flexibility in agenda and use</td>
</tr>
<tr>
<td>Zarski et al, 2016 [20]</td>
<td>395</td>
<td>A total of 7 modules composed of psychoeducation and exercises for every module (4-7 weeks)</td>
<td>CGa: Received intervention; IGb1: Personalized written feedback from e-coach on the completed exercises and reminder by e-coach once in 7 days (content-focused guidance); IG2: Personalized feedback and adherence monitoring on demand of participants (adherence-focused guidance)</td>
<td>Content-focused guidance</td>
</tr>
<tr>
<td>Chou et al, 2017 [21]</td>
<td>__c</td>
<td>Gamified challenges in browser-based community forum; players can invite other players to browser-based community to form allies (4 weeks)</td>
<td>1. Gaming language; 2. Social forum; 3. Bright graphics</td>
<td>NRd</td>
</tr>
<tr>
<td>Dryman et al, 2017 [22]</td>
<td>3439</td>
<td>A total of 5 modules: learning through psychoeducation, core skill development by cognitive restructuring, 2 exposure modules, and final graduation module (12 weeks)</td>
<td>1. Coaches paired with users to provide feedback and support through weekly calls; 2. Coach-initiated and automated emails to encourage participation and progress</td>
<td>Guidance and support through coaching</td>
</tr>
<tr>
<td>Bakker et al, 2018 [24]</td>
<td>44</td>
<td>Assessment of user inputs on distress, followed by daily coping activities or games (30 days)</td>
<td>1. Games designed with real-time coping strategies; 2. Rewards for daily completed games; 3. Push notifications of incomplete games; 4. Bright graphics</td>
<td>NR</td>
</tr>
<tr>
<td>Song et al, 2018 [26]</td>
<td>3076</td>
<td>Self-help tools and a secure account with access to additional resources and links (NR)</td>
<td>NR</td>
<td>Personal email invitations to visit the site</td>
</tr>
</tbody>
</table>

aCG: control group.
bIG: intervention group.
cNot available.
dNR: not reported.

Engagement Strategies Used in the Design

Of the 16 studies, 4 (25%) integrated personalized feedback about intervention content and users’ stress level as an engagement strategy in the intervention design and used reminder SMS text messaging or email according to users’ demand and progress as an engagement strategy. Moreover, of the 16 studies, 3 (19%) used bright colors and neat graphics as an engagement strategy in the intervention design. Guidance regarding content and progress through e-coaching was used in the intervention design of 13% (2/16) of the studies. Gamification of the content was used as an engagement strategy in the intervention design of 13% (2/16) of the studies. Goal setting and providing rewards were engagement strategies integrated into the intervention design of 13% (2/16) of the studies. Push notifications were identified in 13% (2/16) of the studies, whereas a social forum and interactivity with peers, simple content, and flexibility and ease of use were identified as the engagement strategies used in 6% (1/16) of the studies, separately.
**Recommended Engagement Strategies**

Effective engagement strategies were identified by the authors based on usability data and user feedback. The engagement measures of these studies are presented in Multimedia Appendix 5 [18,20-22,24-26,28]. Personalized feedback about intervention content and users’ stress level was identified as an effective engagement strategy in 50% (4/8) of the studies. For example, Clarke et al [18] reported on the myCompass program that assessed users’ self-reported symptoms on registration and provided personalized intervention with real-time self-monitoring of moods and behaviors and sent graphical feedback about users’ self-monitoring history alongside contextual information to their phone or PC as an engagement strategy and concluded that it directly enhanced users’ engagement with the program.

In 25% (2/8) of the studies, guidance regarding content and progress through e-coaching was reported as a strategy with the potential to increase engagement. In 25% (2/8) of the studies, implementing reminders according to users’ demand and progress was identified as a beneficial engagement strategy. For example, Zarski et al [19] analyzed 3 forms of guidance through human support and compared the effects on engagement with a stress-management intervention that involved content-focused guidance, adherence-focused guidance, and administrative guidance. Participants in the content-focused guidance group received personalized feedback after completion of every exercise. Participants in the adherence-focused guidance group received a personalized reminder by an e-coach in case of incomplete exercises. Participants in the administrative guidance group were provided with contact information during the study period. Participants in the content-focused guidance group showed the highest engagement, followed by participants in the adherence-focused guidance group and the sample that received administrative guidance. However, content-focused guidance was not significantly associated with higher adherence compared with adherence-focused guidance, indicating that guidance regarding content and progress through e-coaching improved engagement. Flexibility and ease of use was recommended in 25% (2/8) of the studies as an engaging strategy.

**Randomized Controlled Trials**

**Overview**

Of the 16 included studies, 6 (37%) were experimental studies (15 arms). Table 3 presents the findings of these studies.
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants, n (% female)</th>
<th>Age in years, mean (SD)</th>
<th>Intervention (duration)</th>
<th>Engagement strategy in intervention design by group</th>
<th>Recommended engagement strategy (author conclusion based on the usability of study arms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lappalainen et al, 2013 [15]</td>
<td>24 (0)</td>
<td>47 (7)</td>
<td>A total of 3 group meetings and personal use of web portal, apps, and devices (3 months)</td>
<td>CG*: No intervention; IG*: Personalized feedback</td>
<td>IG: Personalized feedback</td>
</tr>
<tr>
<td>Ly et al, 2017 [23]</td>
<td>28 (54)</td>
<td>26 (7)</td>
<td>Learn strategies of positive psychology through fully automated conversation, daily check-ins, and weekly summaries (2 weeks)</td>
<td>CG: No intervention; IG: Fully automated chatbot (conversational agent)</td>
<td>IG: Fully automated chatbot</td>
</tr>
<tr>
<td>Birk and Mandryk, 2019 [27]</td>
<td>259 (51)</td>
<td>35 (11)</td>
<td>Customization of avatar, ABMTc, and negative mood induction (3 weeks)</td>
<td>IG1: Customized avatar and ABMT; IG2: Customized avatar and no ABMT; IG3: Generic avatar and no ABMT; IG4: Generic avatar and no ABMT</td>
<td>IG1: Avatar customization and personalization</td>
</tr>
<tr>
<td>Renfrew et al, 2020 [30]</td>
<td>458 (78)</td>
<td>46 (1)</td>
<td>Videos, workbook, reading materials related to the topic, and daily and weekly challenges (10 weeks)</td>
<td>CG: Automated email support; IG1: Automated email support and reminder SMS text messaging; IG2: Automated email support and videoconference session per week and 1 reminder SMS text message for videoconference per week</td>
<td>None (Videoconference mode had no effect on intervention engagement, and getting the chosen support style did not result in better engagement or outcomes)</td>
</tr>
</tbody>
</table>

aCG: control group.
bIG: intervention group.
cABMT: attention bias modification training.

**Engagement Strategies Used in the Design**

In all, 4 intervention arms in 50% (3/6) of the studies used reminder SMS text messaging or email according to users’ demand and progress as an engagement strategy. Personalized feedback about intervention content and users’ stress level was used as an engagement strategy in 2 intervention arms in 33% (2/6) of the studies. A social forum and interactivity with peers was an engagement strategy in 2 intervention arms in 33% (2/6) of the studies. Easy accessibility and flexibility was used as an engagement strategy in 1 intervention arm. Personalization of content was used as an engagement strategy in 3 intervention arms in 33% (2/6) of the studies. Videoconference sessions with an e-coach were used as an engagement strategy in an intervention arm in 17% (1/6) of the studies. Push notifications were integrated as an engagement strategy in the intervention arm in 17% (1/6) of the studies. Gamification of content was used as an engagement strategy in an intervention arm in 17% (1/6) of the studies.

Renfrew et al [30] compared 3 modes of support differing in resource requirements on the effectiveness of the intervention, that is, automated emails, personalized SMS text messaging, and facilitated videoconference. Participants in the email group received a weekly email before every session with a 20- to 25-second video motivating users to engage. The personalized
SMS text messaging group received an automated email and a personalized SMS text message, with the participant’s first name, to prompt engagement, and signature of a research team member, thrice weekly for the first 3 weeks and then twice weekly for the remaining 7 weeks. The reduction in messages was carried out with the perception that support has a threshold and a surfeit of messages may reduce engagement. The members of the videoconference group received automated email support and were invited to attend a videoconference session once a week. User engagement was not significantly different among the 3 groups, although notable variability in responses within the groups was indicated by a large SD.

**Recommended Engagement Strategies**

Engagement strategies were reported by authors based on usability data of different study arms. Engagement measures are presented in Multimedia Appendix 6 [15,17,23,27,29,30]. Of the 6 studies, 2 (33%) identified personalized feedback about intervention content and users’ stress level as an effective engagement strategy, and a social forum and interactivity with peers was identified as a useful engagement strategy in 2 (33%) studies. For example, Przybyłko et al [29] included a social forum in the intervention design, where the participants could comment and post pictures regarding daily content. It was concluded that this strategy was highly engaging for users.

Of the 6 studies, 2 (33%) identified content personalization as an effective engagement strategy. For example, Ly et al [23] reported that content personalization through a fully automated chatbot intervention, Shim, which made users learn, reflect, and practice positive psychology through adequate responses and feedback to user’s statements, was found to be highly engaging for users. Birk and Mandryk [27] reported that avatar personalization for the intervention content greatly improved task-specific user engagement.

**Features of Engagement and Tools Used**

Table 4 and Figure 2 present the features of engagement explored in the different studies and the tools used to measure these features. Of the 16 studies, 13 (81%) measured frequency; 8 (50%) measured duration; 7 (44%) measured amount, attention, affect, and interest; and 3 (19%) measured depth. Of the 16 studies, 12 (75%) used automatic measures, 7 (44%) used self-administered questionnaires, and 5 (31%) used qualitative interviews to evaluate engagement.
<table>
<thead>
<tr>
<th>Study</th>
<th>Theory of engagement</th>
<th>Features of engagement</th>
<th>Tool used to measure engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Todkill and Powell, 2013 [16]</td>
<td></td>
<td>Affect, attention, and interest</td>
<td>Interviews on content, medium, functionalities, and experience</td>
</tr>
<tr>
<td>Morris et al, 2015 [17]</td>
<td>Technological interaction and consumption</td>
<td>Attention, interest, and depth</td>
<td>UEQ&lt;sup&gt;3&lt;/sup&gt;+interview</td>
</tr>
<tr>
<td>Morris et al, 2015 [17]</td>
<td>Technological interaction and consumption</td>
<td>Amount, duration, and frequency</td>
<td>Automatic; time per session, time of intervention use total, and number of log-ins</td>
</tr>
<tr>
<td>Clarke et al, 2016 [18]</td>
<td></td>
<td>Affect</td>
<td>Interview</td>
</tr>
<tr>
<td>Clarke et al, 2016 [18]</td>
<td></td>
<td>Frequency</td>
<td>Automatic; number of log-ins, number of modules completed, frequency of self-monitoring, and interviews</td>
</tr>
<tr>
<td>Laurie and Blandford, 2016 [19]</td>
<td></td>
<td>Affect, attention, and interest</td>
<td>Interview and qualitative interviews</td>
</tr>
<tr>
<td>Zarski et al, 2016 [20]</td>
<td></td>
<td>Frequency</td>
<td>Automatic; frequency of app use over study period</td>
</tr>
<tr>
<td>Chou et al, 2017 [21]</td>
<td></td>
<td>Duration and frequency</td>
<td>Automatic; number of completed modules</td>
</tr>
<tr>
<td>Dryman et al, 2017 [22]</td>
<td>Motivational techniques delivered by coaches</td>
<td>Frequency and duration</td>
<td>Automatic; average number of days in the program, average activities per participant, and completion rate of all modules</td>
</tr>
<tr>
<td>Ly et al, 2017 [23]</td>
<td>Fully automated conversational agent</td>
<td>Affect, attention, and interest</td>
<td>Interview</td>
</tr>
<tr>
<td>Ly et al, 2017 [23]</td>
<td>Fully automated conversational agent</td>
<td>Frequency</td>
<td>Automatic; number of reflections completed, number of active days, open app ratio, and interviews on content, medium, and functionalities</td>
</tr>
<tr>
<td>Bakker et al, 2018 [24]</td>
<td>Recommendations by Bakker et al [31] (2016)</td>
<td>Affect, attention, interest, depth, and frequency</td>
<td>Questionnaire, uMARS&lt;sup&gt;5&lt;/sup&gt;, text-entry questions, and HRS-MA&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Morrison et al, 2018 [25]</td>
<td>Recommendation by Dennison et al [32] (2013)</td>
<td>Affect and attention</td>
<td>Questionnaire on satisfaction with the intervention, PEI&lt;sup&gt;f&lt;/sup&gt;, and TAM-2&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Song et al, 2018 [26]</td>
<td></td>
<td>Interest, amount, duration, and frequency</td>
<td>Automatic; number of pages accessed per session, time per session, goal conversion rate, number of returning users, bounce rate, and number of pages accessed per session</td>
</tr>
<tr>
<td>Birk and Mandryk, 2019 [27]</td>
<td>Self-determination theory</td>
<td>Attention</td>
<td>Questionnaire and Player Identification Scale</td>
</tr>
<tr>
<td>Carter et al, 2019 [28]</td>
<td>Patient engagement framework</td>
<td>Frequency, attention, and interest</td>
<td>Automatic+questionnaire; percentage of task completion per user, average completion time of tasks, average CSAT&lt;sup&gt;8&lt;/sup&gt; scale score, Nielsen–Shneiderman heuristics, and SUS&lt;sup&gt;h&lt;/sup&gt;</td>
</tr>
<tr>
<td>Przybylko et al, 2019 [29]</td>
<td>Experiential pedagogical framework</td>
<td>Duration</td>
<td>Automatic; attrition rate</td>
</tr>
<tr>
<td>Renfrew et al, 2020 [30]</td>
<td>SAM&lt;sup&gt;i&lt;/sup&gt;</td>
<td>Duration</td>
<td>Automatic; total duration of videos viewed, number of videoconference sessions attended, and challenge score</td>
</tr>
</tbody>
</table>

<sup>a</sup>Not available.<br><sup>b</sup>UEQ: User Experience Questionnaire.
### Discussion

#### Principal Findings

This scoping review aims to identify the strategies that improve user engagement and explore how the engagement is evaluated in the context of digital interventions for mental health promotion. The findings from this scoping review suggest that there are 6 strategies that can positively influence engagement, with various design features to implement them. The methods to measure engagement included objective measures of technology use and subjective measures of user experience through questionnaires or qualitative interviews.

The key finding of our review is that strategies such as personalization, e-coaching, social forums, reminders, gamification, and flexibility and ease of use seem to promote engagement with digital interventions for mental health promotion.

#### Comparison With Prior Work

Our review corresponds to previous findings in the broader literature of digital health well-being interventions and digital behavior change interventions, which concluded that personalization, support, and guidance through the intervention’s duration can increase user engagement and uptake [9,10]. Similar to previous studies, one of the most recommended strategies for increasing engagement identified in this review is e-coaching and human support [9,10,33]. Another interesting finding of this review is that personalization of intervention content or advanced design features that mimic human support, such as an automated chatbot or avatar customization, can increase engagement. This was also recently demonstrated in an experimental study on a smoking cessation app: users who were provided support through an automated chatbot were found to have higher engagement than users without the automated chatbot [34]. Other engagement strategies identified in this review include reminders, gamification (goals and rewards), and flexibility and ease of use. Likewise, Perski et al [10] identified reminders and incentives as engaging strategies in digital behavior change interventions. The authors also reported certain delivery features that they hypothesized to positively influence engagement. These included an esthetic design, ease of use, and the right message tone.

In general, digital interventions for mental health need to adopt some suitable strategies to motivate users to take up and continue use as well as use the full potential of the intervention [9]. In the following section, each of the identified engagement strategies and design features to tailor them are discussed in turn.

#### Engagement Strategies

##### Personalization

Engagement strategies that incorporate personalization and allow customizing to user requirements and needs seem to enhance engagement [15-18,23,26-28]. The included studies used various design features to tailor personalization, including feedback on content, feedback on stress level, and
The results here are comparable to those across mental health [35] and other areas of health promotion, such as in smoking cessation [36], physical activity promotion [37], and suicide prevention [38]. In the initial stage, the intervention can be tailored to user expectations on autonomy versus support. Accordingly, the level and kind of support provided during the intervention can be adapted to the user’s preference [5]. Examples of individualized support are personalized feedback and reminders [5].

**e-Coaching**

Guidance through e-coaching is another engagement strategy identified in this scoping review. The included studies [20,22,30] have used content-focused guidance and adherence-focused guidance design features, and evaluation has found them to greatly increase user engagement.

Previous research has demonstrated that e-coaching led to better engagement with digital interventions for mental health. Persuasive e-coaching and guidance have been associated with better treatment outcome, engagement, and retention in psychological web-based interventions for the treatment of depression according to a systematic review [33]. Although a recent scoping review concluded that providing structured support improved engagement with an internet-based psychological intervention, the variability in the provision of human support, such as delivery mode, intensity, and type, resulted in heterogeneous outcomes, making comparisons difficult [39].

**Social Forum**

Social forums and interactivity with peers has been identified as a strategy to increase user engagement with digital interventions for mental health promotion [17,21,29]. This has also been supported by recent studies that found that human interaction of any kind is greatly valued by users of digital interventions for mental health [6]. Therefore, human influence should be accorded the same priority as the technology itself [1]. A narrative review recommended that social forums and social media should be harnessed to provide mental health services for youth to increase access to, and engagement with, digital therapeutic solutions for their mental health [40].

**Reminders**

Reminders have been identified as an engagement strategy in various included studies [17,18,22,25,28-30]. Different design features have been used to tailor reminders: push notifications, personalized SMS text messaging, personalized email, reminder SMS text messaging or email by an e-coach according to the use pattern of the user, and passive reminder SMS text message or email. Personalized SMS text messaging and reminder SMS text messaging or email by an e-coach according to the use pattern of the user have the potential to greatly increase engagement.

Consistent with this finding, a factorial screening experiment explored the impact of 4 different types of SMS text messages on a behavior change smoking cessation intervention and demonstrated that reminders through SMS text messaging based on users’ use pattern of content can boost overall levels of engagement with the intervention [41].

**Gamification**

Gamification of content has been identified as an engagement strategy in this scoping review [19,21,24,28,29]. Various design features have been used in the intervention designs of the included studies to tailor gamification. These include gamification of content, goal setting, rewards or badges for a completed mission, and provision of new content daily.

A systematic review examining the effect of gamification on adherence to web-based interventions for mental health treatment concluded that various gamification features have been incorporated in the design of web-based interventions. The effect of gamification on user engagement and adherence remains inconclusive because this has not been explored explicitly [42].

**Flexibility and Ease of Use**

Flexibility and ease of use was identified as an engagement strategy in this review. Various design features such as flexibility of content use, offline availability of content, bright graphics, big colorful icons, easy-to-understand content, and web-based and mobile app options have been used in the included studies to tailor this strategy. In line with this, the latest literature review analyzed users’ public reviews for mental health apps to gain insights into user perceptions and concluded that ease of use was a feature both liked and recommended by users of mental health apps [35].

**Methods to Evaluate Engagement**

The methods to evaluate engagement in the included studies can be broadly described as objective users’ use measures and subjective experience measures. The result demonstrates heterogeneous reporting of engagement measures and a wide range of assessment measures and reporting data. The heterogeneity of engagement data makes the result incomparable and hinders the understanding of the effectiveness of engagement strategies. Consistent with this finding, other reviews examining engagement with health and well-being apps also reported heterogeneity of data and incomparable results [9]. In addition, the reviews examining the effectiveness of different design features of a single engagement strategy reported inconclusive findings because of the heterogeneity of data [39,42].

Similarly, a recent systematic review investigating measurement and reporting methods of user engagement with mental health apps concluded that high heterogeneity of the measuring and reporting methods and different methodologies used to assess mental health apps, such as user satisfaction, acceptability, feasibility, and usability, make it difficult to report actual engagement with these apps. In addition, there is a need for careful understanding of engagement before claiming engagement strategies used by these apps as effective engagement strategies [43].
Recommendation for Future Design and Research

First, the engagement strategies identified and recommended in this scoping review were primarily explored as a by-product in the included studies and were not evaluated systematically. Of the 16 studies, only 2 (13%) [20,30] were identified that methodologically explored the effectiveness of different engagement strategies for user engagement. The remaining studies merely recommended strategies based on the authors’ analysis of user feedback or participant use data for the intervention. This shows that, so far, the focus has only been on effectiveness, acceptability, feasibility, or use of digital technologies for mental health promotion and there is a lack of interest in the effectiveness of engagement strategies because the interventions address healthy people rather than clinical samples. Thus, more experimental studies are required to investigate the effectiveness of engagement strategies for digital technologies for mental health promotion based on the percentage of participants who report their engagement with such technologies.

In addition, the identified engagement strategies are presented as a separate component in this scoping review. However, these strategies have been used in combination in the intervention designs of the included studies. A review of digital mental health interventions recommended the incorporation of different persuasive technological features that can result in different synergies compared with their use [44]. Therefore, future studies should focus on exploring and evaluating various engagement strategies, their dosage, and different combinations to identify the most effective set of strategies for use and engagement.

Second, engagement was explored and measured heterogeneously. Even among studies with the same designs, the reported engagement data were heterogeneous, making it impossible to determine the most effective engagement strategy. The approach to implementing engagement strategies for digital health interventions is relatively new and highly varied. There is a need for harmonization of research, evaluation, and reporting standards to produce high-quality evidence for engagement. This could be achieved with the development and adoption of guidelines or a minimum set of indicators to measure engagement. Furthermore, digital technologies allow for the creation of large data sets that may be used to assess outcomes based on engagement with specific intervention components [45]. More research is required to identify what characteristics or correlates of engagement can be consistently recorded over time to investigate how engagement changes over time and how engagement is related to the intervention’s duration, as well as to develop new statistical approaches for analyzing these large and complex data sets. Future research should also report attrition rates to explore possible relationships between engagement and attrition.

Third, research is required on the healthy level of engagement to achieve the desired outcomes and reduce attrition. In general, the optimal dose of engagement is still unclear in the field of digital health interventions. Yardley et al [46] propose that establishing and promoting “effective engagement” rather than merely “more engagement” may be more useful for digital interventions for behavior change, with “effective engagement” defined as “sufficient participation with the intervention to accomplish desired effects.” The findings of Zhang et al [47] suggest that digital apps addressing mental health should follow the Goldilocks concept of just right. Like many other digital technologies, mental health apps do not ensure that the more engagement, the better the results. The benefits of using an app can only be achieved when the dosages of various sorts of intervention features are just right. Exhaustion can result from too much engagement, whereas inefficiency might result from too little engagement. As a result, mental health technology should be designed in such a way that it encourages optimal use [47]. Fourth, engagement was not explored in depth. Most of the studies explored the objective measures of technology use, including frequency, duration, and amount, whereas subjective measures of user experience, such as affect, attention, and interest, were explored less commonly. Engagement with digital interventions for behavior change can be described as the extent of use and subjective experience [10]. Perski et al [10] conceptualized engagement with digital behavior change interventions and proposed a framework through a systematic interdisciplinary approach to assess different features of engagement. The authors emphasized that the future research avenue should include assessment of all features of engagement to reduce the fragmentation in digital health research and establish standard optimal procedures to achieve engagement across different kinds of digital behavior change interventions [10]. Although objective measures of technology use can provide data on user engagement, the exploration of subjective measures of user experience can help in identifying correlates of engagement. Therefore, future studies should explore engagement features in depth, that is, both objective use and subjective experience measures, to generate better evidence for engagement with digital interventions.

Limitations

To our knowledge, this is the first scoping review to explore engagement strategies for digital interventions for mental health promotion. The findings have been summarized taking into consideration the authors’ recommendations based on user engagement data or user feedback. Nevertheless, this review includes a few limitations. It focuses on digital interventions for mental health promotion for the nonclinical population; thus, the findings may not be applicable to other settings. Another limitation is that our inclusion criteria were very narrow for a scoping review, and it cannot be ruled out that studies with clinical samples included healthy control groups that could have been included in this scoping review. This review included only published data and excluded gray literature; therefore, some relevant literature may have been missed.

