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Editorial

The Digital Therapeutic Alliance: Prospects and Considerations

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Abstract

The growing prevalence of digital approaches to mental health care raises a range of questions and considerations. A notion that has recently emerged is that of the digital therapeutic alliance, prompting consideration of whether and how the concept of therapeutic alliance, which has proven to be a central ingredient of successful traditional psychotherapy, could translate to mental health care via digital technologies. This special issue editorial article outlines the topic of digital therapeutic alliance and introduces the five articles that comprise the special issue.

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KEYWORDS

therapeutic alliance; digital therapeutic alliance; digital mental health; mental health apps; teletherapy; chatbots

The therapeutic alliance [1], a measure of the relationship quality between a therapist and their client or patient, is associated with the effectiveness of psychological interventions and successful therapeutic outcomes. Recently, many are turning to online and digital options as a less expensive and more accessible means of therapy than traditional face-to-face care [2]. A growing incidence of mental illness has led to the development of online services by both evidence-based providers operating within health systems and more opportunistic commercial software developers. The need to access help online brought about by COVID-19 can only increase both the demand for online interventions and the desire by developers to meet that demand, which in turn makes the need for online services to prove their efficacy more significant. The increasing prevalence of digital mental health research and interventions has given rise to the term "digital therapeutic alliance" (DTA), which aims to conceptually capture and measure the therapeutic quality of online psychological therapy or digital mental health interventions.

The term DTA is a broad one that can apply to a range of types of digital mental health care. The most straightforward of these systems where the term DTA arises is the alliance between client and therapist in the case of therapy sessions conducted via email, online chat, or videoconferencing. These systems

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require active input from the therapist despite the intermediary presence of technology to facilitate the interaction. Research suggests that the therapeutic alliance can also be achieved in online modes, such as described above, in the same way that it is in face-to-face therapy and that such digital interventions can have a similar effect as face-to-face therapy [3]. These interactions involve what is known as computer-mediated communication, which is a field of study concerning computing technology use that is relevant to online teletherapy [4].

At the other end of the spectrum of forms of digital mental health care is engagement between a human client and an artificial intelligence (AI)–driven therapy agent. This could range from an online chatbot for mental health [5,6] to robotic or virtual human therapists [7,8]. Such AI-driven therapy agents, from the relatively simple to the more complex, raise a plethora of interesting questions around the nature of the relationship between the human client and the AI therapist. In terms of input from a computing/technology field, human-robot interaction is pertinent [9,10], including questions concerning the psychology of an interaction between a human and an AI agent, particularly its anthropomorphic aspects.

However, most of the work being carried out under the banner of digital mental health concerns web and mobile apps for

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mental health. Given their prevalence, it is important to determine a conceptualization of therapeutic alliance that users might form with an app and whether this is associated with app effectiveness.

Previous work examining the ability of mental health apps to support therapeutic relationships has stressed the importance of establishing whether the factors that make regular face-to-face therapy effective are the same for digital therapy [11]. If this is the case, how can we incorporate these factors into digital therapies, and if not, what features of an app make it likely to support DTA? Should app developers be trying to recreate face-to-face therapy online, or should the online model have completely different characteristics to traditional therapeutic models? Previous starting points for constructing a conceptualization and measure of DTA include work by Berry et al [12], which adapted the Agnew Relationship Measure (ARM) of therapeutic alliance and developed it into a measure called the mobile Agnew Relationship Measure (mARM). Similarly, Henson et al [13] devised a short DTA measure by selecting 6 items from the Working Alliance Inventory measure of therapeutic alliance and rewording "therapist" to "app." However, given that such measures are more or less based on existing measures of the traditional therapeutic alliance and simply replace "therapist" with "app," with possibly a few other minor modifications, ultimately such an approach seems unsatisfactory or incomplete, as it does not account for the possibility of certain nuances, particularities, and complexities that could arise in the context of digital interventions. Furthermore, while there is bound to be some overlap between traditional and digital therapy, one would expect that not all aspects of a traditional therapeutic alliance will necessarily apply to a DTA, and that there may also be dimensions of alliance in the digital context that are not accounted for in traditional therapeutic alliance models.

It is in this context that we invited papers for this special edition on DTA.

The 5 papers published showcase the range of different means through which digital technologies can be used to manage the psychotherapeutic process. They provide an analysis of the current literature in this nascent area and examine the arguments for and against the likelihood of a therapeutic alliance emerging through digital means and how we should view this phenomenon going forward. We need to ask whether the current view of a therapeutic alliance translates well into the digital arena or whether new models should be developed.

In the paper "The Therapeutic Alliance in Digital Mental Health Interventions for Serious Mental Illnesses: Narrative Review" [14], the authors indicate that digital mental health applications offer advantages not found in traditional therapies. These include increased accessibility and autonomy, which can enhance adherence and engagement. They suggest that opportunities for self-guided therapy can lead to unique characteristics for therapeutic alliance in digital contexts. They show that currently the greatest support exists for the effectiveness of digital interventions for anxiety and depression, as opposed to other mental health conditions. They also emphasize the complexity of reaching conclusions in this very diverse field.