Conclusions

Various engagement strategies have been reported in digital interventions for mental health promotion, including personalization, human and social support, gamification, personalized feedback, and reminders. User engagement was predominantly reported in terms of frequency, duration, and amount, as well as subjectively (affect, attention, and interest). Human support and e-coaching during the intervention, access to social support, human support–mimicking design features,
and personalized feedback or reminders may work best to promote engagement. The findings need to be interpreted with caution because the included studies were heterogeneous, had small sample sizes, and typically explored engagement strategies only as a by-product. All studies were from high-income, nonclinical settings that may not be applicable to other contexts. Despite the importance of user engagement for the effectiveness of digital interventions, this area has not yet received much attention; therefore, conclusions cannot be drawn regarding the most effective engagement strategy because of the heterogeneity of data. Further experimental research is needed on the effectiveness of different types of engagement strategies to facilitate user engagement with digital interventions for mental health promotion.

Acknowledgments

The authors gratefully acknowledge the support of the Leibniz ScienceCampus Digital Public Health Bremen, which is jointly funded by the Leibniz Association (W4/2018), the Federal State of Bremen, and the Leibniz Institute for Prevention Research and Epidemiology—BIPS. The publication of this article was funded by the Open Access Fund of the Leibniz Association.

Authors’ Contributions

MS, HB, and TB conceived and planned the study. MS developed the protocol. LC assisted in the development of the search strategy and conducted the literature search for this review. HB and TB verified the analytic methodology for the scoping review and were responsible for overall supervision. MS and LK conducted title and abstract screening and full-text screening. HB resolved conflicts during the screening. MS developed data charts for extraction in consultation with HB. MS and LK extracted data. MS, LK, and KKDS wrote the manuscript. All authors discussed the results and commented on, and approved, the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Extension for Scoping Reviews checklist. [PDF File (Adobe PDF File), 150 KB - mental_v8i12e30000_app1.pdf]

Multimedia Appendix 2
Systematic searches of electronic databases. [PDF File (Adobe PDF File), 103 KB - mental_v8i12e30000_app2.pdf]

Multimedia Appendix 3
Search syntax for primary studies in MEDLINE. [PDF File (Adobe PDF File), 138 KB - mental_v8i12e30000_app3.pdf]

Multimedia Appendix 4
Full-text assessment and list of excluded studies. [PDF File (Adobe PDF File), 219 KB - mental_v8i12e30000_app4.pdf]

Multimedia Appendix 5
Overview of observational and process data studies. [PDF File (Adobe PDF File), 123 KB - mental_v8i12e30000_app5.pdf]

Multimedia Appendix 6
Overview of experimental studies. [PDF File (Adobe PDF File), 118 KB - mental_v8i12e30000_app6.pdf]

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Abbreviations

DALY: disability-adjusted life year

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
Review

The Extent of User Involvement in the Design of Self-tracking Technology for Bipolar Disorder: Literature Review

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Abstract

Background: The number of self-monitoring apps for bipolar disorder (BD) is increasing. The involvement of users in human-computer interaction (HCI) research has a long history and is becoming a core concern for designers working in this space. The application of models of involvement, such as user-centered design, is becoming standardized to optimize the reach, adoption, and sustained use of this type of technology.

Objective: This paper aims to examine the current ways in which users are involved in the design and evaluation of self-monitoring apps for BD by investigating 3 specific questions: are users involved in the design and evaluation of technology? If so, how does this happen? And what are the best practice ingredients regarding the design of mental health technology?

Methods: We reviewed the available literature on self-tracking technology for BD and make an overall assessment of the level of user involvement in design. The findings were reviewed by an expert panel, including an individual with lived experience of BD, to form best practice ingredients for the design of mental health technology. This combines the existing practices of patient and public involvement and HCI to evolve from the generic guidelines of user-centered design and to those that are tailored toward mental health technology.

Results: For the first question, it was found that out of the 11 novel smartphone apps included in this review, 4 (36%) self-monitoring apps were classified as having no mention of user involvement in design, 1 (9%) self-monitoring app was classified as having low user involvement, 4 (36%) self-monitoring apps were classified as having medium user involvement, and 2 (18%) self-monitoring apps were classified as having high user involvement. For the second question, it was found that despite the presence of extant approaches for the involvement of the user in the process of design and evaluation, there is large variability in whether the user is involved, how they are involved, and to what extent there is a reported emphasis on the voice of the user, which is the ultimate aim of such design approaches. For the third question, it is recommended that users are involved in all stages of design with the ultimate goal of empowering and creating empathy for the user.

Conclusions: Users should be involved early in the design process, and this should not just be limited to the design itself, but also to associated research ensuring end-to-end involvement. Communities in health care–based design and HCI design need to
work together to increase awareness of the different methods available and to encourage the use and mixing of the methods as well as establish better mechanisms to reach the target user group. Future research using systematic literature search methods should explore this further.

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**KEYWORDS**

user-centered design; participatory design; human-computer interaction; patient and public involvement; self-monitoring technology; bipolar disorder; mobile phone

**Introduction**

**Overview**

Smartphone apps focused on mental health are increasing in number [1]. There are approximately 10,000 mental health and wellness apps available for download for mental health diagnosis, treatment, and support. Self-monitoring apps are predominant, and it was found that most applications for serious mental illnesses (such as bipolar disorder [BD], schizophrenia and schizoaffective disorder, major depressive disorder, and psychotic disorder with suicidality) fall into this category [2]. As a case example, we focus on self-monitoring apps for BD. Despite the growth of this market, little supporting literature exists to guide best practice design and evaluation of the effectiveness of mental health apps [3]. Murray et al [4] have argued that to establish and optimize the reach, adoption, and sustained use of health interventions, the principles of user-centered design (UCD) are required. The application of participatory approaches such as UCD principles and activities (International Organization for Standardization 9241-210:2010) are becoming standardized more increasingly, an example being the approaches used by the National Health Service in the United Kingdom and also internationally in private and public health and the industries that provide them, such as medical technology and pharmacological companies. Given that UCD is a commonly adopted approach, we first need to explain how it is articulated to contextualize this to other approaches of user involvement that are being adopted. The principle is outlined as follows and further illustrated in Figure 1 [5]:

**Figure 1.** User-centered design process adapted from McCurdie et al [5].

1. The design is based on an implicit and explicit understanding of users, tasks, environments, and interactions in the context.
2. Users are involved throughout design and development.
3. The design is driven and refined by user-centered evaluation.
4. The process is iterative.
5. The design addresses the whole user experience.
6. The design team includes multidisciplinary skills and perspectives.

This paper presents the current landscape of user involvement approaches in the design and evaluation of self-monitoring apps for BD. This is investigated via 3 specific questions: (1) are users involved in the design and evaluation of technology? (2) if so, how does this happen? and (3) what are the best practice ingredients regarding the design of mental health technology?
Regarding the first question, Goodwin et al [6] state that there is a lack of parity of user involvement in the design of physical and mental health apps, where for mental health, users are involved less frequently than they are for physical health. A recent review [7] examined the last decade of studies on affective health (including BD) and human-computer interaction (HCI). User involvement was considered, and it was identified that more ethically sensitive design practices, including the voices of people living with affective disorders, need to be integrated. Of the 139 publications included in this study, only 16 (11.5%) of the studies reviewed reported clinical evaluations described as involving service users of mental health services or which met the formal criteria for a specific mental health problem. This lack of user involvement is reflected in the quality of mental health apps for BD as Nicholas et al [8] established that a significant proportion of apps contained wish list requests, indicating that users’ needs are not being met by current app designs.

Understanding how a serious mental health condition such as BD has an impact on daily experiences is important and helpful when designing technology to create a meaningful technological experience. A study that examined the pathology of BD [9] described the following unique design considerations for mobile technology that have been reported in the literature: (1) the side effects of medication (such as lithium) on a user’s ability to read on-screen text, (2) the impact of medication nonadherence in BD and how this may affect engagement, (3) sensitivity to reward-based stimuli in BD and how this can be used for novel interventions, and (4) the association of increased creativity in BD and the suggestion that such a user group could contribute greatly compared with other users in involvement-orientated type design.

Regarding the second question, it is important to understand that user involvement in the design of such technology involves an intersection between health care and technology development, both of which traditionally have different approaches when involving the user, although there are exceptions to the rule. Patient and public involvement (PPI) dominates as concept for involvement and engagement within health care studies [10] and improvement. UCD dominates within HCI or service design more broadly and integrates participatory approaches to achieve the involvement and engagement of end users. Both of these approaches look to provide a voice to the patient end users within applied development projects. It is important to consider these approaches and how they are applied, paying particular attention to where they overlap and where the tensions lie, some of which are outlined in Figure 2.

Figure 2. Applications, overlaps, and tensions of health care–based design approaches and human-computer interaction approaches. PPI: patient and public involvement.

Current Research
There is a growing body of research on the design of mental health technology with user input, but little has been done to compare approaches of user involvement to understand best practice. Therefore, this paper explores the current practices of user involvement in the design of mental health technology by surveying the available literature, using self-tracking technology for BD as a case example. Specifically, we aim to understand what practices are being used and the extent to which they
Food for Thought: The Intersection of Vitamin D and the Cardiometabolic Syndrome

Vitamin D is a fat-soluble vitamin that has been widely studied for its potential role in the prevention and treatment of various diseases, particularly those related to the cardiometabolic syndrome. This syndrome, commonly referred to as metabolic syndrome, is characterized by a cluster of conditions including high blood pressure, high blood sugar, and high triglycerides. It is associated with an increased risk of type 2 diabetes and cardiovascular diseases.

Recent studies have suggested a link between vitamin D deficiency and the cardiometabolic syndrome. Vitamin D is produced in the skin under the influence of sunlight and is also obtained through dietary sources. It plays a crucial role in the body, particularly in the regulation of calcium and phosphate metabolism, which is essential for bone health. Additionally, vitamin D has been shown to have beneficial effects on glucose metabolism, insulin sensitivity, and lipid profile.

The relationship between vitamin D and the cardiometabolic syndrome is multifaceted. Vitamin D deficiency has been linked to lower HDL cholesterol, higher triglycerides, and higher blood pressure, all of which are components of the cardiometabolic syndrome. It is hypothesized that vitamin D may act as a signaling molecule, coordinating the immune response, and potentially influencing the development of the cardiometabolic syndrome.

In a study conducted by the researchers at the University of Michigan, participants with higher vitamin D levels were found to have a lower risk of developing diabetes and cardiovascular disease. The study also highlighted the importance of vitamin D in the regulation of inflammation, which is a key factor in the development of the cardiometabolic syndrome.

The Role of Diet and Exercise

Dietary factors and physical activity are also crucial in the prevention and management of the cardiometabolic syndrome. Adequate intake of fruits, vegetables, lean proteins, and whole grains, along with regular physical exercise, can significantly reduce the risk of developing the cardiometabolic syndrome. However, the role of vitamins, such as vitamin D, in this context cannot be underestimated.

In conclusion, while the exact mechanisms by which vitamin D influences the cardiometabolic syndrome are still under investigation, the available evidence supports the importance of vitamin D supplementation in individuals with low levels. Future research in this area is essential to fully understand the role of vitamin D in the prevention and treatment of the cardiometabolic syndrome, and to develop effective strategies for its management.

References


https://journals.mayoclinic.org/digilibrary/mayo-clinic-proceedings/2021/02/24045339

(page number not for citation purposes)
international prospective register of systematic reviews (PROSPERO 2019; CRD42019139319) and used the following search terms: (ehealth OR mhealth OR digital health OR teledhealth OR telemonitoring) AND (remote patient monitoring OR remote monitoring technology OR application OR wearable OR app OR device) AND (central nervous system OR psychiat* OR neurolog* OR neurodegen* OR mental health OR chronic) AND (prefer* OR evaluation OR feedback OR usability OR design OR visual*) AND patient AND (data or symptom OR UI OR user interface) AND (disease OR disorder OR condition) on the following databases: Association of Computing Machinery, PubMed, Embase, IEEE Xplore and Web of Science, and the Cochrane Library for papers published in the English language between 2007 and 2019. During abstract search, papers related to BD and self-monitoring technology form part of this review. A further check of the literature was performed on Google Scholar to review missing papers using the following search for papers published in the English language between 2007 and 2019: (bipolar AND app*).

### Inclusion Criteria

The following inclusion criteria were used for included papers: sample of users with BD and feature novel self-monitoring technology.

**Textbox 1.** Criteria for assessing user involvement in selected papers. The categories used here have been developed specifically for this paper and are different from the degrees of involvement in designing and running a research study as used in patient and public involvement practices.

<table>
<thead>
<tr>
<th>No user involvement mentioned</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No mention of user involvement in design and evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low user involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Users were only involved in 1 stage of design and evaluation with or without iteration</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medium user involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Users were involved in more than one stage of design and evaluation with iteration</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High user involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Users were involved in the concept generation and ideation stage, prototype design and deployment stage, and evaluation stage with iteration, likely to have explicit mention of empowering decision-making and creating empathy</td>
</tr>
</tbody>
</table>

### Expert Panel Review

The expert panel consisted of an individual with >7 years of lived experience of BD and expertise in PPI, Professor of Psychiatry, Assistant Professor of HCI, Assistant Professor in Human Factors, Research Fellow in Involvement and Implementation, Senior Research Data Scientist and lead author SM, who is a PhD student in HCI with a background in mental health research. Included papers and criteria of assessment were subject to discussion with the expert panel via bimonthly web-based meetings with lead author SM over a period of a year. As the inclusion criteria for the study were only 2-fold, there were no disagreements over the included papers. There were also no disagreements over the criteria of involvement as the papers fell distinctly into these based on extracted information, which is limited by what was reported in the studies. Information extracted from the papers was reviewed, and findings were discussed at meetings to make inferences over what constitutes best practice in this context. The expert panel review involved discussing recommendations as a response to the findings of this study to move toward better practice of user involvement. The findings of the study were used as the basis of discussion, which was further built upon with the expertise and working experience of the panel members of user involvement in mental health technology design. SM led the write-up on the findings and research paper, which was shared with the team for comments and changes that were implemented accordingly.

### Results

**Overview**

The results from the literature search are presented in Tables 1 and 2, including the number of participants, description of remote monitoring technology, assessment criteria for user involvement, further description of methods used, and model
of user involvement. In total, 4 studies fell into the category of no user involvement mentioned, 3 fell into the category of low user involvement, 4 fell into the category of medium user involvement, and 2 in high user involvement.

Table 1. Summary of review including characteristics and reference, number of participants, bipolar disorder-specific, description of self-monitoring technology, assessment criteria for user involvement.

<table>
<thead>
<tr>
<th>Characteristics and reference</th>
<th>Number of participants, n</th>
<th>Bipolar disorder–specific</th>
<th>Description of self-monitoring technology</th>
<th>Assessment criteria for user involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No user involvement mentioned (n=4)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[20]</td>
<td>22</td>
<td>Yes</td>
<td>Combination of True Colours Monitoring system and customized app that records geographic location</td>
<td>No mention of user involvement in design and evaluation</td>
</tr>
<tr>
<td>[21]</td>
<td>48</td>
<td>No; borderline personality disorder also included</td>
<td>MoodZoom smartphone questionnaire</td>
<td>No mention of user involvement in design and evaluation</td>
</tr>
<tr>
<td>[22]</td>
<td>118</td>
<td>Yes</td>
<td>Personal Life-Chart App: electronic diary–based smartphone app</td>
<td>No mention of user involvement in design</td>
</tr>
<tr>
<td>[23]</td>
<td>28</td>
<td>Yes</td>
<td>MONARCA system: combination of passive and active self-monitoring smartphone app amended to measure voice feature</td>
<td>No mention of user involvement in design</td>
</tr>
<tr>
<td><strong>Low user involvement (n=1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[24]</td>
<td>76(^b)</td>
<td>No; psychosis also included</td>
<td>Ginger.io: smartphone-based mental health tracking app</td>
<td>Users involved in evaluation stage</td>
</tr>
<tr>
<td><strong>Medium user involvement (n=4)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[25]</td>
<td>N/A(^a); this is a protocol</td>
<td>No; other severe mood disorders</td>
<td>E-care at home: tablet-based self-monitoring tool</td>
<td>Users involved prototype design and evaluation stage with iteration</td>
</tr>
<tr>
<td>[26,27]</td>
<td>7</td>
<td>Yes</td>
<td>MoodRhythm: smartphone app that can track social rhythms</td>
<td>Users involved in prototype design and evaluation stage with iteration</td>
</tr>
<tr>
<td>[28-30]</td>
<td>42 (all papers combined)</td>
<td>Yes</td>
<td>MONARCA system: combination of passive and active self-monitoring smartphone app</td>
<td>Users involved in prototype development and evaluation stage with iteration</td>
</tr>
<tr>
<td>[31-33]</td>
<td>303 (all papers combined)</td>
<td>Yes</td>
<td>OpenSIMPLE: smartphone-based psychoeducation program</td>
<td>Users involved in prototype development and evaluation stages with iteration</td>
</tr>
<tr>
<td><strong>High user involvement (n=2)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[34]</td>
<td>59(^b)</td>
<td>No; other serious mental illnesses also included</td>
<td>QoL(^d)-ME: smartphone-based, personalized QoL assessment app</td>
<td>Users were involved in concept generation and ideation stage, prototype design and deployment stage and evaluation stage with iteration with a goal to empower patient decision-making</td>
</tr>
<tr>
<td>[35,36]</td>
<td>25(^b)</td>
<td>No; also included posttraumatic stress disorder</td>
<td>SPIRIT(^e) App: smartphone self-monitoring app that allows patients to undertake modules and complete questionnaires for mental health assessment</td>
<td>Users were involved in concept generation and ideation stage, prototype design, and deployment stage and evaluation stage with iteration with a goal to empower patient decision-making</td>
</tr>
</tbody>
</table>

\(^a\)MONARCA: Monitoring, Treatment and prediction of bipolar disorder episodes.
\(^b\)Unclear how many of the participants had a diagnosis specifically of bipolar disorder.
\(^c\)N/A: not applicable; the paper mentioned no user involvement.
\(^d\)QoL: quality of life.
\(^e\)SPIRIT: Study to Promote Innovation in Rural Integrated Telepsychiatry.
<table>
<thead>
<tr>
<th>Characteristics and reference</th>
<th>Further description of methods used</th>
<th>Model of user involvement</th>
<th>Further description of user-involvement model</th>
</tr>
</thead>
<tbody>
<tr>
<td>No user involvement mentioned (n=4)</td>
<td></td>
<td></td>
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<tr>
<td>[20]</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>[21]</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>[22]</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>[23]</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Low user involvement (n=1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[24]</td>
<td>Users completed nonstandardized measures for satisfaction and perceived effect on clinical care</td>
<td>None mentioned</td>
<td>N/A</td>
</tr>
<tr>
<td>Medium user involvement (n=4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[25]</td>
<td>Prototype design and deployment stage: 3 rounds of interviews with 8 users where interactive demo materials and screenshots were provided as stimuli and feedback was used to iterate design</td>
<td>Cocreation approach</td>
<td>Aim of the approach was to create a product that would be usable for the specific target population and move away from traditional rigid waterfall methods, which only have a single round of assessment or iteration. This approach affected the tool by uncovering usability requirements, which were implemented.</td>
</tr>
<tr>
<td>[26,27]</td>
<td>Prototype design and deployment stage: participants used the app and shared feedback, design insights and suggestions for improvement at least once a week. Wireframes were sent back to participants, which incorporated this feedback where further feedback was given</td>
<td>Participatory design process</td>
<td>During the design process, participants used the MoodRhythm app in their daily lives and shared their feedback, design insights, and suggestions for improvements to the app. This process allowed participants to provide feedback on an ongoing basis during the design process and helped to identify and address concerns that users might have regarding these technologies, ensuring the app was effective for daily use.</td>
</tr>
<tr>
<td>[28-30]</td>
<td>Prototype design and deployment stage: 3-hour workshops were held for design and iterative prototyping where feedback was incorporated into design</td>
<td>Patient-Clinician Designer Framework using principles of user-centered design</td>
<td>Through this design process, users were “involved” in making decisions regarding system features using collaborative design workshops. The design of the MONARCA system uses a mobile phone app as the main component.</td>
</tr>
<tr>
<td>[31-33]</td>
<td>Prototype design and deployment stage: users were involved in focus groups, interviews, and surveys with research teams. Unclear how findings were used to iterate the prototype</td>
<td>User-centered design</td>
<td>Using the user-centered design approach, suggestions were incorporated based on feedback from the users during the feasibility study as well as modifications to adapt the platform for an open study. Several features were added to OpenSIMPLE using this approach.</td>
</tr>
<tr>
<td>Characteristics and reference</td>
<td>Further description of methods used</td>
<td>Model of user involvement</td>
<td>Further description of user-involvement model</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------</td>
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<td>---------------------------------------------</td>
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</tbody>
</table>
| [34]                         | • Concept generation and ideation stage: 10 participants were to share their experiences with smart devices, apps and QoL questionnaires and to ideate regarding QoL-ME in a focus group  
  • Prototype design and deployment: paper sketches (wireframes) were presented and were gradually refined, expanded, and made to function where a first prototype was developed. 25 participants were involved in this stage  
  • Evaluation stage: prototype was subjected to usability testing and systematically assessed using the SUS with a total of 25 participants.  
  • Goal to empower patient decision-making: no information was found in relation to this | Cocreation approach | The QoL-ME was cocreatively developed in an iterative development process with groups of people with severe mental health. The process consisted of 6 iterations divided over 3 stages: brainstorming stage, design stage, and usability stage. The development process was described as fitting in the framework of participatory design. Feedback was used to make several changes to QoL-ME |
| [35,36]                     | • Concept generation and ideation stage: 1 focus group was run with users to propose the SPIRIT app and a second focus group was run to refine SPIRIT app concept  
  • Prototype design and deployment stage: focus groups were run with user to elicit feedback on storyboard and prototype and prototypes were refined based on feedback  
  • Evaluation stage: developed a usability testing framework, which was conducted with 5 participants where feedback was incorporated into the app  
  • Goal to empower patient decision-making and creating empathy: the study had an advisory group called CAB, which consisted of 8 “consumers” and “consumer advocates” who met monthly to advise the SPIRIT scientific team on all aspects of trial design and conduct, which was resulted in changes to the app and study | Human-centered design process, participatory design process, and Principle of Digital Development | Target users and domain experts were engaged in a participatory design process throughout development via focus groups and usability testing with national consumer advocacy groups and providers and patients in rural clinics. The process also adhered to the principles of digital development which includes the following: design with the user; understand the existing ecosystem; design for scale; build for sustainability; be data-driven; use open standards, open data, open source, and open innovation; reuse and improve; address privacy and security; be collaborative |

aN/A: not applicable; the paper mentioned no user involvement.  
bSUS: System Usability Scale.  
cMONARCA: Monitoring, Treatment and prediction of bipolar disorder episodes.  
dQoL: quality of life.  
eSPIRIT: Study to Promote Innovation in Rural Integrated Telepsychiatry.  
fCAB: Consumer Advisory Board.

**Expert Panel Review**

As per the third question, the findings of this paper have been discussed within a group of individuals who offer academic and clinical expertise in this area as well as an individual with lived experience of BD who also has a good level of experience and participation in PPI. On the basis of these discussions, we recommend the following:

1. Involve users in all stages of design and evaluation, including concept generation and ideation, prototype design and deployment, and evaluation stages with the goal of creating user empathy and empowerment. This process should have an adequate number of participants to welcome diversity in thought. Equal representation is also a crucial consideration that needs to be considered when recruiting users.
2. Ensure early involvement as this will be cost-effective in the long run (avoid redesign and problems with use and implementation in the later stages).
3. Combine principles of PPI and HCI to not only have users assist in designing technology but also in designing and running research (eg, users cofacilitating design workshops) and use end-to-end user involvement.
4. For academic and industry sectors to establish better mechanisms to access target user groups with lived experience of mental health issues, for example, by building relationships with existing patient-directed organizations such as charities and patient-led community groups.
5. Increase awareness of HCI and design communities in PPI principles and practices and increase awareness of PPI community in HCI and design methods or skills.

6. Encourage use and mixing of formal scientific or design methods with informal experiential and empathic practices to capture richness in understanding the dynamic requirements of technology users, which are cognizant of use in context.

7. Keep the user informed at all stages of the process, including final outcomes, future use, and next steps, which are often forgotten about.

Discussion

Principal Findings

This paper presents the current landscape regarding user-led design and evaluation of self-monitoring apps for BD. This was investigated via 3 specific questions: (1) are users involved in the design and evaluation of technology? (2) if so, how does this happen? and (3) what are the best practice ingredients regarding the design of mental health technology?

For the first question, a total of 17 papers were included in this review, which resulted in the evaluation of 11 novel smartphone apps for self-monitoring of BD. In total, 6 of these papers have been grouped together as they have been published with respect to the same smartphone app, which is highlighted in the Tables 1 and 2. Regarding the first question, the results from this review indicate that users are being involved in design and evaluation, but this is highly variable in terms of level of involvement. In total, 4 self-monitoring apps (n=4 papers) were classified as having no mention of user involvement in design, 1 self-monitoring app (n=1 paper) was classified as having low user involvement, 4 self-monitoring apps (n=9 papers) were classified as having medium user involvement and 2 self-monitoring apps (n=3 papers) were classified as having high user involvement.

With respect to the second question, there is variability in the models of user involvement in design and evaluation, where the following have been described: agile development process, cocreation approach, participatory design, patient-clinician designer framework, user- and human-centered design, and principles of digital development. The key characteristics of the models are described in Textbox 2. The standout method mentioned was the agile development process, which is a software development process aimed at producing outcomes fast in relation to market constraints and the ability to accommodate changes during the software development cycle [37]. The use of mental health technology is sparse [38], and there are questions as to how a model aimed at quickly meeting market constraints considers the users’ voice and needs during the process of designing mental technology, which sheds light on why it was ranked low regarding involvement as it only considered users in the evaluation stage. Finally, this large amount of variability sheds further light on the need for quality guidelines in the reporting of user-involved development of mental health technologies.
Textbox 2. Key characteristics of user involvement.

<table>
<thead>
<tr>
<th>Agile development process</th>
</tr>
</thead>
<tbody>
<tr>
<td>An iterative approach to project management which is aimed at product fast outcomes in relation to market constraints and the ability to accommodate changes during the software development cycle</td>
</tr>
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<table>
<thead>
<tr>
<th>Cocreation approach</th>
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<tbody>
<tr>
<td>A process which is aimed at creating “with” users and stakeholders to ensure results meet their needs and are usable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient-clinician designer framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>A process which uses the key principles of user-centered design to be applied in the context of mental health. A framework which aims to involve patients and clinicians in the process of design through collaborative design workshops and iterative prototyping</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human-centered design</th>
</tr>
</thead>
<tbody>
<tr>
<td>A process which is based on designing based on characteristics and intricacies of human psychology and perception which is considered to carry out a deeper analysis that user-centered design</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Principles of digital development</th>
</tr>
</thead>
<tbody>
<tr>
<td>A process which focuses on the following 9 principles during digital development:</td>
</tr>
<tr>
<td>Design with the user</td>
</tr>
<tr>
<td>Understand the ecosystem</td>
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<tr>
<td>Design for scale</td>
</tr>
<tr>
<td>Build for sustainability</td>
</tr>
<tr>
<td>Be data driven</td>
</tr>
<tr>
<td>Use open data, open standards, open source, and open innovation</td>
</tr>
<tr>
<td>Reuse and improve</td>
</tr>
<tr>
<td>Address privacy and security</td>
</tr>
<tr>
<td>Be collaborative</td>
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</table>

The descriptive section of Textbox 2, which describes how models of involvement were implemented as outlined in the selected papers, also uncovers pertinent findings to the second question. It was found that papers that were classified as having high user involvement displayed an increased level of detail on how they implemented their chosen user involvement model. In addition, those papers that were classed as high user involvement not only described their methods as mainly participatory design, but also described a combination of methods such as cocreation, participatory design, and human-centered design. This highlights some early suggestions that it is the combination of methods that could be the driving force of ideal user involvement, which underpins points 5 and 6 of our recommendations of best practice, as outlined in the Results section. These points indicate that there should be a mix of methods to capture the unique and dynamic requirements of mental health technology users and that there should be an increased awareness of these methods in both the HCl and PPI design communities.

Focus groups were the method of choice during the concept generation and ideation stages. For the prototype design and deployment stage, the following methods were shown to have been used: focus groups and workshops, sharing of wireframes, and interviews. For evaluation stages, there was a combination of the use of standardized and unstandardized questionnaires to measure factors such as usability, satisfaction, and usefulness of the smartphone app. For a few studies, completing tasks using the app was also a method used for evaluation. Only 1 study that met the high user involvement criteria had explicit reference to empower patient decisions and create empathy by having a patient advisory board whose role was to advise the scientific team of all aspects of the study and smartphone app. Some studies [26,27] had particularly low participant numbers (ranging from 1 to 7 users), and there are questions as to whether such small samples can adequately capture users’ needs or wants and whether this constitutes a user-focused approach. The aims of these methods are to represent diversity in this voice and capture both an implicit and explicit understanding of users, tasks, environments, and interactions so that technology can be designed better, and it can be argued that such small samples cannot provide the richness of understanding needed for this. The real lived experience of the condition cannot be understood and adequately covered with such a small sample size. That is not to say that a large number of participants capture this adequately either as there is a pool of studies [21,22,24] with a large group of participants that do not adequately describe how the findings were used to iterate the technology. It is both the number of users and the level of engagement that constitutes an appropriate user-centered methodology. In summary, this research provides evidence that despite the presence of recommended standards for the involvement of the user in the
process of design and evaluation of mental health technology specifically for BD, there is large variability in whether the user is involved, how they are involved, and to what extent there is genuine empowerment in the voice of the user, which is the aim of design approaches involved in mental health technology.

Limitations

The limitations of this study may also contribute toward the lack of user involvement mentioned in this paper. This paper reflects the current practices of user involvement to the extent to which authors made this explicitly available in the chosen literature. It could be the case that not all authors disclosed the process of design in the paper for a variety of reasons. With strict word limits in the case of often complex papers in the field of mental health technology, authors may have decided to focus on other parts of the technology, such as results, and omit the design and development of the technology. Likewise, the process of design could be described in other papers, which may not have been included in this review. We did not contact authors to check if there was additional literature on user design or interview authors regarding user design in the development of technology, but such practices might produce a more comprehensive review of user design practices in the future. It is also worth noting as a limitation that only research-led app development projects were assessed and there may be innovations in commercial and nonprofit developments that have not been considered in this paper as only published literature was considered. Finally, there may be limitations around the recommendations of best practice provided by the group of experts, and future studies should consider more structured tools such as the Delphi method.

Comparison With Previous Work

A question for future investigation is why is this variability present? Previous studies have considered this, where it was concluded that there is a lack of parity when involving those with mental health issues in design compared with those with physical health issues [6] and more specifically for BD it was found that only a small proportion of studies for technology included involving the user in a recent review [7], despite the benefits of involvement [9]. The first step to consider is the inherent logistical and ethical issues that arise when working with those with severe mental health issues [39]. In terms of studies that indicated no or low user involvement, 1 potential reason for this may be accessibility to a suitable user group. Academic institutions are often closely linked to health care settings with formal protocols and regulations that allow accessibility to mental health care settings and patients. However, there are drawbacks to this, including only being able to access the same user representatives, which is likely to create inherent bias. In contrast, research conducted in industry settings is likely to not have this type of working relationship, largely because of conflicts of interest, making it more difficult to access the right user group. Academic, clinical, and industrial settings need to work collaboratively to establish mechanisms to enable technology development and the contribution of appropriate users to be accessible, inclusive, and representative.

From a more systemic perspective, this intersection between PPI and HCI may shed more light on the variability of user involvement both in this study and more generally. Both approaches combined describe the umbrella of the types of user involvement methods described in this review. However, both approaches individually have tensions that need to be considered, which are likely to impact the application of these methods. PPI approaches have limitations in that they are currently not versed in considering design within the tensions of cost and regulation, as PPI processes are often the result of existing government funding for research, rather than commercial and industrial funding, which is more typical of technology development. Tensions arise because of the differences in time management and resource allocation depending on the funding source, and there are questions regarding the adaptability of PPI practices for this. These practices tend to be focused on the clinical context and clinical task and are not versed in considering more subjective, hard-to-measure, and tacit aspects when designing technology such as user experience and everyday life practices, which are facets removed from direct clinical care. PPI approaches tend to traditionally linear, static approaches that do not evolve or iterate owing to new information, which is not suitable when designing technology where iteration is a requirement. This is because the origins of PPI do not stem from design or scientific disciplines, such as HCI, where the elicitation of need-finding is not just limited to the anticipated as it is in PPI but also unanticipated or implicit in nature [40]. For example, when reviewing user preferences on data visualization for remote monitoring technology, BD was touched upon, and it was found that the state of readiness and state of health as well as data literacy and familiarity with technology are all factors when considering user engagement with remote monitoring technology [40]. The consideration of factors, such as state of readiness may not be readily captured by PPI.

For HCI approaches, unlike PPI processes, there is a lack of use of these formal methods in the context of mental health service and technology design. Therefore, there is little evidence of their effectiveness [17]. PPI processes based on and in health care provision and improvement work are often conducted by professionals who have a skillset targeted toward working and engaging with those with mental health issues, whereas this cannot be said in the field of HCI where the training background is largely different with little or no experience in mental health. It is unclear whether this is a benefit of technology-based approaches as it has the potential, if planned and implemented well, to remove the power dynamics and hierarchy by not having a clinician taking lead which can sometimes negatively impact meaningful PPI contributions. Alternatively, it may be that if not designed with empathy and in conjunction with the advice from clinical persons or those with lived experience, HCI approaches could be a hindrance and a barrier to disclosure and engagement if the nonclinical professionals do not have the skillset to meaningfully engage those with mental health issues. This research highlights the need to upskill both communities to be better equipped, and it is important for future research should aim to explore this. Conclusively, user-focused approaches can provide a framework for PPI to embed participatory activities within the iterative, fast-paced development process of mental health technology development. Likewise, PPI has developed core standards around establishing
an equal relationship between users and researchers, which can lend itself well in HCI approaches where this is not necessarily present.

Conclusions

In conclusion, this research provides evidence that despite recommendations on the involvement of users in the process of mental health technology design and evaluation, in this case, specifically for BD, there is large variability in whether the user is involved, how they are involved, and the extent to which there is authentic empowerment of the user’s voice. The tensions among the design approaches used in PPI and HCI may shed some light on why there is variability in user involvement. Currently, both design approaches work independently; however, future practices should aim to work together and encourage awareness and mixing of methods. The findings of this research have been reviewed by an expert panel, including an individual with lived experience of BD, and recommendations were made for the design communities to establish better mechanisms for awareness, mixing of methods, and increased user involvement.

Acknowledgments

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Conflicts of Interest

None declared.

References


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Abbreviations

BD: bipolar disorder
HCI: human-computer interaction
PPI: patient and public involvement
UCD: user-centered design

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Evaluation of an Online System for Routine Outcome Monitoring: Cross-sectional Survey Study

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Abstract

Background: The use of routine outcome monitoring (ROM) in the treatment of mental health has emerged as a method of improving psychotherapy treatment outcomes. Despite this, very few clinicians regularly use ROM in clinical practice. Online ROM has been suggested as a solution to increase adoption.

Objective: The aim of this study is to identify the influence of moving ROM online on client completion rates of self-reported outcome measures and to identify implementation and utilization barriers to online ROM by assessing clinicians' views on their experience using the online system over previous paper-based methods.

Methods: Client completion rates of self-reported outcome measures were compared pre- and postimplementation of an online system of ROM. In addition, a survey questionnaire was administered to 324 mental health service providers regarding their perception of the benefits with an online system of ROM. In addition, a survey questionnaire was administered to 324 mental health service providers regarding their perception of the benefits with an online system of ROM.

Results: Client completion rates of self-reported measures increased from 15.62% (427/2734) to 53.98% (1267/2347) after they were moved online. Furthermore, 57% (56/98) of service providers found the new system less time-consuming than the previous paper-based ROM, and 64% (63/98) found that it helped monitor clients. However, the perceived value of the system remains in doubt as only 23% (23/98) found it helped them identify clients at risk for treatment failure, and only 18% (18/98) found it strengthened the therapeutic alliance.

Conclusions: Although the current study suggests mixed results regarding service providers' views on their experience using an online system for ROM, it has identified barriers and challenges that are actionable for improvement.

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KEYWORDS

routine outcome monitoring; progress monitoring and feedback; outcome measures; web-based outcome monitoring; routine outcome monitoring software; outcome measurement questionnaire; measurement-based care

Introduction

The prevalence of mental illness, accompanied by its social and economic burden on the individual and society, has gained global recognition [1,2], creating a push to invest in solutions [3]. Mental health action plans that include evidence-based interventions with measurable outcomes have been identified as important components of future improvements to mental health services [3]. The incorporation of routine outcome monitoring (ROM) into clinical practice has emerged as a method of improving psychotherapy treatment outcomes [4]. ROM involves monitoring client progress throughout their...
course of treatment at regular intervals using standardized measures and feeding the information back in real time to the clinician and client, thereby allowing for the identification of any need to change the care plan [4-6]. According to Lambert and Harmon [7], client progress measurements and feedback appear to work similarly to a physician monitoring patients’ blood sugar in managing their diabetes, and most importantly, it can identify possible impending treatment failure. Studies have shown that ROM contributes to an increased number of clients who improve from the receipt of mental health treatment [8], an increase in the degree to which they improve, and a decrease in the number of treatment failures [7,9].

The use of ROM in clinical settings appears to have a positive effect on patient outcomes in several ways. One key benefit is that ROM can help clinicians identify clients at risk for treatment failure by limiting the effect of overestimating their own abilities (self-assessment bias) [10-12]. Boswell et al [13] state, “Clinicians could benefit from using tracking systems because of their likely overly optimistic estimates of their clients’ outcome and their inability to predict treatment failure, specifically, reliable negative change.” A study by Hannan et al [14] which examined the ability of therapists (clinicians) to identify patient deterioration found that therapists only identified 2.5% (1 of 40) of clients who left treatment worse than when they began. Similarly, Lambert [10] states, “…a significant therapy-related cause of poor outcomes is the failure of therapists to be aware of poor treatment response as it develops over the course of therapy.” When clinicians can identify clients at risk for treatment failure earlier, they can adjust the course of treatment or optimize treatment instead of waiting until the end of treatment [15].

Another positive effect of ROM in mental health treatment is quicker client improvement, which is tied to faster recovery resulting in fewer treatment sessions [14,15]. Fewer treatment sessions mean cost savings for health institutions facing increasing pressures for accountability and cost containment [16]. A quick recovery also means less suffering on the part of the client [16]. ROM with ongoing client feedback is therefore a method of providing more efficient and cost-effective care [15,17].

The use of ROM can also improve the therapeutic alliance between clinician and client. Clinicians who form stronger alliances with their clients can expect better outcomes [14,15,18-21]. Brattland et al [22] found that when ROM was in place, alliance ratings increased more than they did with the treatment-as-usual condition, and this improvement in the therapeutic alliance resulted in less posttreatment impairment.

Despite these benefits of ROM and the fact that many countries are recommending the use of ROM in various mental health settings [10,23-25], previous studies assessing usage suggest that fewer than 14% of clinicians use standardized progress monitoring measures regularly in their provision of mental health services [22,26]. Several obstacles faced by mental health organizations and therapists in implementing ROM in clinical practice may explain the low rates of usage: the time required to administer, score, interpret and report client feedback; the financial burden of implementation; multiple stakeholders with different needs; and philosophical barriers, such as scepticism regarding the relevancy and utility of the measurement tools, fear and mistrust about what the data will be used for, fear of being monitored, and privacy and ethical concerns [12,27,28]. Inadequate training and awareness regarding the use of ROM, how to complete the measures, and a lack of ongoing technical support, compound these issues [27,29].

Previous studies evaluating the organizational benefits of ROM have shown that using online systems provides instantaneous feedback to clinicians and clients [5,7,8,12]. The Partners for Change Outcome Measurement System, which uses web-based software to calculate and track the client’s outcome rating score or the OQ-Analyst software signal alert system, has demonstrated a reduction in client deterioration rates and significant change in clients predicted to have a poor outcome [6]. Barriers to uptake of the use of ROM can also be overcome by implementing a system that is simple and easy to use, is not disruptive to routine mental health therapy practice, and that can “expedite and ease practical difficulties” [12].

The objective of this paper is to identify if moving to an online system of ROM influences client completion rates of the outcome questionnaires. In addition, service providers’ views on their experience using an online system will be examined to identify implementation and utilization barriers and highlight actionable items where improvements can be made to ensure successful future implementations.

Methods

The study was conducted at a large mental health and addiction facility in Canada, and 2 types of data were collected. First, retrospective data were gathered on completion of self-reported measures by clients. Second, a cross-sectional survey of mental health service providers was conducted to investigate their perception of the benefits of using an online ROM in their treatment of clients in the Depression Care and Trauma Care individual outpatient counseling programs. For the purposes of this study, clinicians are referred to as “service providers.” A research ethics board application was submitted, and ethics review was deemed to not be required.

In this study, ROM refers to the repeated measurement of a client’s progress over the course of treatment according to standardized self-reported measurement questionnaires or assessments (see Multimedia Appendix 1 for a list of assessments and their expected frequency). This information regarding the client’s current status is fed back to the clinician or client and is intended to be used by the clinician to assess if a change or alteration in the current treatment plan is necessary [5,7,30]. The self-reported questionnaires commonly measure client progress regarding symptom severity, social functioning, and personal well-being [9,14,28,31].

Before the online ROM was implemented, the self-reported measures (Multimedia Appendix 1), were completed by the service providers in a session with the client and were manually entered into the client system by the service provider or faxed to the main office administration staff for manual entry into the client system. Postimplementation of the online system for
ROM, the same assessments were performed at the same frequency and intervals (Multimedia Appendix 1), but they were to be completed by the client prior to coming to session via their online portal. In this way, feedback would be available in real time to both the service provider and the client.

Rates of completion of the self-reported measurement questionnaires (assessments) by the clients as part of the ROM process were calculated as follows: each client that filled out at least 1 assessment battery at 1 time point during the course of treatment was calculated as 1 client with a completed assessment, both pre- and postimplementation. The total number of clients with a completed assessment was divided by the total number of clients. All clients in the Depression Care and Trauma Care programs were expected to complete assessments; all were included for the time period of 18 months prior to the implementation of the online ROM and again at 18 months postimplementation of the online ROM.

A survey questionnaire was designed by the investigators for this study based on a literature review of research on utilization and attitudes toward ROM in the treatment of mental health and adaptation of the survey questions used in those studies [26,30,32,33].

The questionnaire consisted of ten, 5-point Likert scale questions, asking service providers how they would best characterize their feelings toward the use of an online ROM system in the areas of time savings (Q1), client receptiveness (Q2), allowance for regular progress monitoring of clients (Q3), adequacy of training (Q4), strengthening of the therapeutic alliance (Q5), identification of clients at risk for failure (Q6), increased workload (Q7), help available as needed to assist in using the program (Q8), if confidence in usage increased over time (Q9), and if it positively impacted the care they provided (Q10). In addition, the questionnaire included 1 open-ended free-text question asking for further comments. The questionnaire was offered in both English and French to accommodate the bilingual nature of health care services in Canada (see the English version of the service provider survey in Multimedia Appendix 2). The data collection for the survey occurred between January 20, 2020, and February 20, 2020. Two reminder emails to complete the survey were sent, the first halfway through the data collection period on February 3, 2020, and the second 2 weeks after that on February 17, 2020.

The online survey questionnaire created and used for this study was distributed to 324 mental health service providers via email. All service providers were mental health counselors and had at least a master’s degree in social work, psychology, or another health-related discipline. The inclusion criteria for service providers were that they had an online account and that they had at least 1 client using the program at the time of study. Of the 324 service providers who received the survey, 98 completed the questionnaire, resulting in a response rate of 30.2% (98/324). Of the 98 responses, 10 were completed in French.

**Results**

Client completion rates (total number of clients with at least 1 completed assessment divided by the total number of clients) of the self-reported measurement questionnaires using paper-based methods calculated over an 18-month period preimplementation of an online ROM were 15.62% (427/2734). Postimplementation of an online ROM, client completion rates calculated over an 18-month period were 53.98% (1267/2347).

Survey responses provided the following results. Most service providers (56/98, 58%), responded that the online system was less time-consuming than were previous paper-based methods (Q1); however, only 31 out of 98 (31%) agreed that the system did not increase their workload (Q7).

With regard to the online system of ROM allowing for regular progress monitoring of their clients (Q3), 63 out of 98 (64%) service providers responded that the online system did allow for regular progress monitoring of their clients. However, only 23 out of 98 (23%) responded that the online system helped identify earlier clients at risk for treatment failure (Q6), and only 18 out of 98 (18%) responded that the online system strengthened the therapeutic alliance with their clients (Q5). In addition, only 45 out of 98 (64%) service providers responded that their clients were receptive to using the online system to complete the self-assessment questionnaires (Q2), and only 38 out of 98 (38%) responded that the program positively impacted the care they provided (Q10).

With regard to their ability to successfully use the system, only 36 out of 98 (37%) reported that help was available as needed to assist with using the program (Q8), 46 out of 98 (47%) responded that they received adequate training (Q4), and 50 out of 98 (51%) felt more confident in their ability to use the system since it was first introduced (Q9; Figure 1).
Many of the 48 free-form responses were able to be split into several themes. The service providers who responded with positive feedback indicated their appreciation for the instant feedback on the progress of their clients: “I would say the best part is that it’s easier than paper and results are easy/instant”; “I like the paper savings, instant scoring and ability to visually monitor progress online”; and “Overall I think it is a great tool…”.

Most service providers, however, stated difficulties navigating the software and understanding the process. Many of these respondents specifically stated that they received inadequate training, and many made a request for additional training. Due to their own difficulties using the software, some also described issues with assisting their clients in successfully using the software. In addition, some service providers stated they had to resort back to completing the measures for their clients or completing it with their clients on paper in session and faxing in the results. Reasons given by service providers for this were clients reporting technical difficulties, preferring paper and pen, reporting being too depressed already, or stating the process was frustrating and anxiety-provoking. Some service providers stated they found no benefit with using the online program over previous paper-based methods, some reported an increase in their workload, and some reported accessibility issues due to the platform not being entirely in French.

**Discussion**

**Principal Findings**

The findings of this study suggest that an online system supports adoption of routine outcome monitoring in the treatment of mental health. Despite this study’s findings of low client receptiveness with service providers occasionally having to revert to paper-based completion of the measures, client completion rates increased significantly with the use of the online system of ROM. Previously with a solely paper-based system, only 16% of clients completed assessments; however, after implementation of the online system, the completion rates increased to 54%. A study evaluating the benefits, barriers, and disadvantages of electronic patient-reported outcome measures identified that electronic collection offers more advantages over paper-based methods. The study, conducted via a systematic review of articles that evaluated electronic patient-reported outcome measures identified advantages that included greater patient preference, lower costs, faster completion time, higher data quality, and higher response rates [34].

Upon examination, the benefits of an online system over paper-based methods are clear; however, service providers’ perceptions are mixed. Contradictory results were found with regards to efficiency. Although 56 out of 98 (57%) service providers responded that the online system was less time-consuming than were previous paper-based methods, only 31 out of 98 (31%) responded that the system did not increase their workload. One of the main barriers identified in previous literature to the utilization of ROM has been the significant time burden involved, and it has been suggested that software systems may alleviate some of the burden [5,12,35,36]. The results of the current study, with 58% (56/98) of service providers responding that the online system was less time-consuming, show promise for improvement in ROM utilization if an online system is adopted. However, the low response rate of only 31% (31/98) of service providers reporting that the online system did not increase their workload is concerning.

With regard to the service providers’ views on their experience using an online system of ROM, 63 out of 98 (64%) agreed that the system of the online ROM did allow for regular progress monitoring of their clients. However, only a minimal number...
of service providers recognized benefits with the use of an online ROM for identifying clients at risk for treatment failure (23/98, 23%) or strengthening the therapeutic alliance (18/98, 18%). The online system of ROM that was implemented allowed service providers and clients to view progress in graphs in real time. The service provider was then able to determine if the client’s progress was going in a positive or negative direction. The online system also had a dashboard flag to allow the service provider to identify if the client was suicidal or displaying suicidal ideation. This flag is similar to other ROM systems such as the OQ-Analyst feedback system that provides a red alert signal to indicate that the client is responding poorly to treatment [6]. It may be that service providers are relying on their own abilities and efforts to identify clients at risk for treatment failure or to strengthen the therapeutic alliance rather than using the tools available to them with the online system. This has been demonstrated in previous literature which reports that clinicians have an overly positive self-assessment bias as to their ability to affect client improvement and a tendency to underestimate client deterioration [11,37]. Increase in training and future evaluation to assess if service providers are viewing the real-time feedback that is available to them through the online system should be completed to improve these 2 study results.