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In the paper "A Perspective on Client-Psychologist Relationships in Videoconferencing Psychotherapy: Literature Review" [15], the authors emphasize the prescience of this topic during the time of the COVID-19 pandemic. Suddenly, mental health therapy through digital means has become an imperative for many consumers, and so the quality of these therapies in establishing effective treatment has become a more urgent problem to solve. The paper examines DTA in the context of videoconferencing, a close technological option to face-to-face therapy. They suggest conflicting results across their two participant groups, therapists and clients. Clients of psychotherapy were generally satisfied that it was possible to establish a therapeutic alliance through video conferencing. Conversely, therapists expressed concern about the quality of the alliance and the ability to establish a satisfying therapeutic relationship through digital channels. The paper proposes a new model of interaction to deal with these contrasting experiences.

In the paper "Blended Digital and Face-to-Face Care for First-Episode Psychosis Treatment in Young People: Qualitative Study" [16], the authors examined and found client support for a blended care trial intervention, which combined a digital mental health web platform with human moderator support. In this study of young people aged 18-25 years, qualitative data suggest that the blending of online physical and virtual lives in the therapeutic setting was seen as a natural extension of how the clients live the rest of their lives in the current era. Participants in the study identified one of the benefits of blended therapy as strengthening the relationship between the client and the clinician, which is clearly important for DTA. It would be interesting to see this study extended to cover the views of therapists so that it could be compared to the findings of Cataldo et al [15].

In the paper "Impact of Jointly Using an e-Mental Health Resource (Self-Management And Recovery Technology) on Interactions Between Service Users Experiencing Severe Mental Illness and Community Mental Health Workers: Grounded Theory Study" [17], the authors study a scenario where e-mental health resources are available to mental health consumers and workers to use together. In this study, the digital intervention is intended to augment rather than entirely replace face-to-face care, as in a blended system. However, in contrast to an asynchronous system, in this study, mental health workers and clients used the intervention simultaneously during their regular scheduled consultations. The research found that using this form of interaction, relationships were able to be built between mental health workers and consumers. They leave us with a final message, which summarizes the lessons learned from this special edition well: "digital mental health tools should be reframed as tools that can strengthen and augment therapeutic relationships, provided there is a clear shared understanding about how and when they will be used."

Finally, in the paper "The Digital Therapeutic Alliance and Human-Computer Interaction" [18], the authors start by covering recent nascent work on DTA measures and discussing its limitations, before considering how areas from the field of human-computer interaction (HCI) can play a role in alliance formation and shaping or generating a more suitable, purpose-built measure of DTA. The four areas examined are

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(1) persuasive system design, (2) affective computing, (3) positive computing, and (4) human-smartphone connection. By exploring the mobile Agnew Relationship Measure of DTA through these HCI lenses, the paper also discusses how HCI

methods and knowledge can be used to foster DTA in mental health apps.

We trust that readers will find this special edition interesting, and that it will stimulate future research into the nascent and important topic of DTA.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence ARM: Agnew Relationship Measure DTA: digital therapeutic alliance HCI: human-computer interaction mARM: mobile Agnew Relationship Measure

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Original Paper

Intervention Use and Symptom Change With Unguided Internet-Based Cognitive Behavioral Therapy for Depression During the COVID-19 Pandemic: Log Data Analysis of a Convenience Sample

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Abstract

Background: Internet- and mobile-based interventions are most efficacious in the treatment of depression when they involve some form of guidance, but providing guidance requires resources such as trained personnel, who might not always be available (eg, during lockdowns to contain the COVID-19 pandemic).

Objective: The current analysis focuses on changes in symptoms of depression in a guided sample of patients with depression who registered for an internet-based intervention, the iFightDepression tool, as well as the extent of intervention use, compared to an unguided sample. The objective is to further understand the effects of guidance and adherence on the intervention's potential to induce symptom change.

Methods: Log data from two convenience samples in German routine care were used to assess symptom change after 6-9 weeks of intervention as well as minimal dose (finishing at least two workshops). A linear regression model with changes in Patient Health Questionnaire (PHQ-9) score as a dependent variable and guidance and minimal dose as well as their interaction as independent variables was specified.

Results: Data from 1423 people with symptoms of depression (n=940 unguided, 66.1%) were included in the current analysis. In the linear regression model predicting symptom change, a significant interaction of guidance and minimal dose revealed a specifically greater improvement for patients who received guidance and also worked with the intervention content (β =-1.75, *t*=-2.37, *P*=.02), while there was little difference in symptom change due to guidance in the group that did not use the intervention. In this model, the main effect of guidance was only marginally significant (β =-.53, *t*=-1.78, *P*=.08).

Conclusions: Guidance in internet-based interventions for depression is not only an important factor to facilitate adherence, but also seems to further improve results for patients adhering to the intervention compared to those who do the same but without guidance.