Only 45 out of 98 (46%) service providers reported that their clients were receptive to using the online system. This finding was underscored in the open-ended comments with some indicating that their clients refused to use the program, preferred paper and pen, or preferred to complete the questionnaires in session with the therapist. Clients also reported they were too depressed or lacked the motivation to use the program or felt the program provoked feelings of frustration, agitation, and anxiety. Similar findings regarding client receptiveness have been identified in the literature with some users expressing frustrations with a complicated or unintuitive interface, or technical issues and malfunctioning websites to the point of giving up [38]. In a 2021 research study performed in Australia to improve mental health and well-being health information technology for culturally diverse youth in nonurban areas, participants identified that the technology should be easy to use and understand and should not make the user feel overwhelmed or frustrated [39]. Functionality has been demonstrated in the literature to be of high importance in enhancing user satisfaction for the implementation of a web-based platform [40]. Overall, our findings are consistent with previous research findings and suggest a lack of user-friendliness may be a factor in the low client receptiveness to using the ROM online system in our current study.

Finally, our study showed low results regarding service providers receiving adequate training or having help available when using the system was needed. Previous research concurs with these results in that it has been identified that lack of proper training and support is a barrier to successful implementation and utilization of a ROM program and that both these components are needed for successful adoption of an online system [27]. Therefore, enhancement in training and ongoing technical support could be actioned to improve success of future implementations.

Limitations
A limitation in this study is the low survey response rate by service providers, with just 98 out of 324 (30.2%) participants responding. Although this response rate and sample size are comparable to those of previous survey studies [30,41], obtaining feedback from more service providers using the online system would give a truer picture of the perception of benefits. Another limitation relates to the client completion rates, as the clients only had to fill out 1 assessment battery at 1 time point during the course of treatment to be included in the calculation, which does not necessarily give a true picture of increased rates. Further studies should investigate whether online ROM leads to a sustained completion of assessments.

For the purpose of parsimony, each question investigated a different construct. Future studies should use multiple items to enable a measurement of reliability and validity. Recommendations for future research also include an expansion of sociodemographic characteristics of service providers, which may help to explain the current findings. For example, service provider age, ethnicity, length of employment, years of experience, education details, and physical location they are servicing could be included as factors that may influence perceptions of the use of an online system for ROM. Previous research suggests that mental health therapists who have graduated more recently tend to value ROM and are more inclined to use it [25].

A direct survey evaluation of client experience and perceptions using an online system for completing mental health questionnaires is also recommended for future research given the current low receptiveness of clients. This additional information would be beneficial in highlighting necessary improvements that should be made for future implementations. It also would be helpful to reevaluate service providers’ perceptions on the use of an online system for ROM. Previous research suggests that mental health therapists who have graduated more recently tend to value ROM and are more inclined to use it [25].

Conclusions
Overall, the findings of this study suggest that online ROM has strong potential to lead to increased adoption of ROM, which has been associated with better outcomes for patients. This should encourage researchers and practitioners to identify and address the barriers and challenges, which, with limited intervention, could increase the chances of future implementation success, improved utilization, and completion of the measures.
Acknowledgments
We wish to thank Homewood Health Inc in Guelph, Ontario, for allowing us to perform this study; and the Department of Health Services Management at Ryerson University, Toronto, for their ongoing support.

Conflicts of Interest
SR works for the organization where the study took place.

Multimedia Appendix 1
Routine outcome monitoring (ROM) self-reported measurement questionnaires.
[DOCX File, 13 KB - mental_v8i12e29243_app1.docx ]

Multimedia Appendix 2
Service provider survey.
[DOCX File, 15 KB - mental_v8i12e29243_app2.docx ]

References


Abbreviations

ROM: routine outcome monitoring

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Core Competencies to Promote Consistency and Standardization of Best Practices for Digital Peer Support: Focus Group Study

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Abstract

Background: As digital peer support is quickly expanding across the globe in the wake of the COVID-19 pandemic, standardization in the training and delivery of digital peer support can advance the professionalism of this field. While telehealth competencies exist for other fields of mental health practice, such as social work, psychiatry, and psychology, limited research has been done to develop and promote digital peer support competencies.

Objective: The goal of this study is to introduce the coproduction of core competencies that can guide digital peer support.

Methods: Peer support specialists were recruited through an international listserv and participated in a 1-hour virtual focus group. A total of four focus groups were conducted with 59 peer support specialists from 11 US states and three countries.

Results: Analysis was conducted using the rigorous and accelerated data reduction (RADaR) technique, and 10 themes were identified: (1) protecting the rights of service users, (2) technical knowledge and skills in the practice of digital peer support, (3) available technologies, (4) equity of access, (5) digital communication skills, (6) performance-based training, (7) self-care, (8) monitoring digital peer support and addressing digital crisis, (9) peer support competencies, and (10) health literacy (emerging). The authors present recommendations based on these themes.
Conclusions: The introduction of digital peer support core competencies is an initial first step to promote the standardization of best practices in digital peer support. The established competencies can potentially act as a guide for training and skill development to be integrated into US state peer support specialist competencies and to enhance competencies endorsed by the Substance Abuse and Mental Health Services Administration (SAMHSA).

KEYWORDS
COVID-19; peer support; competencies; training; digital

Introduction
In the wake of the COVID-19 pandemic, digital peer support has rapidly expanded across the globe. Digital peer support is live or automated peer support services delivered through technology media, such as peer-to-peer networks on social media, peer-delivered interventions supported with smartphone apps, and asynchronous and synchronous technologies [1]. Peer support has been described as social emotional support, frequently coupled with instrumental support [2]. It is mutually offered or provided by persons with a mental health condition or substance use disorder to others sharing a similar mental health condition or substance use disorder. Peer support has augmented mental and physical health care by providing support between clinical encounters [3]. Peer support specialists enhance mental health service users’ hope, quality of life, social support, and recovery; are linked to reduced symptoms among mental health service users; and help to improve engagement in mental and physical health services [4,5].

Peer support is defined as an essential mental health service by the World Health Organization [6]. As referenced in the scientific evidence, peer support has expanded from in-person services to telemental health services prior to the COVID-19 pandemic (eg, warmlines) [7]. Prior to the COVID-19 pandemic, there was quite a widespread existence of digital peer support programming. For example, in a study led by Rotondi and colleagues [8], peers used a website and home computers to deliver psychoeducational therapy to individuals with schizophrenia and their family and friends. Participants in that study reported statistically significant improvements in psychiatric symptoms, including fewer positive symptoms. Digital peer support has also been offered through many different platforms, such as Facebook, smartphone apps, and fitness trackers, to promote fitness and self-monitored exercise [9,10]. However, due to the COVID-19 crisis and related lockdown and social distancing measures, digital peer support has rapidly expanded and includes various technology modalities. For example, digital peer support, once commonly offered through the telephone, has transitioned to be offered through technologies such as virtual reality and video games [11]. Peer support specialists are developing and coproducing digital peer support technologies with peer and nonpeer scientists (ie, peer support specialists are offering their lived experience expertise to partner in the development of digital peer support).

Peer-led, medical self-management programs show promise for significantly improving mental health service user activation (ie, “patient activation” is defined as patients’ willingness and efficacy in managing their own health and recovery) and the ability of the individual to manage their illness and health behaviors, collaborate with providers, maintain function, and prevent health decline [12]. Craig et al [13] investigated the feasibility of employing mental health service users as health care assistants within an assertive outreach team. The assertive outreach team consisted of an associate specialist psychiatrist, eight case managers with a nursing background, and a psychiatrist consultant. The team provided service to persons with a record of poor engagement in care, problematic behavior, substance abuse, and multiple hospitalizations. A total of 45 clients of the assertive outreach team were randomly assigned to either the standard team or the assertive outreach team plus a mental health service user who acted as a health care assistant. Craig et al [13] found that individuals with a lived experience of a mental health challenge were valued as role models who had “insight” into the care system and the resource capacity to advocate for clients within the clinical team. In addition, Clarke et al [14] found that an Assertive Community Treatment (ACT) team with case managers had a lower likelihood of psychiatric hospitalization than a nonconsumer-staffed ACT team. Clarke et al [14] theorized that mental health service users who had been hospitalized themselves may have been more motivated to keep service users out of the hospital and may have had greater tolerance for psychotic behavior or extreme states. Some studies have found peer-assisted care is not always more effective than standard or clinical care [15]. However, peer support significantly increases self-reported social contacts with service users and professional staff and enhances social networks [15].

As digital peer support quickly expands across the globe, development of digital peer support competencies is needed to develop a framework for consistency and standardization of best practices. Formal academic training programs for other mental health professionals, such as social workers, psychiatrists, psychologists, medical professionals, and community health workers, address best practices for implementing telemental health services [16]. While core competencies have been developed for in-person peer support (ie, Core Competencies for Peer Workers developed by the Substance Abuse and Mental Health Services Administration [SAMHSA]), to date, digital peer support competencies have not been considered [17]. In 2015, SAMHSA published core competencies for peer support specialists in an effort to identify the skills and abilities needed to provide support to people recovering from a mental health or substance use condition [17]. For example, SAMHSA identified the ability to engage peers in collaborative relationships and value communication as important competencies for in-person peer support specialists.
Peer support’s rapid transition to digital peer support during the COVID-19 pandemic requires the expansion and redefinition of skills and abilities for peer support specialists who are now offering services and support online through digital platforms.

Digital peer support has the potential to expand the reach and practices of in-person peer support. Promising evidence indicates that digital peer support specialists may enhance service users’ ability to live in community settings [18], improve the impact of peer support without the need of in-person sessions [19], and promote engagement in mental and physical health services [18]. Digital peer support sessions have no geographical or time limitations, engage service users in digital mental health, and may increase access to mental health care for hard-to-reach groups, such as rural or home-bound service users.

Introducing core competencies is the first step to standardizing telehealth practices for this mental health workforce. Core competencies could potentially facilitate consistency among digital peer support training programs across state and international borders. The current mental health landscape employs multiple models of peer support practice [20], making consistency across states difficult to ascertain. Similar to other fields, core competencies have the ability to promote best practices, guide delivery, inform training programs, assist in developing standards for certification in digital peer support, and assist in the evaluation of work performance. As such, the purpose of this study was to inform the development of core competencies for digital peer support specialists as an initial first step to promote the consistency and standardization of best practices in digital peer support.

Methods

Using a convenience sample, peer support specialists that currently offer digital peer support services were recruited by an international listserv that includes 1500 peer support specialists. Focus groups were determined as the most appropriate data collection methodology to ensure that the perspectives of peer support specialists were included in the initial development of competencies. Participants were eligible if they were older than 18 years of age and were a peer support specialist. Participants were asked to complete an online presurvey with questions on demographic information (eg, age, race, and gender) to ensure variation in focus group participants, and they participated in a 1-hour online focus group. The questions in the focus group interview guide were coproduced with four peer and nonpeer academic scientists and four peer support specialists using the Peer and Academic Partnership to determine what essential knowledge and abilities are necessary for effectively delivering digital peer support [21]. The Peer and Academic Partnership is the collaboration of academic researchers and certified peer support specialists to guide the development of interventions, trainings, and academic materials [21]. The Peer and Academic Partnership has been used to develop mobile apps, shared decision-making tools, and instruments to measure community-engaged research [21].

Interview guide questions included the following: “What essential knowledge does a peer support specialist need to offer digital peer support?” “What are the essential abilities peer support specialists need to offer digital peer support?” “How do these essential skills vary by lived experience (eg, mental health, physical health, substance use challenges, veteran status, aging, and racial or ethnic diversity)?” and “How do peer support practice standards as defined by the Substance Abuse and Mental Health Services Administration (SAMHSA) align or not align with what we have spoken about today?” SAMHSA’s Core Competencies for Peer Workers includes the following: (1) engages peers in collaborative and caring relationships; (2) provides support; (3) shares lived experiences of recovery; (4) personalizes peer support; (5) supports recovery planning; (6) links to resources, services, and support; (7) provides information about skills related to health, wellness, and recovery; (8) helps peers to manage crises; (9) values communication; (10) supports collaboration and teamwork; (11) promotes leadership and advocacy; and (12) promotes growth and development [17].

The development of competencies is not achieved through individual processes, but rather through collaborative group processes in social contexts [22]. For example, in excluding older adults and their unique perspective of living in a nursing home, we are not able to learn about the person in their specific environment. To reproduce such a group process and to build off of other opinions, we aligned our data collection to promote cross-individual opinions. As such, we employed a series of focus groups to develop the digital peer support competencies. The final set of competencies based on focus group findings incorporated member-checking to ensure accuracy and face validity. Member-checking was used to enhance the credibility of data analysis and participant involvement [23]. Researchers presented data transcripts to all participants for comment, and participants were asked to review the transcripts to determine if the words match their intended meanings and to validate the researcher’s interpretation of the data [23].

The analysis of digital peer support competencies, within the framework of peer-run organizations and Medicaid-reimbursable organizations, was based on four 1-hour focus group discussions with a total of 59 participants across the four focus groups, which took place in October 2020. The focus groups were carried out by two authors (CCP and A Myers) using the interview guide. The interview guide was successfully tested in a pretest. Focus group participants were emailed the interview guide 24 hours prior to the focus group to prepare for the actual focus group. Focus group facilitators had 1 to 5 years of experience conducting focus groups with the sample of interest. To facilitate participation, focus group facilitators developed a set of ground rules with participants, including (1) the confidentiality of the focus group, (2) allowing everyone time to speak, (3) having mutual respect for one another, and (4) being available for follow-up. Focus group facilitators asked every participant for their input on each interview question.

The focus group discussions were recorded digitally, transcribed, and anonymized. Focus groups were conducted until there was saturation (ie, when sampling more data would not lead to more information) [23]. The data were analyzed using the rigorous and accelerated data reduction (RADA) technique, a team-based approach to coding and analyzing qualitative data.
The RADaR method helps to streamline the process of qualitative data analysis and produce qualitative results quickly and thoroughly through its ability to organize, reduce, and analyze data in user-friendly software packages, such as Microsoft Excel [24]. Aligned with the RADaR methodology, data transcripts were formatted into an all-inclusive Excel spreadsheet. The Excel spreadsheet included column headings such as question, participant number, and response. Team members worked in groups to assign codes to each response. After the all-inclusive Excel spreadsheet was produced, the data table was reduced to include only content relevant to the interview questions. The remaining text and codes were then organized into themes. Common codes were derived from the focus groups by carefully reviewing the transcribed text and were grouped together and organized under overarching themes. Consistent with the RADaR methodology, themes were determined by the incidence at which a code aligned with an overarching theme (see Results). To ensure the text and codes were interpreted correctly and were correctly organized into themes, the process of member-checking was employed. Member-checking is a qualitative method used to validate findings, resolve conflicting results, and assess the trustworthiness of qualitative results [25]. The percentage for each theme was found by dividing the frequency in which the theme was present in the focus group quotes by the total number of focus group quotes.

The Committee for the Protection of Human Subjects at the Dartmouth-Hitchcock Institutional Review Board approved the project.

Results

Participants

A total of 59 peer support specialists participated in one of four focus groups. Over 78% of the participants had a degree-level education, and the majority of participants were female (Table 1). The participants were from 11 states and three countries: the United States, Canada, and Australia.

We identified 76 codes and a set of 10 themes relating to the development of digital peer support competencies. Themes covered different knowledge and skills that the participants believed were integral to the practice of digital peer support. The 10 themes were as follows: (1) protecting the rights of mental health service users, (2) technical knowledge and skills in the practice of digital peer support, (3) available technologies, (4) equity of access, (5) digital communication skills, (6) performance-based training, (7) self-care, (8) monitoring digital peer support and addressing digital crisis, (9) peer support competencies, and (10) health literacy (emerging) [26] (Table 2).
Table 1. Participant characteristics.

<table>
<thead>
<tr>
<th>Sociodemographic characteristics</th>
<th>Participants (N=59), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (19)</td>
</tr>
<tr>
<td>Female</td>
<td>35 (59)</td>
</tr>
<tr>
<td>Missing</td>
<td>13 (22)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>19-26</td>
<td>3 (5)</td>
</tr>
<tr>
<td>27-49</td>
<td>15 (25)</td>
</tr>
<tr>
<td>50-64</td>
<td>23 (39)</td>
</tr>
<tr>
<td>≥65</td>
<td>5 (8)</td>
</tr>
<tr>
<td>Missing</td>
<td>13 (22)</td>
</tr>
<tr>
<td><strong>Racial background</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>35 (59)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (2)</td>
</tr>
<tr>
<td>More than one race</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Missing</td>
<td>13 (22)</td>
</tr>
<tr>
<td><strong>Highest grade in school completed</strong></td>
<td></td>
</tr>
<tr>
<td>Completed high school or GED (General Educational Development)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Some college</td>
<td>10 (17)</td>
</tr>
<tr>
<td>Completed college or technical school</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Completed associate degree</td>
<td>11 (19)</td>
</tr>
<tr>
<td>Completed bachelor’s degree</td>
<td>9 (15)</td>
</tr>
<tr>
<td>Some graduate school</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Completed master’s degree</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Missing</td>
<td>13 (22)</td>
</tr>
<tr>
<td><strong>Current workplace organization type</strong></td>
<td></td>
</tr>
<tr>
<td>Peer run</td>
<td>12 (20)</td>
</tr>
<tr>
<td>Medicaid reimbursable</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Commercial health system</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Other</td>
<td>23 (39)</td>
</tr>
<tr>
<td>Missing</td>
<td>13 (22)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>32 (54)</td>
</tr>
<tr>
<td>Part time</td>
<td>6 (10)</td>
</tr>
<tr>
<td>Volunteer</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Student</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Missing</td>
<td>14 (24)</td>
</tr>
<tr>
<td><strong>Type of lived experience impacting participant</strong></td>
<td></td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>8 (14)</td>
</tr>
<tr>
<td>Major depression</td>
<td>13 (22)</td>
</tr>
<tr>
<td>Other mental health concerns</td>
<td>6 (10)</td>
</tr>
<tr>
<td>Sociodemographic characteristics</td>
<td>Participants (N=59), n (%)</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Alcohol use disorder</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Opioid use disorder</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Other substance misuse concerns</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Obesity</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Heart disease</td>
<td>1 (2)</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Other physical health conditions</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Missing</td>
<td>14 (24)</td>
</tr>
</tbody>
</table>

**Offers digital peer support**

- Yes: 35 (59)
- No: 10 (17)
- Missing: 14 (24)

**If offering digital peer support, modes by which digital peer support is provided**

- Smartphone app: 15 (25)
- Text messaging: 21 (36)
- Phone calls: 25 (42)
- Videoconference: 24 (41)
- Social media: 5 (8)
- Virtual reality: 2 (3)
- Other: 2 (3)

**Training received to offer digital peer support**

- Digital peer support certification (short course): 22 (37)
- Learned by doing: 9 (15)
- Have not received formal training: 10 (17)
- Other: 4 (7)
- Missing: 14 (24)

**Credentials**

- Digital peer support certification (short course): 22 (37)
- Recovery coach training: 8 (14)
- Certified peer support specialist: 34 (58)
- Noncertified peer support specialist: 5 (8)
- Forensic peer support: 5 (8)
- Certified older adult peer support specialist: 2 (3)
- Wellness Recovery Action Plan: 17 (29)
- Whole Health Action Management: 6 (10)
- Emotional CPR: 4 (7)
- PeerTECH: 2 (3)
- Digital peer support engineer: 1 (2)
- None of the above: 2 (3)
- Other: 6 (10)

**Types of digital peer support technologies developed by participant**

- Filmed digital peer support videos: 5 (8)
<table>
<thead>
<tr>
<th>Sociodemographic characteristics</th>
<th>Participants (N=59), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed scripted text messages</td>
<td>8 (14)</td>
</tr>
<tr>
<td>Developed scripted social media posts</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Developed digital peer support program content</td>
<td>13 (22)</td>
</tr>
<tr>
<td>Developed smartphone apps</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Developed videoconference software</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (15)</td>
</tr>
</tbody>
</table>
Table 2. Digital peer support core competencies.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Description</th>
<th>Observable behavior of competencies</th>
<th>SAMHSA® competencies</th>
</tr>
</thead>
</table>
| Protecting the rights of service users     | • Understanding of cybersecurity and how to protect the information and the privacy of service users  
• Understanding how to protect the confidentiality of service users  
• Complying with local, state, national, and international (if applicable) privacy laws and regulations | • Evaluating how data are being collected on certain digital platforms  
• Obtaining informed consent from service users  
• Facilitating meetings with service users in settings where confidentiality can be maintained  
• Understanding the Health Insurance Portability and Accountability Act (HIPAA) privacy laws and whether devices are HIPAA compliant | N/A |
| Technical knowledge and skills in the practice of digital peer support | • Acquiring the skills and knowledge necessary to comfortably use technology devices and platforms | • Ability to understand different platforms and devices and teach service users how to comfortably use their devices and digital platforms that are required for their digital peer support, both in person and remotely | N/A |
| Available technologies                     | • Ability to provide information and support through devices and platforms accessible to, and preferred by, service users | • Adapting to the digital preference of the service user; for example, with young adults communicating via text | Supports recovery planning |
| Equity of access                            | • Ability to connect with service users from diverse backgrounds and locations  
• Knowledge of resources around technology accessibility | • Acquiring knowledge of tools and technological resources available for special populations; for example, knowledge on accessibility of resources for rural populations | N/A |
| Digital communication skills               | • Skills that digital peer support specialists need to effectively communicate via digital platforms | • Empathetic listening and constant “checking-in” with the service user when body language is less visible | Values communication  
• Shares lived experiences of recovery  
• Links to resources, services, and supports  
• Provides information about skills related to health, wellness, and recovery |
| Performance-based training                 | • Standardized training in which peer specialists acquire the knowledge and skills of digital support; necessary to peer support specialists’ ability to transition to digital peer support | • Practice phone call or virtual interaction between supervisor and digital peer support specialist to assess knowledge and skills | Engages peers in collaborative and caring relationships  
• Provides support  
• Promotes growth and development  
• Supports collaboration and teamwork |
| Monitoring digital peer support and addressing digital crisis | • Aware of agency’s crisis plan and of resources available to support service users between meetings | • Transparency with service users around digital peer support specialist’s role and training around digital crisis intervention | Helps peers to manage crises |
| Peer support competencies                  | • Maintaining the core competencies of peer support within the practice of digital peer support | • Ability to cultivate hope, empathy, engagement, and mutuality and to share lived experiences | All of the SAMHSA competencies |
Protecting the Rights of Service Users

The most prevalent theme was protecting the rights of service users. This core theme was made up of four key subthemes: confidentiality, security, privacy, and informed consent. Protecting the rights of service users constituted 19.2% (28/146) of the themes discussed in the focus groups. Peer support specialists questioned how telehealth policy and regulation would inform the use of different technologies and platforms.

A peer support specialist mentioned, “telehealth rules are going to affect what you can and can’t do.” Multiple participants cited understanding and evaluating the security features of technology as essential knowledge for digital peer support. For example, one participant said, “one piece of essential knowledge is how to evaluate the security and the privacy aspects of a digital platform.” Guidelines for confidentiality protections were frequently encouraged by participants. Participants recommended constructing agreements with service users on privacy and the protection of personal information. A participant reported that there should be “guidelines that people have to agree to before they undertake support so that they know...they can’t have people around that are going to be hearing stuff that might be confidential.” Participants also referred to the importance of informed consent. Transparency about the digital peer support role and regarding shared information was recommended. For example, a participant stated, “it’s about transparency and trust...If their information is being shared or if I can see their phone number, I’m going to be honest...we have to be up-front.”

Technical Knowledge and Skills in the Practice of Digital Peer Support

The second theme, technical knowledge and skills in the practice of digital peer support, constituted 15.1% (22/146) of the themes discussed in the focus groups. Participants recommended that digital peer support specialists should have the knowledge necessary to comfortably use technology in a meeting. A participant stated, “so when I’m doing one-on-one peer support over the phone or on a Skype call, I need to know how to use the technology.” The majority of participants believed that digital peer support specialists should also have the basic skills to use different platforms and devices. For example, one participant stated, “they need to understand the difference in how to use the different platforms.” The ability to teach service users how to access and comfortably use different digital platforms, devices, and resources was also encouraged. A participant stated the following:

[Digital peer support specialists] need some basic knowledge of computers and a virtual format, like accessing applications like Zoom, not only to be able to navigate it, but to teach others how to access it and to navigate it on different platforms, like a computer and a mobile phone.

However, peer support specialists also encouraged digital peer support specialists to use a blend of both digital and nondigital resources. For example, a participant stated, “I mail out the material before the groups start so any time I get a new participant, I make sure that they have the material instead of just doing the screen sharing.”

Available Technologies

The third theme, available technologies, included the subtheme of preference. The theme of available technologies constituted 11.6% (17/146) of the themes discussed in the focus groups. Many peers emphasized how the preferred type of device or digital platform may vary by mental health condition and age group. The type of mental health condition may affect whether
or not the service user wants to communicate with or without a webcam and visual component. A participant stated the following:

I know for just living with substance use disorder, sometimes, the idea of a video chat can be very triggering for some because during certain drug uses, especially in the heavy forms of it, it’s actually used as a platform to connect with other people who are using the same drug as you as a means to sort of show off and that was, I know when Zoom came around for therapeutic services, there were a lot of people in the substance use community that are in recovery that I’ve spoken with that have definitely said that it’s very hard for them to be on any kind of webcamming.

Many peer support specialists also suggested technology preference may differ by age group. Based on experience, younger adults seemed to prefer communicating via text, while older adults preferred communicating via tablet; for example, a participant stated, “many of the young adults that I work with in our first episode psychosis program don’t have a tolerance or a desire to sit through a 1-hour video call like we’re doing now. They prefer texting.” Another added, “with older adults...a tablet is the technology that is most preferable because of the size of it.”

Equity of Access

The fourth theme was equity of access and included the subthemes accessing technology, accessibility of platforms for people with physical challenges, accessibility of platforms for people with environmental challenges, and cultural competence. The theme of equity of access constituted 11.0% (16/146) of the themes discussed in the focus groups. The ability to connect with service users from different backgrounds and cultures was cited as an essential ability for digital peer support specialists. One participant mentioned the following:

Well, I think that engagement is a cultural matter of having cultural humility and understanding and empathy for a person’s worldview. And being able to meet a person where they are whether it’s in a rural situation, whether it’s in a homeless situation, whether it’s in an urban high rise, you know, there needs to be a way that the specialist can extend him or herself, to make an effort to understand the environment out of which a person served is coming and where they’re at.

Participants encouraged digital peer support specialists to gain knowledge of technological resources for special populations, like rural service users, who may have difficulties accessing technology. For example, a participant stated the following:

Having tools to be able to be proactive and kind of have insight and awareness to meet the needs of various populations in terms of location and access and or maybe having, for example...knowledge of different programs that may offer certain phones, and that kind of awareness to meet the needs of different populations as well.

Knowledge of platforms and devices that are accessible to people with physical challenges was also encouraged:

There are like, automated, like voice-to-text generators that you can get that will provide subtitles for people that have sensory issues. And that’s something that can make it accessible for people who might not otherwise be able to attend. So looking at those sorts of accessibility options is something that’s probably important or asking people who are going to be attending whether they have any accessibility needs and trying to work out a way to accommodate them.

Many participants also encourage the continuation of digital peer support because of its ability to reach marginalized populations. A participant stated, “we need to maintain this online stuff because it is accessible to so many people that would probably not be accessing anything otherwise.”

Digital Communication Skills

The fifth theme, digital communication skills, constituted 10.3% (15/146) of the themes discussed in the focus groups. The majority of participants cited effective communication as a necessary component to digital peer support. With the lack of body language and, at times, visual interaction, multiple peer support specialists recommended that digital peer support specialists rely on verbal cues and engagement skills while interacting with service users virtually:

Part of the biggest thing for us as peers is to listen...So how do you do that without being able to convey verbal cues?...I just have to use my verbal cues, and then just kind of, you know, let him know, I’m there. I’m with you. I understand, I hear you.

Participants cited strong group facilitation skills as a necessity for digital communication. For example, a participant stated, “it’s really important to have good facilitation skills, especially if you’re doing groups online, because it can be harder than in person because people don’t always see the cues, they don’t always notice the body language of other people.” Comfort with digital platforms and devices was believed to facilitate digital communication skills:

I think a peer support specialist needs to have a comfort with whatever virtual platform they are using to interact with the service user. And beyond that, just needs to really extend him or herself in kind of a wholehearted way, to convey their concern, to convey hope, to convey their experience to the service user.

Overall, peer support specialists suggested that, as with in-person peer support, digital peer support should focus on the building of relationships, no matter what digital device is being used. For example, one participant said, “very simply, engagement is about building relationship. If you don’t build a relationship you cannot engage. So it doesn’t matter if we’re talking smartphones, tablets, laptops, Webex, Zoom. It’s about building a relationship.”
Performance-Based Training

The sixth theme, performance-based training, constituted 8.9% (13/146) of the themes discussed in the focus groups. Many participants encouraged digital peer support specialists to attend a digital peer support course. A participant stated, “I think the digital peer support course would be really helpful.” Other peer support specialists believed there should be agency or state-specific trainings for digital peer support specialists:

In addition, it would be really cool if there was another layer of training. So for a specific agency, for example, if there were certain regulations that were different...or [if there were] certain requirements or different kind of policies at the state level.

Some participants recommended agencies or supervisors give feedback to peers based on their digital peer support skills. One participant believed “there should be a competency quiz so maybe a quiz or checking back and having them be able to repeat that information.” Practice digital conversations were also recommended as a training option for digital peer support specialists:

After completing the training what we do is we have a fake call or fake message conversation where for an hour the supervisor pretends to be in crisis and reaches out and we have to provide ample support to them and then they critique us on everything that we said after the hour’s up and they tell us if we are allowed to go on and do peer support provider.

Self-Care

The seventh theme, self-care, was an emerging theme that constituted 8.9% (13/146) of the themes discussed in the focus groups. Many participants recommended planning in times throughout the day for self-care:

Scheduled blocks throughout the day that you’re not in a meeting so that 1) you can avoid fatigue and 2) get other things done...That’s part of the boundary of self-care that we practice, putting in those blocks of time so I don’t have a meeting during that time because I need to go for a walk, or I need to finish my emails or a report or whatever it might be.

Some peer support specialists encouraged physical activity as a break from digital peer support. For example, “getting up for a walk” or “physical activities have helped a lot with my own personal fatigue.” Participants also categorized the ability to ask for help as an important aspect of self-care:

I think an essential ability is to that when you are having those tough moments to make sure that people reach out for help, so that they don’t feel like they’re struggling on their own, and that they do get feedback on some of those maybe tougher cases...Because I think with peer support, you know, we talk about the trauma informed, because it’s a part of our lived experience to share those pieces where it builds connection, we might get retraumatized all over again.

Many participants referenced the ability to separate work from personal life and the ability to set boundaries as essential skills when providing digital peer support. A participant stated, “having that maintenance of boundaries so you don’t wear yourself out.” Peer support specialists recommended the formation of plans and set time periods for when service users could and could not call. For example, one participant shared, “come up with a plan to be able to have set time periods that you can call, whether it be certain hours that you know that person’s not going to be there to strictly making it within those hours...just setting those agreements with them.” Participants also encouraged digital peer support specialists to be mindful of digital fatigue while setting boundaries with service users. A participant stated, “just being mindful of when you are starting to get that fatigue and being able to go, ‘okay, I need to take a break.’”

Monitoring Digital Peer Support and Addressing Digital Crisis

The eighth theme, monitoring digital peer support and addressing digital crisis, constituted 8.2% (12/146) of the themes discussed in the focus groups. Transparency about the role of a digital peer support specialist was encouraged while addressing digital crisis:

Understanding one’s role as a peer support specialist, versus a different kind of service provider. A peer specialist is not a person who is geared or trained to respond to a full-fledged crisis. By nature, most peer specialists, unless they’re in an emergency response setting, are not trained or oriented to respond to crisis situation.

However, multiple participants encouraged the formation of trainings around digital crisis intervention. For example, one participant said, “if not a training, even just a conversation about how to respond to someone that is in crisis virtually...so I think that’s a really important discussion that needs to be had and maybe training that needs to be developed.” Peer support specialists questioned how they could better support service users, virtually, while in a crisis. A participant stated, “It’s very easy to sit with someone and make them feel not alone, but how can we make them feel not alone, when they can click a button and cut us off?”

Peer Support Competencies

The ninth theme consisted of peer support competencies and included the subtheme self-determination. The theme of peer support competencies constituted 5.5% (8/146) of the themes discussed in the focus groups. The majority of participants believed that peer support competencies were essential to digital success. A participant stated, “I think still an essential ability is really the fundamentals of peer support.” Empathy, engagement, mutuality, sharing lived experiences, and the cultivation of hope were some of the competencies mentioned that peers believed were important to both in-person and digital peer support. For example, a participant said, “the ability to cultivate hope, to communicate, to partner with, to enhance self-determination, are all things that feel, to me, very important, as well as abilities.” The majority of participants believed that
the peer support competencies developed by SAMHSA aligned with those of digital peer support. A participant stated, “relationship focused, trauma informed: all of this should definitely align with digital peer support.”

**Health Literacy**

The last theme, health literacy, was an emerging theme that constituted 1.4% (2/146) of the themes discussed in the focus groups. Many participants emphasized the importance of health literacy in digital peer support. One participant encouraged the use of a “checklist” as a mechanism of checking “basic digital health literacy.” Communication, with, and extracting information from, members of the medical field was cited as a challenge for peers. For example, one participant shared, “[COVID-19] has definitely made it hard to get information that I need from doctors to deal with my members…trying to get the doctors to connect with me at the same time is a work in progress.” Some participants believed more knowledge around digital peer support may help with peer-to-doctor communication during COVID-19. A participant stated, “I feel as if that with digital and the more knowledge we have and the more educational stuff we can put out with the doctors and also in our members, it will definitely help during this time at COVID.”

**Discussion**

**Principal Findings**

The purpose of this study was to introduce the coproduction of core competencies for digital peer support specialists to promote the consistency and standardization of best practices. The following themes emerged from the four focus groups with 59 participants: (1) protecting the rights of service users, (2) technical knowledge and skills in the practice of digital peer support, (3) available technologies, (4) equity of access, (5) digital communication skills, (6) performance-based training, (7) self-care, (8) monitoring digital peer support and addressing digital crisis, (9) peer support competencies, and (10) health literacy (emerging). The established competencies may act as a guide for training and skill development to be integrated into state peer support specialist competencies and enhanced established competencies endorsed by SAMHSA.

Peer support specialists are increasingly using mobile and online technologies to deliver peer support [19]. While SAMHSA has developed core competencies for in-person peer support, peer support’s rapid transition to digital forms during the COVID-19 pandemic requires the expansion and redefinition of skills and abilities for peer support specialists who are now offering services and support online and through digital platforms. For example, participants in the focus groups recommended that digital peer support specialists require knowledge about digital platforms and devices and on cybersecurity and privacy. Digital peer support specialists need specific skills and abilities to communicate effectively with service users via technology while still maintaining boundaries between work and personal life. Based on the themes that emerged from the focus groups, the authors make a number of recommendations, as discussed in the following sections.

**Ensure Equity in Digital Peer Support Delivery**

Technological advances can lead to health care disparities for underresourced populations. It is important for those who develop digital health technologies to understand the challenges faced by disadvantaged populations, including older adults; people who have mobility or cognitive challenges; lesbian, gay, bisexual, and transgender people; justice-involved people; and Native American groups. Interventions designed with community-engagement methods may be better equipped to address inequities, health disparities, and linguistic and cultural considerations. The decision to meet people where they are individually, culturally, and digitally can benefit the implementation of digital interventions and help to achieve health equity [27]. Digital peer support specialists need to be aware of mental health service users’ biopsychosocial needs and leverage technology tools that can enhance service and resource delivery. For example, digital peer support specialists should communicate using large font when communicating with older adults due to common impairments in vision and should include closed captioning while communicating with adults who are hard of hearing. Digital communication skills also include peer support specialists’ ability to adapt their background setting to the needs of the service user. Digital peer support specialists should communicate in a well-lit setting with low background noises to ensure that service users can correspond comfortably.

**Understand Available Technologies and Analytical Techniques**

Technology is frequently changing. Being fluent and up to date in technology literacy may facilitate a peer support specialist’s capacity to educate service users on the dynamics of digital technologies. Research, to date, indicates that peer support specialists and service users are commonly not informed of benefits and disadvantages of using specific technologies and their respective analytical techniques. Thus, some technologies and respective analytical strategies may not be aligned with peer support specialists’ values and practice principles [17]. For example, research indicates that individuals, including peer support specialists and service users that have a unique social-cultural history with the mental health system, may not perceive a chatbot as ethical. Chatbots constitute a software that allows for online text with an artificial (ie, nonhuman) agent. With mastery of technology literacy, digital peer support specialists could adhere to the technological preferences (eg, if they prefer a certain digital platform) and accessibility (eg, if service users do not have financial access to certain digital devices) of service users. Peer support specialists would have the skill to use clear, understandable, and value- and judgement-free language, and would have the tools to discuss technologies and to support themselves and service users in making informed decisions in engaging with technologies.

**Preventing Digital Fatigue Through Separating Work and Personal Life**

Unlike in-person peer support, digital peer support can be offered anytime and anywhere. As a result, digital peer support may lead to more frequent and more casual interactions and behaviors. Separating work from personal life is important for
avoiding digital fatigue. “Digital fatigue” is defined as a state of mental exhaustion and reduced motivation and concentration due to the overuse of digital devices and platforms [28]. Digitalization of the workplace has been cited as a common reason for a decrease in energy levels [28]. During COVID-19, the majority of business activities have been performed through digital platforms [29]. Separating work and personal life is also important for avoiding potential boundary issues that could occur in asynchronous communications. For example, providing feedback during nonbusiness hours could lead service users to expect nearly instantaneous feedback. Service users’ unimpeded access to digital peer support specialists could potentially lead to digital fatigue, exhaustion, and increased burnout rates. Similar to other fields of study, it is important for digital peer support specialists to maintain normal hours and locations, ensure timely and consistent feedback, and ensure private, consistent, and professional meetings (eg, do not smoke cigarettes during a meeting). A supportive management structure may be important for facilitating self-care. A supportive management structure offers ongoing support, is nonpunitive, and has been shown to be effective with peer support specialists [1].

Self-Determination Is Key to Engagement

Supporting services users’ preferences for available technologies has the potential to promote engagement in digital peer support services. Self-determination theory represents a general theory of human motivation that explicitly identifies autonomy as a human need that, when supported, facilitates more autonomous forms of motivation [30]. Promoting service users’ autonomy, then, might promote better mental and physical health management. Service users with greater autonomy orientations might also be more motivated to make positive health-related behavior changes [30]. Shared decision making in research allows for greater personal autonomy and takes into account the extent to which service users want to be involved in the decision-making process [31]. Shared decision making in research proposes that individual preferences—what matters to service users and families—should play a major role in determining health care decisions [31]. The majority of peer support services are offered through videoconference-based services, smartphone services, and social media, followed by burgeoning digital platforms offered through virtual reality and video games. Peer support organizations are developing multiple ways for people to connect based on preference.

Protecting the Rights of Service Users

Complying with privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, protects individuals’ personal health information and sets boundaries on the use and release of health records [32]. It establishes the appropriate safeguards that health care providers and others must adhere to in order to protect the privacy of health information, and it sets standards for HIPAA-compliant software and products [32]. Communication through, and storing information in, HIPAA-compliant devices ensures the protection of electronic health information [33]. Storing information, records, and devices in a secure location and using trusted networks increases cybersecurity measures and helps provide a private, consistent, and professional setting [33]. International privacy laws include Australia’s Privacy Law, the European Union’s General Data Protection Regulation, Canada’s Personal Information Protection and Electronic Documents Act, and Singapore’s Personal Data Protection Act. Like HIPAA, these privacy laws safeguard personal data and provide guidelines on security storage and informed consent [34]. Understanding cybersecurity and how to secure one’s phone, laptop, remote desktop, and data storage is important to digital peer support specialists’ ability to ensure privacy and confidentiality for their service users. Understanding where information is being stored, for example, on iCloud, is also important to digital peer support specialists’ ability to protect service users’ data. Digital peer support specialists can potentially increase cybersecurity measures by securing all devices, checking that VPNs (virtual private networks) and firewalls have necessary updates, uploading the most recent security patches, using strong passwords, implementing multifactor authentication, and only accessing trusted networks or cloud services—not free hotspots [35]. Digital peer support specialists are required to obtain informed consent from service users and to conduct meetings in a confidential setting. Digital peer support specialists must keep information discussed confidential, yet mandated reporting is required when abuse is observed or suspected. Digital peer support specialists need the capacity to inform service users of their rights and of what data are collected by technologies at the time of service. For example, messaging on Facebook Messenger falls under the category of “nonpublic-facing” communication in the US Office for Civil Rights, meaning that only intended parties are allowed to participate in communication. However, health information provided on Facebook’s chat platform is unprotected under HIPAA [36]. Health information provided through Facebook may be regulated under Facebook’s privacy policy, but it is not subject to HIPAA standards [36].

Technical Knowledge and Skills in the Practice of Digital Peer Support

Lastly, as an overarching recommendation, peer support specialists are encouraged to ensure competence in the digital peer support services they provide. This includes acquiring the skills and knowledge necessary to comfortably use the technologies being used. For example, digital peer support specialists should have the ability to navigate videoconferencing software and have basic knowledge on devices like computers and tablets. Technical knowledge and skills could potentially equip digital peer support specialists with the ability to adapt to technical difficulties, such as communicating with service users who have a poor data signal. At a minimum, this should include consultation with information technology professionals, web design developers, and expert digital peer support specialists in the field. Practicing with different digital platforms or devices and seeking feedback is important for skill development. However, having advanced expertise in technology skills and troubleshooting may not be the role of peer support specialists. As such, having a dedicated person on-site, in person, or virtually, who understands the philosophy, values, and practices of peer support specialists, could facilitate advanced troubleshooting. That individual could be a peer or a nonpeer.
Ongoing consultation with experts in the field of digital peer support will be important for peer support specialists who are new to digital peer support. All peer support specialists are encouraged to seek continuing education and ongoing consultation from their supervisors and others regarding any work and personal life issues that arise at any point. In Table 3, we outline recommendations for digital peer support competencies and provide some examples of support efforts.

**Table 3.** Authors’ recommendations for digital peer support competencies based on focus group analysis.

<table>
<thead>
<tr>
<th>Authors’ recommendations for digital peer support competencies</th>
<th>Examples of digital peer support efforts to enhance best practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure equity in digital peer support delivery</td>
<td>Interventions should be designed using community-engagement methods to address inequities, health disparities, and linguistic and cultural considerations.</td>
</tr>
<tr>
<td>Understand available technologies and analytical techniques</td>
<td>Gaining technology literacy is important to digital peer support specialists’ ability to adhere to and use technologies that best fit the preferences and accessibility of service users.</td>
</tr>
<tr>
<td>Prevent digital fatigue through separating work and personal life</td>
<td>Digital peer support specialists should maintain normal hours and locations and ensure timely and consistent feedback to maintain boundaries and prevent exhaustion.</td>
</tr>
<tr>
<td>Self-determination is key to engagement</td>
<td>Supporting service users’ technology preferences has the potential to promote engagement in digital peer support services.</td>
</tr>
<tr>
<td>Protect the rights of service users</td>
<td>Complying with privacy laws, such as HIPAA, can help protect service users’ personal health information and ensure the secure storage of records and safe communication.</td>
</tr>
<tr>
<td>Technical knowledge and skills in the practice of digital peer support</td>
<td>Practicing with different digital platforms or devices and seeking feedback on skill development can help digital peer support specialists to acquire the skills necessary to comfortably use technologies used in digital peer support.</td>
</tr>
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</table>

*HIPAA: Health Insurance Portability and Accountability Act.

**Limitations**

This study is not without limitations. First, there are potentially other competencies that have not been identified. Second, the sample lacked diversity based on racial and ethnic background and age. Future studies should consider the inclusion of disadvantaged populations, such as Hispanic, Latinx, and LGBTQIA (lesbian, gay, bisexual, transgender, queer/questioning, intersex, and asexual/aromantic/agender) populations. Third, as technology changes, so will these competencies. Fourth, the findings cannot be generalized to all digital peer support specialists, as the participants were selected from one listserv, which may have biased the results. In addition, it is unknown if there was international saturation. However, as the purpose of this study was to introduce the development of digital peer support competencies, future research could consider saturation of qualitative inquiry with an international sample. Fifth, the data could not be stratified by the role of the participant, and the data could not be stratified by volunteer-run services versus paid professional services. Sixth, the percentage of participants that completed a training in digital peer support is unknown and could have potentially biased the data. Seventh, the interview guide was not pretested, as it was developed with end users as partners. Further, we used an iterative process to modify the guide based on the focus groups. Eighth, focus group participants were not asked whether they were paid or volunteer peer support specialists, which may have introduced variation in the themes. Ninth, peer support has been around in some form for centuries. Note, the interest from the research community is more recent (ie, beginning with the seminal paper by Solomon [2]), and the interest from the health care field is very recent. Thus, some instances of cited references may not be referring to the more current use of peer support. Last, there may be certain functions of peer support that are not appropriate for technology. As such, exploring digital formats versus nondigital formats could explain which technologies are well suited for individuals. Future research looking at the integration of digital peer support competencies within digital peer support supervision is needed.

**Conclusions**

Introducing the definition of digital peer support competencies is the first step to creating a standardization of best practices. Core competencies identify the skills and abilities that all digital peer support specialists need in order to provide support to people recovering from a mental health or substance use condition. These competencies may create consistency among digital peer support programs and could be used to develop potential reimbursement models. The COVID-19 pandemic has resulted in a rapid expansion of digital peer support services. The identification and definition of abilities that peer support specialists will need in order to offer services and support online and through digital platforms will be used to guide the training and practice of digital peer support. The core competencies listed establish how skills and values can be applied and verified through practice. Future research should work to verify and build off of the digital peer support competencies defined in this study.

As this study is the initial first step toward the development of digital peer support competencies, these competencies can be used as a starting point for organizations (eg, hospitals and community mental health centers) and businesses (eg, peer-led or coproduced telehealth commercial start-ups). The authors recommend the collective review of these competencies with peer support specialists, patients, caregivers, family members of people with mental health challenges, clinicians, administrators, and policy makers to determine the value of integrating each competency into their system of care. Policy makers may consider collective review and determination of
the value of the inclusion of these initial competencies as part of (1) private and public health insurance, (2) peer support accreditation standards (eg, CARF [Commission on Accreditation of Rehabilitation Facilities] International and the Joint Commission), or (3) enhancements to SAMHSA’s existing competencies. As geographic regions and needs of systems of care and service users differ, organizations and businesses can select a milieu of competencies as a starting point and consider the integration of each competency based on their specific needs.

Conflicts of Interest
KF offers consultation services through Social Wellness, LLC, and receives payment from K Health.

References


Abbreviations

ACT: Assertive Community Treatment
CARF: Commission on Accreditation of Rehabilitation Facilities
HIPAA: Health Insurance Portability and Accountability Act
LGBTQIA: lesbian, gay, bisexual, transgender, queer/questioning, intersex, and asexual/aromantic/agender
RADaR: rigorous and accelerated data reduction
SAMHSA: Substance Abuse and Mental Health Services Administration
VPN: virtual private network
Evaluation of a Web-Based Stress Management Program for Persons Experiencing Work-Related Stress in Sweden (My Stress Control): Randomized Controlled Trial

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Abstract

Background: Stress is one of the most common reasons for sick leave. Web-based interventions have the potential to reach an unlimited number of users at a low cost and have been shown to be effective in addressing several health-related problems. Handling stress on an individual level is related to behavior change. To support behavioral changes in stress management, My Stress Control (MSC) was developed. The development of MSC was based on several health psychology theories and models; however, central in the development were Social Cognitive Theory, Theory of Reasoned Action, Theory of Planned Behavior, Transactional Theory of Stress and Coping, and the Transtheoretical Model and Stages of Change. MSC is a fully automated program. The program is tailored to the user’s specific needs for stress management and behavior change.

Objective: In this study, we aim to conduct a randomized controlled trial to evaluate the extent to which MSC affects perceived stress in persons experiencing work-related stress.

Methods: This was a randomized controlled trial with 2 arms. Study participants were recruited by visiting the worksites and workplace meetings. Participants were assigned to the intervention or wait-list group. Web-based questionnaires were used before and after the intervention to collect data. Perceived stress measured using the Perceived Stress Scale-14 was the primary outcome measurement. Analyses were conducted for both between-group and within-group changes.

Results: A total of 92 participants were included in this study: 48 (52%) in the intervention group and 44 (48%) in the wait-list group. Overall, 25% (12/48) of participants in the intervention group and 43% (19/44) of participants in the wait-list group completed the postintervention assessment. There were no significant effects on perceived stress between the intervention and wait-list groups or within the groups. A small effect size (Cohen d=0.25) was found when comparing mean change over time on the primary outcome measure between the intervention and wait-list groups. In addition, a small effect size was found between pre- and postintervention assessments within the intervention group (Cohen d=0.38) as well as within the wait-list group (Cohen d=0.25).

Conclusions: The effect of MSC on perceived stress remains uncertain. As adherence was low in the intervention group, elements or features that facilitate adherence and engagement must be further developed before firmer conclusions regarding the effect of MSC can be made.

Trial Registration: ClinicalTrials.gov NCT03077568; https://clinicaltrials.gov/ct2/show/NCT03077568

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KEYWORDS
behavior change; behavior medicine; internet; stress prevention
**Introduction**

**Background**

The landscape of the work environment in Western countries is changing [1]. Traditional industries with work tasks demanding lower education levels are declining, whereas work with higher demands on education, creativity, and analytic competence is increasing. This change leads to a necessity for higher-skilled employees who are able to perform qualified work with higher demands on education and analytic competence [2]. These changes might contribute to stress being one of the main reasons for sick leave in many countries, including Sweden [3]. It has been estimated that one-fourth of the workers in Europe are at risk of developing stress-related problems [4]. In this study, stress is defined as “a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being” [5].

Encouraging health-related behavior change using the internet provides the opportunity to reach out to a theoretically unlimited number of users at a lower cost than face-to-face or partly web-based solutions [6], and several web-based interventions supporting changes in different health-related behaviors have been shown to be effective [7-9]. Stress management interventions have been shown to be effective in different target groups [10-12]. Although the weaknesses of existing web-based programs for stress management have been identified, they are not often tailored or interactive and do not build on a solid theoretical framework [13].

Adherence to web applications for the management of different health-related behaviors for groups with and without various diagnoses is often low, with an average adherence of 50% [14]; this may be the result of low-grade tailoring and interactivity and program design issues. A similar pattern was observed with web-based stress management programs. A study on a web-based stress management program had a dropout rate of 40% in the intervention group [15], whereas programs with some type of coach have lower dropout rates [14,16]. One type of coach presented in an earlier study was an e-coach, providing written text within 48 hours of module completion [16]. However, this is resource demanding, and the study reported that the e-coach spent approximately 30 minutes for each person and module completion [16].

To address stress in the working population and issues related to adherence to self-management, the web application My Stress Control (MSC) [17] was developed and evaluated in a feasibility study [18]. MSC is a fully automated, interactive program tailored to the user’s individual needs for stress management based on Social Cognitive Theory (SCT), Theory of Reasoned Action, Theory of Planned Behavior, Transactional Theory of Stress and Coping, and the Transtheoretical Model and Stages of Change [17]. It was developed for persons with perceived stress who are not on sick leave and thus is used as a stress prevention intervention. The development was based on evidence within multiple fields and based on a solid theoretical framework [17] (Methods section).

**Objective**

The hypothesis was that the newly developed web-based, self-management program built on a solid theoretical frame and incorporating evidence from multiple fields would decrease perceived stress compared with a wait-list group. Thus, the aim of this randomized controlled trial (RCT) is to evaluate the extent to which a web-based, self-management program, MSC, affected perceived stress for persons experiencing work-related stress.

**Methods**

The CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guidelines [19] were used for reporting this study (Multimedia Appendix 1).

**Design**

This study was conducted as an RCT. After recruitment and signing informed consent forms in paper format, the participants were assigned randomly to 1 of 2 conditions: self-help stress management using the newly developed web application MSC or the wait-list control. Blinding was not applied in this study. Both participants in the intervention group and the wait-list group knew what group they were assigned to.

**Sample Size**

Power for estimation of sample size was calculated using a study comparing acceptance and commitment therapy with a wait-list group and a primary outcome of perceived stress [20] measured with the Perceived Stress Scale, 14-item (PSS-14) [21]. The characteristics of the participants in both studies were expected to be similar, as both were performed in the same country. In a study by Brinkborg et al [20], the participants were divided into 2 groups: one group with lower stress and the other reporting higher stress levels [20]. The power for this study was calculated using the outcome scores from the group in the Brinkborg et al [20] study that at inclusion had stress scores <25 on the PSS-14. The estimated effect size was calculated for the expected changes in PSS-14 scores. An estimated effect size of 0.40 with power equal to 0.80 and a significance level of 0.05 gave an estimated sample size of 98 individuals in each group. With an estimated dropout rate of 20%, each group was estimated to require 118 persons for a total sample size of 236 individuals. A total of 244 persons returned the informed consent and were allocated to either the intervention or wait-list group. Thus, a number over the target sample size was recruited because it was expected that some of these persons would be excluded by MSC because of high scores on the Hospital Anxiety and Depression Scale (HADS) or low scores on PSS-14. Unfortunately, during the intervention, more persons than expected were excluded or dropped out of the study, and the sample size was not as large as expected. In the intervention group, 60% (29/48) of persons were excluded, and in the wait-list group, 86% (38/44) were excluded because of PSS or HADS scores. Overall, 52% (48/92) of persons in the intervention group and 48% (44/92) of persons in the wait-list group answered the preassessment. For the final assessment,
25% (12/48) of persons in the intervention group and 43% (19/44) of persons in the wait-list group answered.

This study was registered at ClinicalTrials.gov (NCT03077568), with a sample size of 95. This was a miscalculation where 3 persons excluded because of HADS were included in that number. These individuals did not have access to MSC and were therefore correctly excluded from the analysis in the study.

Recruitment

Participants were recruited by the first author visiting different work sites and workplace meetings at some of the largest work sites in the region. Employers with a larger number of staff required fewer contacts with executives and gatekeepers. All participants had access to a computer or tablet and internet connection, and most of them both at work and at home. The first author visited 28 different work sites, some of them twice, representing the private sector, municipality, and county council.

Multimedia Appendix 2 shows the demographic characteristics of the participants. Eligible persons were informed both verbally and by an information letter about the study and inclusion and exclusion criteria. The inclusion criteria were a perceived stress score, measured with the PSS-14 [21], of 17 or higher [20]; being employed; being aged 18 to 65 years; able to speak and understand the Swedish language; and consenting to participate in the study. Exclusion criteria were being currently on sick leave or scoring 11 or more on either of the subscales of the HADS [22]. Persons who perceived themselves as stressed were encouraged to sign up for the study, return the signed informed consent form, and provide an email address for further communication. The enrollment and flow of participants are shown in Figure 1. All correspondence with the participants was through email with the first author. Recruitment for this study started during autumn 2016. The participants had access to MSC from December 2016 to May 2017. Follow-up measures were conducted on an ongoing basis.

Figure 1. Flowchart of enrollment, randomization, and exclusion. HADS: Hospital Anxiety and Depression Scale; ITT: intention-to-treat; PSS: Perceived Stress Scale.
Randomization

To have persons from the same work site in both groups (intervention and wait-list groups), randomization was conducted by randomizing the participants from each work site to either the intervention or wait-list group in blocks of 6 persons. We chose blocks of 6 persons to be more certain that we would have an equal number of participants in both groups; we also included participants from work sites where few persons consented to participate. Randomization was conducted using a web-based randomizer [23] with a set of equal figures of ones and twos in a 6-number set, meaning that each set contained 3 ones (randomized to the intervention group) and 3 twos (randomized to the wait-list group). The first author performed the randomization procedure. See Multimedia Appendix 2 for demographic data, descriptive statistics for primary outcome measures, and secondary outcomes at baseline for all participants completing the first assessment.

Intervention

The intervention group received access to the web-based program for self-management of stress, MSC [17,18], after a baseline assessment. MSC tailors to each user in 2 main ways: by recommending different stress management strategies depending on stress-related problems experienced by each unique user (using a functional behavioral analysis) and by assessing the stage of change [24,25]. The web application is fully automated and does not provide the user with any contact with a therapist or coach. Information in the program is delivered as text, film, and audio recordings. Feedback is provided using tables and charts of how stress levels and stress-related problems and symptoms are changed during the course of the program. The theoretical framework for the program includes SCT [26], Theory of Reasoned Action, Theory of Planned Behavior [27], Transactional Theory of Stress and Coping [28], and the Transtheoretical Model and Stages of Change [29]. SCT is the overarching theory of MSC and links the individual, behavior, and environment in a reciprocal manner. Furthermore, it is the basis for the psychoeducational module and the functional behavioral analysis where the user is educated about how the individual’s resources and environmental factors and behavior interact. MSC is also designed to support self-efficacy, a central concept in SCT, for coping with stressful situations. In Theory of Reasoned Action and Theory of Planned Behavior, identifying key behavioral beliefs and controlling these beliefs as determinants of behavioral intention is central [27]. This is integrated in MSC by components designed to increase perceived control over new behaviors. All modules, including stress management strategies, start with a film in which behavioral beliefs are addressed. Finally, the Transactional Theory of Stress and Coping includes the central concepts of primary and secondary appraisal and coping and influenced both the design of MSC as a program aiming at affecting both primary and secondary appraisal as well as coping and has influenced both the information throughout the program as well as the included stress management strategies.

Feedback in MSC is both ipsative and normative. Tailoring according to stages of change as well as recommended stress management strategies can be seen as a type of normative feedback. Normative feedback is also provided depending on the number of log-ins and also regarding examples the users receive on how to solve some of the assignments related to specific stress management strategies after completing them. The feedback the users of MSC receive after completion of each stress management strategy module is ipsative, and the users can follow their changes in stress-related symptoms in a table.

Screening is conducted when the users log in for the first time. The users are screened for stress levels using the PSS-14 [21,30] and for depression and anxiety with the HADS [22,31]. Stress scores <17 on the PSS-14 or ≥11 on one or both subscales of the HADS deny the user access to the program. To reach the intended persons, a cutoff score is used so that the users will reach a minimum stress level. The cutoff score on the PSS-14 was based on a study in which a stressed sample was divided into 2 groups of lower and higher stress levels [20]. The cutoff score of 17 in this study was based on the mean PSS-14 of the lower stress group minus one SD. This cutoff score was considered acceptable in a previous interview study [32].

The MSC consists of 12 modules. All users must go through the first 2 modules: introduction to the program (including navigation and origin of the program) and psychoeducation (with information on what stress is, symptoms of stress, and how to lower stress). In the psychoeducation module, the specific needs of users for stress management were assessed. These individual needs are the basis for tailoring. The psychoeducation module prompts the user to conduct a functional behavioral analysis using an Antecedent-Behavior-Consequence model. An ambivalence module appears for those who are not ready to start a recommended stress management module in the program. There are 7 modules for stress management strategies (assertiveness training, relaxation, pleasant activity scheduling, time management, cognitive restructuring, techniques and advice for better sleep, and support for becoming physically active) and one module for maintenance of behavior. Users are recommended one stress management strategy at a minimum or all are recommended if relevant according to the tailoring. Most assignments in the modules are designed for working within 1 week, although the users are free to choose to work faster or stay with an assignment longer. See Figure 2 for an example from the relaxation module. In the final module, techniques for supporting maintenance and planning for future stress management training are provided. Techniques to support behavior change are integrated into every module. Prompting intention to change, self-monitoring, goal setting, re-evaluation of goals, and feedback on performance are the central techniques in the program [17,18,33]. See Multimedia Appendix 3 for the screen capture of the MSC. This intervention has been described elsewhere [17]. See Figure 2 for an exemplary run-through.
Figure 2. Overview of the flow through the program, content of each step and with a more detailed example from the relaxation module. ABC-model: Antecedent-Behavior-Consequence model; HADS: Hospital Anxiety and Depression Scale; PSS-14: Perceived Stress Scale, 14-item.

Procedure

The participants received user names, passwords, and links to the questionnaires and the MSC at a preferred email address provided in the consent form. Only study participants had access to the program, and only as study participants, the program could be accessed. All questionnaires were converted to a web-based format and looked as similar as possible to the original version. The questionnaires were connected to the user names for the web application. All users had personal log-in, not connected to their name or work site, connected to the email provided. Most participants chose their work-connected email addresses. Information on security using the platform was provided, and participants were told that all communication to and from the web application was encrypted using the Secure Sockets Layer protocol. In addition, IP addresses from multiple failed log-ins were temporally banned. Backup procedures were performed regularly to avoid the loss of user data. The study participants were informed about the security of web-based applications.

Outcome Measures

Primary Measures

The primary dependent measure was the Swedish version of the PSS-14 [21,30]. The PSS-14 assesses the frequency of stress-related thoughts and feelings using 14 items. Responses are given on a 5-point scale, ranging from never to very often. In 7 of the items, the response very often indicates high stress, whereas in the other half, the responses are reversed. Responses are summed to a total score ranging from 0 to 56, with high scores indicating high stress. PSS-14 was used both at baseline and postintervention assessments. The Swedish version [34] and the original English version [21] of the PSS-14 have shown good psychometric attributes. The Cronbach $\alpha$ was .75 at baseline assessment in this study.

Secondary Measures

The 26-item Coping Self-Efficacy Scale measures one’s perceived self-efficacy with coping behaviors when faced with challenges in life [35]. This scale has demonstrated good validity and reliability [35]. The items concern beliefs in performing
behaviors important to adaptive coping scored on an 11-point scale, where 0 means cannot do at all and 10 means being certain that one can do. Items are summed to obtain a total score between 0 and 260. High scores indicate high self-efficacy in coping with stress. The Coping Self-Efficacy Scale was used both at baseline and postintervention assessments.

The General Nordic Questionnaire for Psychological and Social Factors at Work (QPS) measures psychological and social factors at work [36] and has shown good validity and reliability [37]. In this study, the short form, QPS Nordic 34+, was used [36]. It contains 37 items divided into 23 subscales and single items. All items are scored on a 5-point Likert scale. The mean of each subscale is calculated. The QPS Nordic 34+ questionnaire was used for both the baseline and postintervention assessments.

The shortened version of the Utrecht Work Engagement Scale [38] is a 9-item scale with 3 subscales measuring a person’s engagement in his or her work. All items are scored on a seven-point Likert scale (0-6). The Utrecht Work Engagement Scale yields 3 subscales (vigor, dedication, and absorption) and a total score. The mean for each subscale and the mean of the total score are calculated. Each subscale consists of 3 items. High scores indicate high work engagement, which is negatively related to burnout. This questionnaire was used at both baseline and postintervention assessments. The scale has shown acceptable psychometric properties [38], and the Swedish version has shown good reliability [39].

The situational version of the Brief Coping Orientation to Problems Experienced Inventory (COPE) [40] is a 28-item scale with a four-point response scale that measures coping strategies in stressful situations. It has shown good reliability [41] and validity [42,43]. Each item ranges from never to very often and measures 14 different coping strategies. A confirmatory factor analysis [44] led to the conversion of the original 14 subscales into 6 subscales (used in this study): self-distraction (scoring 2-8), problem-focused coping (scoring 4-16), avoidant coping (scoring 6-24), social support coping (scoring 6-24), emotion-focused coping (scoring 8-32), and self-blame (scoring 2-8) [44]. In addition, two 4-item emotional approach coping scales were embedded in the Brief COPE [45]. The items for each subscale are summed, except for the 2 last subscales about coping through emotional processing and emotional expression, where the means of the items are calculated. The range of scores on the last 2 subscales ranged from 1 to 4. This questionnaire was used at both baseline and postintervention assessments.

The Motivation for Change Questionnaire (MCQ) [46-48] measures motivation for change in life and work situations. The MCQ showed good reliability [46] and validity [47] in the development samples. The MCQ contains 48 items forming 7 subscales related to life situations and 6 subscales related to work situations. The subscales related to life situations are social support in life, control in life, mastery in life, challenges in life, values, self-efficacy, and self-confidence. The subscales related to work situations are coworker support, supervisory support, challenges in work, job control, interactions, and goals. Owing to technical errors, the subscale interaction was omitted in this study. Responses are given on a 4-point scale, ranging from never to very often. The scoring is reversed for 5 items. The median of each subscale is calculated. High scores indicate high motivation [48]. The MCQ was used to study whether motivation to change could predict adherence to MSC and was used at baseline assessment.

Internal consistency was calculated for the measures at the preassessment, both for total scales and subscales for the secondary outcomes, with the Cronbach $\alpha$ or Spearman-Brown coefficient as applicable. The reliability was 0.7 or higher for all total scales and subscales save for 3 subscales of the Brief COPE (self-distraction: 0.4; avoidant coping: 0.5; and emotion-focused coping: 0.6). 7 of the subscales of the MCQ (control in life: 0.3; mastery in life: 0.6; challenges in life: 0.4; values: 0.4; self-efficacy: 0.6; job control: 0.3; and goals: 0.5), and 5 of the subscales of the QPS (positive challenges at work: 0.6; control over decisions: 0.2; innovative climate: 0.6; inequality: 0.4; and work satisfaction: 0.6).

**Procedure for Data Collection**

The exclusion and inclusion criteria were measured using the PSS-14 and HADS after randomization. Demographic data were collected together with baseline assessments after randomization. This procedure was chosen because the PSS-14 and HADS were built into the screening section after opening the program for the first time. The postintervention assessment was sent out 4 months after the initial log-in. Reminders were sent out 2 and 4 weeks after each time point, including the baseline. The wait-list group received the assessments at the corresponding time points as the intervention group from the same work site. All data were collected in a web-based format.

**Wait List**

The persons in the wait-list group received questionnaires on 2 occasions. The first occasion coincided with the preintervention assessment for the intervention group, and the second occasion was 2 months after the first assessment. The 2-month follow-up was decided, as this time point was estimated to be the shortest time frame for completing the intervention in the intervention group. After the second assessment, the wait-list group received access to MSC.

**Statistical Analysis**

Analyses were performed using SPSS 24 [49]. The significance level was set at $P<.05$. Student $t$ tests (2-tailed) were used for differences between and within intervention and wait-list groups on the PSS-14 and demographic data. Chi-square and Fisher exact tests were used to detect differences between the 2 groups on categorical demographic data. Demographic data were presented using descriptive statistics. Comparisons of demographic data and outcome measures were conducted between dropouts and completers of the 2 assessments in the intervention and wait-list groups using the Student $t$ test, chi-square test, or Fisher exact test. Effect sizes were calculated by adjusting the calculation using the pooled SD (Cohen $d$) [50].

For secondary outcome measures, Wilcoxon signed rank tests were used to calculate within-group changes, and Mann-Whitney U tests were used for between-group differences at baseline and for between-group changes at the postintervention assessment.
Mann-Whitney *U* tests were also used for dropout analysis for secondary outcomes for differences between completers and dropouts. The primary and secondary outcome analyses were conducted according to the intention-to-treat. The data for the primary outcome, PSS-14, were normally distributed without any outliers. Participants who completed 2 rounds of assessment were defined as completers. Dropouts were defined as participants who completed the first assessment only.

**Compliance With Ethical Standards**

All procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all participants included in the study. The ethical application of Dnr 2015/555 was approved on January 20, 2016, by the Regional Ethical Review Board in Uppsala County, Sweden. An amendment application was approved for this study on December 16, 2016.

**Results**

**Effects of MSC**

For the primary outcome, the PSS-14, there were no significant differences between the intervention (mean 3.1, SD 7.66) and the wait-list group (mean 1.42, SD 6.16) in mean change from baseline to postintervention assessment. A small effect size was detected for the between-group mean change (Cohen *d*=0.25). There were no significant within-group differences in either the intervention group from preassessment (mean 24.25, SD 4.67) to postassessment (mean 21.17, SD 10.54) or in the wait-list group from preassessment (mean 24.26, SD 6.26) to postassessment (mean 22.84, SD 5.24) on PSS-14. Small within-group effect sizes were observed (Cohen *d*=0.38) in the intervention group and the wait-list group (Cohen *d*=0.25).

There were differences between the intervention and wait-list groups in two secondary outcomes: the subscale of coping through emotional processing (*Z*=−2.3; *P*=.02) from the Brief COPE and predictability (*U*=46.5; *P*=.03) from the QPS.

There were significant within-group changes for the completers in the intervention group on 2 secondary outcome measures. The subscale of self-blame from the Brief COPE was significantly lower in the intervention group at the postintervention assessment (*Z*=2.06; *P*=.04). In addition, in the intervention group, there were significant within-group differences in the 2 subscales from the QPS, showing higher role conflicts (*Z*=2.06; *P*=.04) and lower stress (*Z*=2.43; *P*=.02) at the postintervention assessment. Role conflict was reported to be significantly higher in the wait-list group from pre- to postintervention assessment (*Z*=2.39; *P*=.02), and there were more problematic situations with social interaction (*Z*=−2.12; *P*=.03). Multimedia Appendix 4 shows the medians and ranges of the pre- and postintervention scores for completers in the intervention and wait-list groups.

**Discussion**

**Principal Findings**

In this study, a web-based self-management program for stress management named MSC was evaluated for its effect on users’ perceived stress, coping self-efficacy, work engagement, coping strategies, and psychosocial factors at work compared with a wait-list group. The main results showed that there were no significant differences in the outcome measures between the wait-list group and the intervention group in the primary outcome (perceived stress). However, a small effect size was found for perceived stress both between the intervention and wait-list groups and within the intervention group as well as within the wait-list group.

**Comparison With Prior Work**

A meta-analysis of stress management interventions in occupational settings showed that the interventions, on average, had a medium to large effect on stress [51]. However, most of the interventions in the meta-analysis were face-to-face or relaxation interventions using audio tapes. For web-based stress management, one study showed a large effect size [16], but that

**Dropout Analysis**

There were no differences in demographic data between the completers and dropouts in the intervention group. See Multimedia Appendix 5 for medians and ranges of the preintervention assessment for dropouts in the intervention group and dropouts in the wait-list group. In the wait-list group, there was a significant difference between completers and dropouts regarding the sector in which the participants were employed. Persons in the private sector had the highest dropout rate (100%).

There was a significant difference in perceived stress, the PSS-14, between the completers (mean 24.25, SD 4.67) and dropouts (mean 27.69, SD 5.25) in the intervention group (*t*=−2.0; *P*=.049). Self-efficacy, measured with a subscale of the MCQ, was significantly higher in the intervention group than the dropouts in the intervention group (*U*=110.5; *P*=.02). For the QPS, support from colleagues was significantly higher in the intervention group than for dropouts in the intervention group (*U*=97.5; *P*=.02), and the completers had a better perceived social climate (*U*=108.5; *P*=.049) and teamwork (*U*=68.5; *P*=.002). On the Brief COPE, the intervention group reported significantly higher use of coping through emotional processing (*U*=77.5; *P*=.01) compared with the dropouts.

In the wait-list group, the subscales of vigor (*U*=65; *P*<.001), dedication (*U*=95; *P*=.01), and absorption (*U*=74.5; *P*<.001) and the total score on the Utrecht Work Engagement Scale (*U*=67; *P*<.001) were all significantly higher in completers than the dropouts in the wait-list group. On the QPS, role clarity was significantly higher in completers than the dropouts in the wait-list group (*U*=98; *P*<.03), as was predictability (*U*=87; *P*=.01), experience of mastery (*U*=99.5; *P*=.02), social climate (*U*=100; *P*<.03), innovative climate (*U*=98; *P*=.02), teamwork (*U*=78; *P*<.004), and work satisfaction (*U*=85.5; *P*=.01). There was also significantly lower role conflict in completers than the dropouts in the wait-list group (*U*=31; *P*<.001).
intervention included feedback from an e-coach, a person giving written feedback and sending reminders, thereby placing a greater demand on resources than MSC. Few resources are necessary to administer and deliver MSC because it is a fully automated program. A program demanding few resources with a small effect size could be considered important and could still be worth investigating with MSC in a larger study. A stress management program that demands fewer resources focused on stress-preventive actions in persons not on sick leave is valuable for preventing stress-related ill health. A score of 25 or higher on the PSS-14 has been used as a cutoff for high stress levels [20]. In this study, the median for perceived stress in the intervention group was 24 at preassessment and 19.5 at postassessment. In a previous population study, the average stress level was 17 in the PSS-14 [30]. Thus, our participants decreased their stress level to near the population level of 17, as seen in an earlier study [30], and our study participants may have reached their potential for change. This factor may have contributed to the nonsignificant differences between groups. Thus, difficulties in finding significant changes were expected because this application was developed for health promotion, and the study participants were not expected to have very high levels of stress at baseline.

The wait-list group reported higher role conflict postintervention assessments. To have yet another task to complete, such as an extensive battery of questionnaires, additional persons to satisfy (the researchers) could lead to feelings of conflicting roles. Nevertheless, there was a small effect size on perceived stress in the wait-list group over time. Effects in the wait-list group have also been reported in other studies [16]. This effect could depend on how a person in an ongoing study becomes aware of, in this case, his or her stress-related problems and automatically starts to handle them and changes their behavior. Filling in the questionnaires could be considered self-monitoring, which is known as a strong technique for creating behavior change [33]. However, the effect in the wait-list group could also depend on contamination between the intervention group and the wait-list group because the participants from the same workplace were included in both groups.

It could be considered controversial to launch a program for individual stress management because work-related stress is often described as deriving from organizational features [1,52] and demands [4] at work. Putting a lot of focus on individual responsibility to, on his or her own, handle stress that might have been caused by work conditions could make the individuals feel that the stress is their responsibility. Nevertheless, the fact that self-blame was significantly lower at postintervention assessment in the intervention group indicates that the goal of educating the participants on stress, the causes of stress, and the role that both environmental and individual factors have in stress management was successful and even contributed to lower self-blame.

Only 25% (12/48) of the intervention group completed the postintervention assessment. Adherence in this study was thus low compared with that in earlier studies [14]. The low adherence could be associated with the technical issues a handful of early participants encountered, the high number of questionnaires used, and the program was perceived as extensive. The technical issues, which led to irritation among the early participants, may also have contributed to the higher dropout rate in the intervention group compared with the wait-list group. Although the feasibility of MSC was evaluated in our previous studies [18,32], and the MSC was further developed to be less extensive, it may still have been too extensive and perceived as too complicated for the participants to feel motivated to use it. The results from previous studies on MSC also influenced how the program was presented to potential study participants so the study participants would have realistic expectations about the program in terms of the time required to use it. As mentioned previously, access to a coach or therapist has been shown to support adherence [14,16], but it can also hinder the distribution of a web application because real-life support requires more resources than a fully automated program such as MSC. Providing an e-coach is resource demanding, and one study reported that the e-coach spent approximately 30 minutes for each person and module completion [16]. The fully automated nature of MSC may have contributed to the low study adherence, even if tailored but automated feedback was provided. Adherence to MSC may benefit from having some kind of e-coach giving individualized feedback and prompting the participants to adhere to the program and assignments. In MSC, a problem-solving model for identifying social support to identify persons who could, for example, be involved as a coach, was integrated into one of the final modules of the MSC to support better adherence to the recommended assignments. The problem-solving module may work earlier in the program. A weakness of this study was that use and adherence to assignments were not monitored and the dose the study participants received was not known. The choice not to monitor was due to the tailoring, that the study participants were free to choose parts other than the recommended and work at their own pace.

In future trials of MSC, the number of log-ins and use of the different functions in MSC should be more carefully monitored to understand how the users use MSC. In the administrations tool of MSC, the users were followed regarding how many times they logged in but not for how long they used the app, which means that they could have been logged in for several days without logging out. In future studies of MSC, the administration tool needs to have more detailed information and tracking possibilities regarding traffic and use (eg, time spent on each assignment) and the functions that were used the most. The dropout analysis revealed some significant differences between completers and dropouts in both the intervention and wait-list groups. In the intervention group, completers had higher self-efficacy, higher support from colleagues, better social climate, and scored higher on teamwork, whereas dropouts had significantly higher stress at baseline. These differences may indicate that the completers perceived having resources, both external and internal, to work with their own stress management using MSC. Exposure to psychosocial risk factors at work, such as low coworker support, has been associated with stress-related health problems [53]. The findings in this study imply that those with the most to gain in preventing stress-related ill health dropped out to a greater extent. Thus, a stress management
program such as MSC can never be seen as an absolute solution to work-related stress, and psychosocial risk factors for stress must also be handled at an organizational level [54]. A focus on heightening self-efficacy [55] has been associated with reduced absences from illness in coping-related interventions in an occupational setting [56,57]. Thus, self-efficacy could be considered an important resource for maintaining health when exposed to stress. MSC is developed based on evidence to strengthen self-efficacy [58], but it seems important to find ways for those with low self-efficacy to engage in the intervention. Completers also reported higher use of coping through emotional processing, indicating that they may have been more prone to take time to reflect on their own situation. Coping through emotional processing has been identified as an adaptive coping strategy [59]. Indications that MSC evokes self-reflective processes were also found in our previous study evaluating the feasibility of an earlier version of MSC [32].

The dropouts from the wait-list group could be considered similar to the dropouts from the intervention group in that they reported more exposure to psychosocial situations at work. They reported a lower innovative and social climate at work, scored lower on teamwork, reported lower work satisfaction, role clarity, predictability, and lower experience of mastery. This similarity could guide researchers in environmental circumstances at work that hinder participation when perceiving oneself as stressed but might also depend on how people with fewer internal and external resources do not prioritize completing the multiple questionnaires, which was an issue identified in an earlier study [32].

The amount of time required to complete the study questionnaires negatively affected adherence to the program. In this study, several closely related domains of stress and factors at work were studied, and data were collected with a relatively high number of items. However, work-related stress is complex; the causes of developing stress-related ill health are multifactorial, and the experience of the consequences of stress is varied. The rationale for using multiple questionnaires was to capture the multifactorial aspects of stress in a work-related context. This choice was also a relevant choice in light of the difficulties in operationalizing work-related stress. The second round of measurements may have been a barrier for adherence, and more persons might have used the program than those who answered the second round of measures. In future trials, the possibility of asking for reasons for dropouts should be investigated. Nevertheless, this is an ethical dilemma that needs to be further investigated because the study participants were informed that they could drop out from the study at any point without giving reasons.

The behavior change model for internet interventions describes the factors affecting behavior change in web-based interventions. According to the model, adherence is affected by the characteristics of the user and the program, degree of support, and environmental factors [60]. All possible characteristics and needs of the users intended for MSC may not have been considered when developing the MSC. For example, the program needs to support users in prioritizing self-management. To handle difficulties in prioritizing self-management, there is a time management module in MSC [17]. This module could have been integrated partly in the psychoeducation module to help study participants prioritize their own stress-related problems at an early stage. It is also possible that MSC needs to be simpler in both content and technology. Furthermore, reminders have been shown to be an important characteristic of a program that facilitates adherence [61], but few web-based interventions use them [14], which could depend on the related costs for an SMS or technical difficulties such as deciding the best time to send reminders. A function for sending out reminders should be further developed to facilitate adherence to MSC.

One of the strengths of this study was the RCT design, even if a weakness was the lack of blinding in this study. In an RCT with a proper randomization procedure, it is possible to control for factors that might influence the results, in addition to the intervention. In addition, earlier research has shown that it is a strength [62] to build programs such as MSC on theory. The content of the program and causalities between its concepts can be motivated, validated, and understood by theories. In addition, integrating several scientific fields in program development could contribute to a more holistic program in terms of content and presentation.

The randomization procedure in blocks of 6 persons was chosen to increase the chance for persons from the same work sites to be randomized to both groups. This randomization was desired to minimize the risk of other work-site–related incidents to bias the results. This procedure can be considered a risk factor for contamination [63]. Having persons from the same work site in both groups could have contributed to the small positive effect size in the wait-list group because of contamination. However, baseline data showed that randomization was successful. The randomization was conducted before screening for depression and anxiety as well as before they completed the baseline. This might have had a negative effect on study attrition and could be a limitation of this study. This strategy was chosen because the application (MSC) was developed to screen for depression and anxiety, as well as for perceived stress levels, and was designed to be as close as possible to how MSC is planned to be distributed in the future, except for the integrated measurements for primary and secondary outcomes for the study purpose.

At baseline, no significant difference between the intervention group and wait-list groups was detected regarding the work sector (private, municipality, and county council; Multimedia Appendix 2).

In addition, the small sample size is a limitation that could have caused the nonsignificant effects, thus increasing the risk of type II error. The sample size was insufficient to provide power for this study. Although one additional work site was included after the start of the study, the included work sites were depleted. Although ad hoc, the expected dropout rate has been estimated to be 50% instead of 20%, which is in line with the average dropout from web-based applications for behavior change and self-management of different health-related conditions [14]. Nevertheless, a focus on features that facilitate adherence was hypothesized to increase adherence to MSC compared with earlier web-based stress management programs, which was not
enough to facilitate adherence to MSC. Nonetheless, nonsignificant results in a small sample can still produce a relevant effect size. Thus, MSC should be further studied for its effect on perceived stress, but with a focus on support adherence in the intended group.

Gamification has been used in several studies to improve mental health and well-being [64]. In a systematic review, the argument for gamification in the included papers was to promote engagement and enhance an intervention’s intended effect [64]. The authors of the systematic review also identified common gamification elements such as levels or progress feedback, points or scoring, rewards or prizes, narrative or theme, personalization, customization, artificial assistance, unlockable content, social cooperation, exploratory or open-world approach, artificial challenge, and randomness [64]. Even if MSC have some of these functions, for example, levels or progress feedback, personalization, and unlockable content, it may be useful in subsequent iterations of the intervention to have more engaging mechanisms built in the application. Gamification may have a positive effect on how participants experience the intervention by increasing cognitive engagement and the combination of cognitive and affective engagement [65].

There was a significant difference in dropouts between the different sectors. This difference could be associated with the postintervention assessment and reminders that were sent out during a summer vacation period to the persons employed in the private sector. The timing of starting an intervention and planning the postintervention assessment must be considered in future studies.

Approximately 30% (244/720) of the eligible participants provided informed consent. This percentage includes both included and excluded persons. On the basis of this percentage, issues with selection bias must be considered. Consequently, the external validity of the results is limited to persons with perceived stress who are willing to find solutions on an individual level. Participants in the intervention group who reported higher general self-efficacy at baseline were more likely to complete the 2 rounds of assessments. This finding could indicate that the program suits persons who believe they have resources to handle stress at an individual level. In addition, the participants in this study were mostly women, which must be considered when generalizing the results.

When analyzing with intention-to-treat, there is a risk of type II errors [66], but intention-to-treat was chosen instead of per protocol because we did not study the extent to which participants took part in and adhered to the assignments.

The procedure for introducing and using MSC in this study was designed to, as far as possible, resemble how it would be done if MSC was a commercial product except the baseline and postassessment.

**Conclusions**

It is still uncertain what effect MSC may have on perceived stress, but the effect size regarding the primary outcome indicates that it could be worthwhile to develop and evaluate MSC further. The result must be interpreted with caution because of the high dropout rate, which may have biased the results. As the focus of this study was to prevent stress levels that could lead to sick leave, the participants were not expected to have very high initial stress levels. Consequently, the participants’ potential to decrease their stress scores might have been rather limited, which probably contributed to the small effect size and nonsignificant results. Moreover, the power in this study was too low to ensure significant differences. MSC could, after further development and evaluation, be an alternative or complement to face-to-face interventions, as stress management could be valuable for decreasing stress on a large scale in the workforce, but further studies that focus on facilitating adherence are required. In addition, further studies should focus on determining the effective elements of the program to condense the program. Condensing the program may, in turn, contribute to higher adherence rates. Furthermore, the length of the test battery in the study may have been a heavy burden to the participants, and the study may have reduced the length of the tests and thus might have contributed to the low adherence. Finally, the technical issues encountered may have been prevented by more extensive beta testing with the target group.

**Acknowledgments**

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**Conflicts of Interest**

The authors are the developers of the web-based program My Stress Control (MSC) together with a programmer. The authors declare that they have no conflicts of interest.
Demographic data, descriptive statistics for primary outcome measures, and secondary outcomes at baseline for all participants completing the first assessment.

[PDF File (Adobe PDF File), 139 KB - mental_v8i12e17314_app2.pdf ]

Multimedia Appendix 3
Screen capture video of My Stress Control (MSC) showing log-in, screening for depression, anxiety and stress levels, film regarding navigation of MSC, introduction to MSC, Antecedent-Behavior-Consequence model, and time management module.
[ZIP File (Zip Archive), 209415 KB - mental_v8i12e17314_app3.zip ]

Multimedia Appendix 4
Pre- and postintervention assessment for completers in the intervention group and completers in the wait-list group.
[PDF File (Adobe PDF File), 110 KB - mental_v8i12e17314_app4.pdf ]

Multimedia Appendix 5
Medians and ranges in the pre- and postintervention assessments for dropouts in the intervention group and dropouts in the wait-list group.
[PDF File (Adobe PDF File), 64 KB - mental_v8i12e17314_app5.pdf ]

References


Abbreviations

CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
COPE: Coping Orientation to Problems Experienced Inventory
HADS: Hospital Anxiety and Depression Scale
MCQ: Motivation for Change Questionnaire
MSC: My Stress Control
PSS-14: Perceived Stress Scale, 14-item
QPS: General Nordic Questionnaire for Psychological and Social Factors at Work
RCT: randomized controlled trial
SCT: Social Cognitive Theory

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Evaluation of Repeated Web-Based Screening for Predicting Postpartum Depression: Prospective Cohort Study

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Abstract

Background: Postpartum depression (PPD) is a severe mental disorder that often results in poor maternal-infant attachment and negatively impacts infant development. Universal screening has recently been recommended to identify women at risk, but the optimal screening time during pregnancy has not been defined so far. Thus, web-based technologies with widespread use among women of childbearing age create new opportunities to detect pregnancies with a high risk for adverse mental health outcomes at an early stage.

Objective: The aim of this study was to stratify the risk for PPD and to determine the optimal screening time during pregnancy by using a web-based screening tool collecting electronic patient-reported outcomes (ePROs) as the basis for a screening algorithm.

Methods: In total, 214 women were repeatedly tested for depressive symptoms 5 times during and 3 times after pregnancy by using the Edinburgh Postnatal Depression Scale (EPDS), accessible on a web-based pregnancy platform, developed by the authors of this study. For each prenatal assessment, the area under the curve (AUC), sensitivity, specificity, and predictive values for PPD were calculated. Multivariate logistic regression analyses were applied to identify further potential predictors, such as age, education, parity, relationship quality, and anxiety, to increase predictive accuracy.

Results: Digitally collected data from 214 pregnant women were analyzed. The predictive accuracy of depressive symptoms 3 and 6 months postpartum was reasonable to good regarding the screening in the second (AUC=0.85) and third (AUC=0.75) trimester. The multivariate logistic regression analyses resulted in an excellent AUC of 0.93 at 3 months and a good AUC of 0.87 at 6 months postpartum.

Conclusions: The best predictive accuracy for PPD has been shown for screening between the 24th and the 28th gestational week (GW) and seems to be beneficial for identifying women at risk. In combination with the aforementioned predictive factors, the discriminatory power improved, particularly at 3 months postpartum. Screening for depression during pregnancy, combined with the women’s personal risk profile, can be used as a starting point for developing a digital screening algorithm. Thereby, web-based assessment tools constitute feasible, efficient, and cost-effective approaches. Thus, they seem to be beneficial in detecting high-risk pregnancies in order to improve maternal and infant birth outcomes in the long term.

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KEYWORDS

postpartum depression; Edinburgh Postnatal Depression Scale; screening; pregnancy; algorithm
Introduction

The perinatal period represents a period in life where women turn to digital resources, particularly in the field of medical health care [1]. The growing supply of e- and mHealth technologies and the increasing desire to access and monitor health data generate the need for an empirical proof as intervention and information tools [2-4].

Vice versa, the assessment of patient-reported outcomes (PROs) in pregnancy has been shown to be a highly valid method for data acquisition [5]. Characteristics of female m- and eHealth seekers during pregnancy encompass a younger age, a lower self-rated health status, being pregnant for the first time, and being easily influenced by online sources in terms of pregnancy [6]. Furthermore, current research has shown that especially women with a higher risk of depression and anxiety disorders use pregnancy apps more extensively [7].

According to the literature, especially pregnant women show increased vulnerability for the onset or relapse of a manifest depressive disorder during the perinatal period, as pregnancy and childbirth represent 2 major events in a woman’s life, along with substantial changes in their responsibilities [8-10]. The prevalence of postpartum depression (PPD) varies depending on study type, measurement, time of assessment, and nationality from 10% to 15% during the first year after childbirth [11-15]. According to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10), and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), diagnostic criteria, PPD is diagnosed if symptoms such as sadness, anhedonia, disturbance in appetite or sleep, fatigue, psychomotor symptoms, worthlessness/guilt, attention deficits, and suicidality persist for at least 2 weeks with a peripartum onset [16,17].

Regarding the first days postpartum, PPD must be distinguished from baby blues. While PPD occurs within the first year postpartum, baby blues affects 50%-85% of mothers during the first 10 days postpartum but usually ameliorates within 2 weeks [18]. Baby blues is characterized by transient mood swings, tearfulness, and mild depressive symptoms [19,20].

Prior research identified risk factors for PPD, such as a history of mental disorders, stressful life events, limited social support, low socioeconomic background, and especially depression and anxiety, that have been reported to be the strongest predictors for adverse mental health outcomes in the postpartum period [21-25].

Suffering from PPD not only constitutes a burden for the mothers and families but also has a high impact on early mother-child interaction and parenting [26,27]. The long-term effects for the child include impaired mother-child bonding [28] and cognitive, emotional, and behavioral problems [29,30].

However, PPD often remains undetected and thus untreated as women who suffer from depressive disorders are sometimes unable to evaluate their emotions and reluctant to seek support and help on their own [31,32]. Even though early identification and support for mothers at risk are crucial to prevent PPD, only 20% of affected women are detected in the perinatal period and around 10% of those women receive adequate treatment and support [10,33].

According to the current literature, the most commonly used screening tool for perinatal depression is the Edinburgh Postnatal Depression Scale (EPDS) [34]. This self-report questionnaire contains 10 items measuring depressive symptom severity during the past week and has been validated for antenatal and postnatal application [35]. In fast-paced clinical settings, it has been shown to be practicable, takes less than 5 minutes to complete, and is highly accepted by women with and without depression alike [36,37].

Current evidence suggests that there is an overall benefit of perinatal depression screening [38]. The American College of Obstetricians and Gynecologists (ACOG) recommends perinatal screening for depressive symptoms at least once during pregnancy and after childbirth [39]. However, no optimal screening time and routine have been established in obstetrical care so far. There is still uncertainty about which screening tool provides the best predictive accuracy and how often and at what time point it should be applied [40,41].

Thus, web-based pregnancy tools provide new opportunities for real-time data acquisition, including the feasibility to capture symptom deterioration and upcoming adverse events [6,42,43]. Growing mHealth technologies can be used for prevention and intervention of depressive disorders at an early stage and may even reduce barriers to seeking psychotherapeutic support [44-51]. The feasibility and acceptability of web-based depression screening by means of the EPDS have been shown in the previous literature. In comparison to conventional paper-based methods, patients perceived web-based technologies as more convenient, discrete, and favorable [52].

Only few studies have assessed whether PPD can be reliably predicted during pregnancy by using the EPDS. The overall results show high negative predictive values and specificity but low positive predictive values and sensitivity with a reasonable discriminatory power [53]. Although Lau et al [54] first described a strong correlation among depressive symptoms in the second trimester and up to 6 weeks postpartum, Meijer et al [53] and Venkatesh et al [55] assumed that predictive accuracy is limited but that it can be improved by adding the history of depression. Both recommend a cut-off threshold of >5 for initial screening, followed by clinical diagnostics if positive.

The aim of this study was to longitudinally monitor EPDS scores by monthly assessments during the second and third trimester of pregnancy as well as 1 week, 3 months, and 6 months postnatally. By using this longitudinal approach, this work aimed to find the best screening time during pregnancy, with the highest predictive accuracy for PPD, based on the use of a web-based pregnancy tracking tool. In the next step, we aimed to refine the discriminatory power by including the women’s personal risk profiles, such as prenatal maternal anxiety or depressive symptoms, age, education, parity, or relationship quality. The absence of a standardized, widely accepted screening program in routine prenatal care underlines the need for testing the feasibility and validity of web-based data acquisition methods.
Methods

Participants and Study Design
This prospective bicentric study based on electronic patient-reported outcome (ePRO) questionnaires was conducted between October 2016 and September 2018 in the maternity departments of the University Hospitals Heidelberg and Tuebingen, Germany. In total, 214 pregnant women participated in the study. Inclusion criteria for recruitment were maternal age >18 years, sufficient knowledge of the German language, adequate internet access, and a singleton pregnancy between the 20th and the 27th gestational week (GW). Exclusion criteria encompassed a multiple pregnancy and known fetal anomalies and malformations. After participants provided their written consent to participate in the study, they completed the first set of web-based questionnaires on a tablet device on-site after registration with pseudo-anonymous user credentials on a self-developed platform called Patient-informiert-interaktiv-Arzt (patient-informs-interactively-physician [PiiA]; see Figure 1).

At the time of enrollment, trained clinical staff provided participants assistance. Furthermore, an online tutorial was provided on the platform explaining the technical use. Further data acquisition was supposed to take place in the participants’ domestic environment on their preferred device. The participants received web-based assessments at 8 time points: every 4 weeks during pregnancy (Prae1=20th, Prae2=24th, Prae3=28th, Prae4=32nd, and Prae5=36th GW) up to 6 months postpartum (Post1=7 days, Post2=3 months, and Post3=6 months postpartum). In addition, 2 days prior to the scheduled assessment as well as 3 and 5 days afterward, the participants received an email reminder from the study team to complete the web-based questionnaires. Furthermore, sociodemographic and health-related data were obtained by means of ePROs.

To monitor maternal symptoms of depression and anxiety during the entire antenatal and postnatal period, the EPDS was applied at every time point, whereas the State-Trait Anxiety Inventory (STAI) was applied twice, at the 24th and the 32nd GW. The participants’ data were stored pseudo-anonymized and securely on a local storage device.

Ethics
Ethics approval was obtained from the ethics committee at Heidelberg University (project no. S158/2016).

Instruments
Edinburgh Postnatal Depression Scale
The EPDS [34] is a widely used screening tool validated for assessing pre- and postpartum symptoms of depression [35,56]. The 10-item self-report questionnaire measures depressive symptoms during the past 7 days. Every question is scored from 0 (no depressive symptoms) to 3 (severe depressive symptoms); thus, the total score varies between 0 and 30. Higher scores indicate a higher risk of minor or major depression. The recommended cut-off score is ≥10 points, which predicts minor depression and has shown good sensitivity and specificity of 0.96 and 1, respectively [57].

State-Trait Anxiety Inventory
The STAI [58] is used to assess anxiety as a temporary condition (State-Trait Anxiety Inventory, state scale [STAI-S]) as well as general anxiety as a personal trait (State-Trait Anxiety Inventory, trait scale [STAI-T]). In this study, the German versions of the STAI-T as well as the STAI-S were administered [59]. The questionnaire contains 20 items measured on a 4-point Likert scale from 1 (low) to 4 (high). Total scores vary from 20 to 80. In previous studies, the STAI has shown good discriminatory and predictive validity in perinatal populations [60]. The recommended cut-off score of >40 reached a sensitivity of 80.95%, a specificity of 79.75%, and a positive predictive value of 51.5% [61].

Questionnaire on Relationship Quality
The questionnaire on relationship quality (Partnerschaftsfragebogen [PFB]) [62,63] was applied to assess the participants’ self-rated relationship quality and satisfaction with their partners. The questionnaire encompasses 3 scales:

Figure 1. Screenshot of the PiiA platform. PiiA: Patient-informs-interactively-physician.
(1) tenderness, (2) communication, and (3) conflict behavior. Each subscale contains 10 items measured on a 4-point Likert scale. While higher scores on the conflict behavior scale indicate less satisfaction, higher scores on the tenderness and communication scales indicate a higher relationship quality. In a representative study conducted on a German population, good to very good reliability was achieved for all 3 subscales (conflict behavior: $\alpha=.88$; tenderness: $\alpha=.91$; communication: $\alpha=.85$; total scale: $\alpha=.93$) [64].

**Statistical Analyses**

Descriptive statistics, including mean scores, absolute and relative frequencies, and standard deviations, were used to analyze demographic variables of the entire study sample. The prevalence of antenatal and postnatal depressive symptoms (EPDS $\geq 10$) was calculated at each point of assessment. To evaluate the discriminatory power of the EPDS, we constructed receiver-operating characteristic (ROC) curves for each of the relevant assessment times (5 antenatal assessments vs 3 postnatal assessments) by plotting sensitivity against 1-specificity for all possible cut-off values. Afterward, the respective area under the curve (AUC) was calculated for each ROC curve. A high AUC indicates a good selection of women with PPD symptoms as distinguished from those without. A widely used classification of the AUC is as follows: $\leq 0.50$: useless (worse than a coin flip); 0.50-0.70: poor; 0.70-0.80: reasonable; 0.80-0.90: good; and $>0.90$: excellent [65]. Moreover, specificity, sensitivity, and positive and negative predictive values for specific cut-offs of the EPDS were calculated.

The predictive value of the EPDS was investigated by using multivariate logistic regression models. Here, the models were adjusted for the following factors [21-23]: age (in years), EPDS score at the best predictive time point of assessment during pregnancy, educational level, parity (previous births), general anxiety (STAI), and partnership quality (PFB). The models were described by odds ratios (ORs, 95% CI), $P$ values, and the AUC compared to the AUC based on the respective best EPDS score.

$P$ values were set at $<.05$. All analyses were performed using the statistics software R [66] based on the packages pROC [67] and PRROC [68].

**Results**

**Sociodemographic and Birth-Specific Characteristics**

In total, 214 women aged 22-44 years (mean age 33.5 years) completed the self-report questionnaires provided on the web-based pregnancy platform PiiA and were included in the analyses. The majority of the participants were married or in a relationship and well educated with a higher socioeconomic status. More than half of the women already had at least 1 child and were working part-time during pregnancy. About 14% of the children were born prematurely, and 48.6% were delivered vaginally without complications. Table 1 shows the sociodemographic data and further sample characteristics in detail.
Table 1. Distribution of sociodemographic and birth-specific variables (N=214).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relationship status</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>154 (72.0)</td>
</tr>
<tr>
<td>In a relationship</td>
<td>52 (24.3)</td>
</tr>
<tr>
<td>Without a partner</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (1.4)</td>
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<tr>
<td><strong>Parity</strong></td>
<td></td>
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<tr>
<td>0</td>
<td>85 (39.7)</td>
</tr>
<tr>
<td>1+</td>
<td>124 (57.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td><strong>Graduation</strong></td>
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</tr>
<tr>
<td>No degree</td>
<td>7 (3.3)</td>
</tr>
<tr>
<td>General or intermediate degree</td>
<td>74 (34.6)</td>
</tr>
<tr>
<td>Advanced technical certificate</td>
<td>25 (11.7)</td>
</tr>
<tr>
<td>A level</td>
<td>101 (47.2)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>Missing data</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td><strong>Employment of participants at time of recruitment</strong></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td>Part-time</td>
<td>171 (79.9)</td>
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<tr>
<td>Unemployed</td>
<td>29 (13.6)</td>
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<tr>
<td>Missing data</td>
<td>11 (5.1)</td>
</tr>
<tr>
<td><strong>Monthly family income</strong></td>
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<td>&lt;€1000 (&lt;US $1130.01)</td>
<td>20 (9.4)</td>
</tr>
<tr>
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<td>60 (28.0)</td>
</tr>
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<td>€2000-€3000 (US $2260.03-€3390.04)</td>
<td>41 (19.2)</td>
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<td>&gt;€3000 (&gt;US $3390.04)</td>
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<td><strong>GW\textsuperscript{a} of delivery</strong></td>
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</tr>
<tr>
<td>&lt;38th GW</td>
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</tr>
<tr>
<td>≥38th GW</td>
<td>162 (75.7)</td>
</tr>
<tr>
<td>Missing data</td>
<td>22 (10.3)</td>
</tr>
<tr>
<td><strong>Mode of delivery</strong></td>
<td></td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>104 (48.6)</td>
</tr>
<tr>
<td>Planned cesarean section</td>
<td>34 (15.9)</td>
</tr>
<tr>
<td>Unplanned cesarean section</td>
<td>47 (22.0)</td>
</tr>
<tr>
<td>Forceps delivery or vacuum extraction</td>
<td>18 (8.4)</td>
</tr>
<tr>
<td>Missing data</td>
<td>11 (5.1)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}GW: gestational week.
Prevalence of Depressive Symptoms Pre- and Postnatally

During pregnancy, a reasonable number of women in our study sample were at risk for a depressive episode (EPDS ≥ 10): 12.6% (22/175) at the 20th GW, 25% (48/192) at the 24th GW, 18.2% (36/198) at the 28th GW, 13.2% (27/205) at the 32nd GW, and 18.3% (33/180) at the 36th GW. After childbirth, 18.5% (34/184) of the women showed an increased risk for PPD 7 days postpartum, 9.6% (13/136) at 3 months postpartum, and 13.2% (18/136) at 6 months postpartum.

Predictive Value of PPD Symptoms

Table 2 presents the results of ROC analysis. The best predictive values according to the risk of PPD symptoms 7 days postpartum (Post1) are shown in the 32nd GW (Prae4). The AUC was reasonable (0.76), and the specificity and negative predictive value for a cut-off of 10 were high at 93.0% and 87.1%, respectively, while the sensitivity and positive predictive values were moderate at 60.8% and 85.1%, respectively. Regarding depressive symptoms 3 months postpartum (Post2), the AUC had good predictive accuracies in the 24th (Prae2; AUC=0.85) and 28th (Prae3; AUC=0.84) GW, showing once again high specificity (80.4% vs 84.5%) and negative predictive values (98.0% vs 96.0%) and lower sensitivity (83.3% vs 64.3%) and positive predictive values (27.0% vs 36.0%). Regarding the last measurement 6 months postpartum (Post3), the best predictive accuracy was found in the 28th GW (Prae3), with a reasonable AUC of 0.75, high specificity (84.5%), high negative predictive value (93.9%), moderate sensitivity of 60.0% and low positive predictive value of 34.0%.

The highest AUC values for the respective postnatal assessments are presented in Figure 2. The dots indicate the EPDS cut-off value of 10.

Table 2. Area under the curve for prediction of postpartum depression (EPDS≥10) by means of depressive symptoms assessed during pregnancy.

<table>
<thead>
<tr>
<th>PPDb</th>
<th>AUCc at 20th GWd</th>
<th>AUC at 24th GW</th>
<th>AUC at 28th GW</th>
<th>AUC at 32nd GW</th>
<th>AUC at 36th GW</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 days</td>
<td>0.73</td>
<td>0.69</td>
<td>0.64</td>
<td>0.76 e</td>
<td>0.76</td>
</tr>
<tr>
<td>3 months</td>
<td>0.79</td>
<td>0.85 e</td>
<td>0.84 e</td>
<td>0.74</td>
<td>0.79</td>
</tr>
<tr>
<td>6 months</td>
<td>0.70</td>
<td>0.74</td>
<td>0.75 e</td>
<td>0.72</td>
<td>0.70</td>
</tr>
</tbody>
</table>

aEPDS: Edinburgh Postnatal Depression Scale.  
bPPD: postpartum depression.  
cAUC: area under the curve.  
dGW: gestational week.  
eAll values in italics are significant.

Figure 2. Highest AUC values for each postnatal assessment and the respective prenatal assessment including sensitivity and specificity. AUC: area under the curve; circle, cross, and triangle: respective optimal cut-off points (according to the Youden index); GW: gestational week; PPD: postpartum depression (at 7 days, 3 months, and 6 months postpartum).
Detecting Predictors for Postnatal Depression

Multivariate logistic regression analyses revealed that postnatal symptoms of depression (assessed at 7 days postpartum) were significantly predicted by the depression scores during pregnancy (assessed at the 32nd GW, \( P < .001 \)). Depressive symptoms 3 months postpartum were also predicted by prenatal depressive symptoms (assessed at the 24th GW, \( P = .02 \)). Furthermore, the factor parity showed a significant influence \( (P = .049) \).

In the regression model regarding the time point at 6 months postpartum, the depression score during pregnancy at the 28th GW showed a highly significant impact \( (P = .001) \). The variable trait anxiety (STAI-T), assessed at 24 and 28 weeks prenatally, showed a tendency \( (P = .12) \) to increase but did not become statistically significant. Furthermore, in the multivariate models for PPD, the AUCs could be even improved by including the aforementioned factors compared to the univariate models. At 3 months postpartum, an excellent AUC of 0.93 in the multivariate model versus 0.85 in the univariate model was found. At 6 months postpartum, we found an AUC of 0.87 in the multivariate model versus 0.75 in the univariate model. Hence, the results of the multivariate logistic regression models show the best predictive accuracy for PPD for screening between the 24th and the 28 GW and are displayed in Table 3.

### Table 3. Uni- and multivariate logistic regression models for the potential confounders age, prenatal depression, state and trait anxiety, education, parity, and partnership quality at 1 week, 3 months, and 6 months postpartum.

<table>
<thead>
<tr>
<th>Variable</th>
<th>PPD(^a) 7 days OR(^b) (95% CI) ( P ) value</th>
<th>PPD 3 months OR (95% CI) ( P ) value</th>
<th>PPD 6 months OR (95% CI) ( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.97 (0.87-1.08) ( .62 )</td>
<td>1.16 (0.96-1.44) ( .14 )</td>
<td>1.02 (0.87-1.20) ( .80 )</td>
</tr>
<tr>
<td>EPDS(^c)</td>
<td>1.41 (1.23-1.65) ( &lt; .001 ) (^d)</td>
<td>1.38 (1.12-1.83) ( .01 )</td>
<td>1.24 (1.09-1.43) ( .001 ) (^d)</td>
</tr>
<tr>
<td>Education</td>
<td>0.69 (0.25-1.87) ( .47 )</td>
<td>1.30 (0.22-9.05) ( .77 )</td>
<td>1.179 (0.253-5.728) ( .83 )</td>
</tr>
<tr>
<td>Parity</td>
<td>1.318 (0.45-4.032) ( .62 )</td>
<td>0.118 (0.002-8.55) ( .05 )</td>
<td>1.043 (0.194-5.688) ( .96 )</td>
</tr>
<tr>
<td>STAI-S(^e)</td>
<td>1.007 (0.94-1.067) ( .82 )</td>
<td>1.064 (0.922-1.132) ( .69 )</td>
<td>0.998 (0.906-1.08) ( .96 )</td>
</tr>
<tr>
<td>STAI-T(^f)</td>
<td>0.953 (0.895-1.012) ( .12 )</td>
<td>1.064 (0.951-1.213) ( .31 )</td>
<td>1.083 (0.985-1.211) ( .12 )</td>
</tr>
<tr>
<td>PFB(^g)</td>
<td>0.500 (0.163-1.509) ( .22 )</td>
<td>1.967 (0.303-16.477) ( .5 )</td>
<td>1.348 (0.230-8.699) ( .74 )</td>
</tr>
<tr>
<td>Multivariate AU(^{ch})</td>
<td>0.82 — ( .93 ) (^d)</td>
<td>— — ( .87 ) — — ( .75 ) —</td>
<td></td>
</tr>
<tr>
<td>Univariate AU</td>
<td>0.76 — — ( .85 ) — — ( .75 ) —</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)PPD: postpartum depression.
\(^b\)OR: odds ratio.
\(^c\)EPDS: Edinburgh Postnatal Depression Scale.
\(^d\)All values in italics are significant.
\(^e\)STAI-S: State-Trait Anxiety Inventory, state scale.
\(^f\)STAI-T: State-Trait Anxiety Inventory, trait scale.
\(^g\)PFB: Partnerschaftsfragebogen.
\(^h\)AUC: area under the curve.
\(^i\)Not applicable.

### Discussion

#### Principal Findings

Due to the high prevalence of PPD and the high percentage of women who remain undiagnosed and untreated, this study aimed to define the optimal time point for web-based self-report screening for women at risk of PPD during pregnancy. We increased the impact of our results by conducting a prospective longitudinal study with a detailed assessment of maternal symptoms of depression at 8 follow-up assessments from the 20th GW onward up to 6 months postpartum, accessible on the self-developed web-based platform PiiA. We could also prove that the inclusion of further personal factors can significantly improve the accuracy of predicting PPD symptoms, which can potentially be used as a starting point for developing a screening algorithm.

Implementation of an Online-Based Pregnancy-Screening Tool Using ePROs

The antenatal period represents a window of opportunity for adapting a healthy lifestyle, on the one hand, and to successfully integrate technology in clinical care, on the other hand. Thus, the implementation of a web-based screening algorithm to detect women at risk should be a common aim for the health benefit of both expecting mothers and their offspring [38]. Previous research has already shown that electronic data acquisition represents equal validity and reliability compared to paper-based methods [69,70]. Furthermore, a personalized lifestyle intervention or psychoeducational treatment approach in order to improve health-related behavior seems to be beneficial, especially among women with mild-to-moderate symptoms of depression or anxiety [71]. Former studies have
reported higher compliance rates, optimized cost efficiency, and better overall mental health outcomes due to web-based therapeutic tools compared to traditional practices [72]. Even a short-term electronic mindfulness-based intervention program resulted in reduced anxiety levels in pregnant women after just 1 week of use [73].

However, due to the rising amount of easily accessible web-based sources, there are also existing tools without scientific evaluation and a considerable risk of misinformation [74,75]. Only an estimated marginal amount of 6% of the available health-related apps are validated in a scientific manner [76]. Thus, due to the evolving digitalization in medicine, there is an emerging need to test web-based tools for reliability and internal consistency before integrating into standard clinical practice. However, the presented results prove that web-based screening for detecting early symptoms of depression and anxiety by means of the EPDS is suitable. In a further approach, the EPDS should be implemented in web-based format at best into routine clinical obstetrical care. Hence, this could be the first step toward the establishment of a standardized screening algorithm for adverse mental health outcomes in the peripartum period.

**Prevalece of Depressive Symptoms During the Course of Pregnancy Until 6 Months Postpartum**

In this prospective cohort study, we found that a high percentage of women who developed PPD symptoms already showed significantly higher antenatal EPDS scores. These findings are in line with previous studies showing that depressive symptoms may be more common during than after pregnancy [77,78]. Regarding merely the period of pregnancy, the highest prevalence rates were found at the 24th GW, initially followed by a decrease and then an increase at the end of pregnancy. These findings are comparable to the prevalence rates reported by Bennet et al [79]. Using an exploratory approach, Lau et al [54] (2010), who observed the same phenomenon, suggested that the relatively high prevalence of depressive symptoms during the second trimester might be caused by a high percentage of affected women who are undiagnosed and untreated [80,81]. Likewise, the possible persistence of pregnancy-related physical adverse events that can negatively affect mental health and the discontinuation of antidepressant medication that may lead to recurrent depression are conceivable [81,82].

Consistent with previous studies, we found that the proportion of women with depressive symptoms in the postpartum period (34/184, 18.5%) was similar to that in the third trimester (33/180, 18.3%). The increasing number of women who show depressive symptoms in the third trimester of pregnancy might be explained by greater physical discomfort, increased anxiety about the upcoming childbirth, and transition into a new role as a mother [83]. After delivery, the high prevalence of depressive symptoms can be explained by the onset of baby blues shortly after childbirth [84]. Baby blues being a transient condition, the prevalence of depressive symptoms in our sample decreased 3 months postpartum to 9.8% and increased slightly once again 6 months postpartum to 13.2%. These findings are in line with the results of a review published in 2018, in which an increase in depressive symptoms 6 months postpartum was reported and may reflect the added stress due to caring for a newborn and the constant demands of the infant [85]. A similar prevalence of PPD measured by the EPDS (cut-off > 10) was found in another German sample: 20.4% at 2 weeks postpartum, 15.8% at 6 weeks postpartum, and 15.4% 3-5 months postpartum [13,86].

**Predictive Accuracy of PPD Symptoms**

The predictive accuracy for PPD 1 week postpartum increases with the progress of pregnancy, with the best results at the 32nd and the 36th GW. These findings imply that assessing depressive symptoms in late pregnancy gives a more precise prediction of depressive symptoms after childbirth. An explanation of that finding might be the higher level of distress and anxiety toward childbirth and parenthood, which can continue up to a few days after childbirth, representing the baby blues [84]. Although baby blues is a rather transient condition, the prediction of PPD symptoms 3 and 6 months postpartum is of higher clinical relevance.

Referring to depressive symptoms 3 months postpartum, the antenatal depressive symptoms, assessed at the 24th and the 28th GW, showed good discriminatory power. Although the positive predictive value was low, with only 27%-36% of positively screened women, indeed, presenting depressive symptoms 3 months postpartum, the negative predictive value was remarkably high, between 96% and 98%. Thus, women with a negative screening between the 24th and the 28th GW are quite unlikely to develop PPD 3 months postpartum.

The assessment of antenatal depressive symptoms at the 28th GW showed the most promising results in predicting depressive symptoms 6 months postpartum. The test criteria are similar to 3 months postnatally with high specificity (84.5%) and negative predictive value (93.9%) and lower sensitivity (60%) and positive predictive value (34%).

In conclusion, our findings show that predictive accuracy is highest in the period between the 24th and the 28th GW among all other time points of assessment during pregnancy.

According to the overall discriminatory power and predictive accuracy of the antenatal EPDS scores, previous research has shown similar AUC values ranging from 0.66 to 0.78 [53-55]. All of these studies have in common a high specificity and negative predictive values but present lower sensitivities and positive predictive values. To increase the negative predictive value and not to miss a woman at risk, Meijer et al [53] and Venkatesh et al [55] recommend a lower cut-off of 5 for the initial screening. Thus, negative results would indicate a low risk for developing PPD, while positive results would require further observation. However, this may cause a high number of false-positive cases and require increased clinical effort [15,22,53].

Our findings suggest that antenatal screening using the EPDS between the 24th and the 28th GW is the best predictor for depressive symptoms 3-6 months postpartum. This time interval also showed the highest prevalence rates of antenatal depressive symptoms among our study cohort. This is in line with the study of Lau et al [54] confirming the strong relationship between the
EPDS score in the second trimester and 6 weeks postpartum. In contrast to our findings, however, Meijer et al [53] assumed that the time point of screening, whether it is in the first, second, or third trimester, does not show any influence regarding the predictive accuracy.

**Further Potential Predictors for PPD Symptoms**

Previous studies have shown that a better predictive power for PPD can be achieved by combining antenatal EPDS scores with other potential factors, such as partner support or a prior history of depression [22,55].

Our results show that prenatal symptoms of depression, measured by the EPDS, constitute strong independent predictors of PPD at all postnatal times of assessment. This finding confirms once again the strong association between antenatal and postnatal depressive symptoms.

In addition, we detected parity as another marginally significant predictor for PPD 3 months postpartum. Regarding parity as a predictor for PPD, previous studies have reported heterogeneous findings. Giving birth for the first time is often considered a risk factor for PPD in the first postpartum month. One reason may be that women are confronted with totally changed living conditions and insecurities owing to their inexperience in parenting, while already experienced mothers are usually more familiar and have adapted to their new role [87-89]. Other studies, in contrast, have reported multiparity being a risk factor for PDD as caring for more than 1 child can lead to additional stress and may overwhelm mothers in their everyday life [78,90]. These heterogenous findings imply that the influence of parity cannot be generalized and that further research in this field is required.

Regarding the relationship between antenatal anxiety and postpartum depression, inconsistent findings have been reported in the current literature so far. Multiple studies have shown that perinatal anxiety and depression often occur simultaneously. In addition, early symptoms of depression, anxiety, and distress predict impending mental health problems during and after pregnancy [83,91]. Both trait as well as state anxiety have been shown to be significant and independent risk factors for PPD in previous research [53]. In the study of Grant et al [61], anxiety was more than sixfold increased among participants diagnosed with PPD (OR 6.12). In contrast, however, our findings presented no significant impact of anxiety on PPD and are thus in accordance with other studies. In the work of Austin et al [92], for instance, the STAI showed no significant association with PPD after controlling for antenatal depression scores on the EPDS. More recent prospective studies are in line with our results, confirming once again the heterogeneous impact of anxiety during pregnancy on postpartum mental health [93,94].

According to the previous literature, an older maternal age and a higher educational level are associated with a decreased risk of PPD [95,96]. However, we did not find any significant effects of age and education at any time of assessment. This may be due to the fact that our study group was at a marginally older age and consisted of well-educated women, predominantly. In our study group, the quality of partnership measured by the PFB did not show any significant impact as a predictor for PPD either. The majority of our participants live together with their partners and probably consider their social support as sufficient.

The discriminatory power improved significantly by including all these personal risk factors in the model, so the multivariate AUC resulted in excellent and good values for depressive symptoms 3 and 6 months postpartum.

Although the EPDS is a simple and universally applicable screening tool, every patient should be considered individually with a different and unique psychosocial risk profile. By paying attention to and screening for additional risk factors, more women at risk can be identified than by merely using the EPDS.

**Strengths and Limitations**

One strength of our study is the prospective longitudinal and innovative design, including frequent and repeated measures of depressive symptoms (8 assessments: 5 prenatally and 3 postnatally), whereas previous studies have analyzed only 1 time point in the postpartum period.

All of the applied questionnaires are internationally established and were provided as online questionnaires. The online assessments were easily accessible, universally applicable, and cost efficient. Furthermore, the participants were able to complete the questionnaires comfortably in their home environment, which may have had positive effects on their compliance and may have reduced their barriers to reporting mental health symptoms and personal information about emotions, partnership, etc., due to the greater privacy and easy access allowed by using their own personal computer or smartphone.

Another strength of our study is that we assessed not only symptoms of depression in detail but also anxiety symptoms, which is often a comorbid condition [91,97]. Thus, we were able to control for confounding effects of anxiety. Additionally, we distinguished between state, trait, and pregnancy-related anxiety to capture a large variety of mental affections. Beyond this, we assessed a broad range of further possible confounding factors that might contribute to the prediction of PPD.

A limitation of our study is the well-known fact that the EPDS is a screening tool and does not generate a valid DSM-5 diagnosis. Those women who scored ≥10 on the EPDS are only at higher risk for minor or major depression but still require established clinical diagnostic testing to confirm the presence of PDD. Furthermore, different cut-off thresholds are validated in studies and clinical screening. Regarding a cut-off of ≥10, the sensitivities range from 59% to 100% and the specificities range from 44% to 97% [98]. For antenatal use, however, lower cut-off values have to be considered [99]. Still, a universal and established cut-off point is lacking, which contributes to the difficult comparability among previous studies. However, the EPDS is capable of capturing even subclinical depressive symptoms, which also potentially impacts clinical outcomes [100].

As we could not distinguish between women who were depressive or nondepressive at baseline, there is also a risk of a self-selection bias, as mentally affected women are more likely to refuse a study participation [101]. Regarding the self-report
data acquisition used in our study, there are diverging findings in previous research concerning accuracy and validity. Former research has claimed that the use of ePRO parameters can lead to response and recall bias and thus to a loss of validity, as affective symptoms are often overestimated [102,103]. Other studies, in contrast, are providing evidence of good reliability of self-administered questionnaires in clinical practice [104,105].

Our study group consisted of mostly well-educated women with a higher socioeconomic status, and nearly all are married or in a partner relationship. Therefore, these findings can only be generalized to a limited extent. Despite these limitations, our results provide valuable information of substantial clinical importance.

This is the first essential measure before creating a digital screening algorithm and implementing real-time PRO-derived data into clinical care in order to capture adverse mental and physical health symptoms as early as possible.

Conclusion

Based on our results, we determined the best predictive accuracy of digital, self-report screening for PPD during pregnancy to be between the 24th and the 28th GW. Although the EPDS may not be sufficient for predicting PPD alone, and some new risk factors may contribute after childbirth, the predictive accuracy achieved an excellent value, especially in combination with the women’s personal factors, such as anxiety, age, education, parity, and partnership support. Systematic antenatal screening is important to identify the proportion of women at risk as early as possible and thus avoid the detrimental consequences of untreated depression for both mother and child. Therefore, increased awareness of affective disorders during and after pregnancy is needed. It is crucial to implement a valid online screening tool for symptoms of depression in clinical routine, and establishing a routine screening program between the 24th and the 28th GW might be most promising to identify both women at risk for depression during pregnancy and a high proportion of women at risk for PPD. Therefore, our results have the potential to be used as a starting point for developing a screening algorithm for perinatal depression. As the pregnancy period is an emerging target for health interventions, the clinical implementation of a tracking and screening tool regarding mental symptoms from the beginning of pregnancy seems to be applicable and beneficial. In the next stage of development, therapeutic and educational treatment modalities based on the upcoming possibilities due growing e- and mHealth technologies should be incorporated.

Acknowledgments

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Authors' Contributions

KL, KH, CES, SW, and MF wrote and edited the manuscript and interpreted the data; SW, MW, and CES developed the study concept, supervised the project, and wrote the manuscript; KH, KL, LMM, KB, MG, and CES performed data collection and project management; and MF analyzed the data and edited the manuscript.

Conflicts of Interest

None declared.

References


Abbreviations

ACOG: American College of Obstetricians and Gynecologists
AUC: area under the curve
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EPDS: Edinburgh Postnatal Depression Scale
ePRO: electronic patient-reported outcome
GW: gestational week
ICD-10: International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
OR: odds ratio
PFB: Partnerschaftsfragebogen
Piia: Patient-informiert-interaktiv-Arzt
PPD: postpartum depression
ROC: receiver operating characteristic
STAI: State-Trait Anxiety Inventory
STAI-S: State-Trait Anxiety Inventory, state scale
STAI-T: State-Trait Anxiety Inventory, trait scale

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