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iCBT; internet-based cognitive behavioral therapy; internet-based treatment; internet- and mobile-based intervention; depression; guidance; unguided; COVID-19

Introduction

When the COVID-19 pandemic hit Germany in spring 2020, many patients with depression suddenly lost their access to care [1]. Face-to-face appointments were cancelled, self-help groups could not meet and planned or started inpatient treatments were suspended. In this situation, great expectations were placed on internet- and mobile-based interventions (IMIs). IMIs have repeatedly been proven efficacious in the treatment of depression [2]. In particular, when they are implemented with some form of professional guidance, the benefits for patients with depression are substantial [3] and might even reach the level obtained with face-to-face interventions [4].

Although evidence suggests that guided IMIs should be preferred to unguided ones [5], limited resources of the health care system or other circumstances often prevent professional guidance from being provided. Previously, smaller effect sizes in unguided interventions have been explained in part by lower adherence. Lower adherence, in turn, has been associated with reduced treatment effects [6]. However, it is possible that guidance also enhances intervention effects in other ways, such as improving treatment credibility [7] or deepening understanding of the material, but this relationship has not been conclusively established. In order to fully utilize the possibilities of IMIs, it is in turn necessary to understand factors contributing to their efficacy and effectiveness.

One of these guided programs is the iFightDepression tool (iFD). It is based on cognitive behavioral therapy (CBT) techniques and its effectiveness has been demonstrated in comparison to an active control group [8]. Usually, people with depressive disorders receive access to iFD only through their physician or psychotherapist, who then also provides guidance. Guidance is meant mainly to encourage users and to help when questions or difficulties with the material arise. Users can decide if they want to share the entries they make in iFD with their guides. They are advised to work through the six core workshops in 6-12 weeks, but access to iFD is not limited to a certain time span. Due to significantly increased demand coinciding with the limited accessibility of health care providers during the first months of the COVID-19 pandemic, interested persons could contact the iFD team directly and receive unguided access to the tool from March to June 2020. This initiative was publicized in a press release, which was picked up by various digital and print media as well as by radio stations. An announcement was also posted on the home page of the Stiftung Deutsche Depressionshilfe and was met with great interest.

This situation provides a natural laboratory to compare user behavior and self-reported symptoms from a guided sample in routine care to an unguided sample. This short paper assesses the following questions:

- 1. Does the change in symptoms of depression differ between guided and unguided users of an IMI in routine care and is this related to use of the intervention when controlling for the available covariates?
- 2. Are there factors such as concomitant treatment, age, or gender that could explain possible differences concerning changes in depressive symptoms?

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Methods

Sample

The current analysis used routinely collected log data from users of the iFightDepression tool (iFD), a web-based CBT intervention [9] for patients with depression. Data were extracted for patients who were at least 18 years old and had given informed consent to participate in the ongoing evaluation of the tool, as is mandatory at registration; had at least minimal symptoms of depression (indicated by a score greater than 4 on the Patient Health Questionnaire [PHQ-9]); and logged onto the tool at least twice. Anonymized log data from all regular, guided accounts of the German version of iFD were used (collected from October 2016 to October 2020). These patients had received access to iFightDepression through their general practitioner, their psychotherapist, or another physician who then also provided guidance. Equivalent log data were extracted for all users who had registered for the unguided version (March-June 2020). The latter received no personalized guidance whatsoever but instead got automated weekly reminder emails for the first 6 weeks of intervention use. Those emails contained encouragement to continue using the intervention and commented on key learnings, one workshop at a time. They were sent regardless of workshop participation or completion.

Measures

During the registration process, participants filled in a questionnaire that yielded basic sociodemographic information (age, gender, current and past treatment). As a brief measure of depression severity, the PHQ-9—a short, well-validated, and widely used measure—is integrated for self-monitoring purposes [10,11]. The PHQ-9 is mandatory at the beginning and can be filled in again at any time during the intervention. Once per week, patients are prompted to fill in the questionnaire to monitor their symptoms. Sum scores of the PHQ-9 as filled in by the users during their work with iFD were used in the current analysis.

Anonymized log files were used to study symptom development and user behavior. These log files included time-stamped logs of all activities within the iFD tool. From those, a composite measure for usage was generated. Each user who completed at least two workshops (by reading at least 70% of the texts) within the first 6 weeks was regarded as having received a minimal dose of treatment that is potentially effective. This definition was chosen based on the findings that even the use of individual components of CBT can lead to reductions in symptoms of depression [12-14]. It is reasonable to assume that after completing at least two of the six workshops, patients will have learned about some CBT techniques that have the potential to alleviate their symptoms.

Statistical Analysis

For this analysis, only data from participants who completed the PHQ-9 at least once at 6-9 weeks after enrollment were considered. Baseline differences in sociodemographic variables were tested for statistical significance using chi-square tests for categorical variables, analysis of variance for normally distributed numeric data, and Wilcoxon rank-sum tests in case

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of nonnormally distributed data. The *P* values were corrected for multiple testing using a false discovery rate correction [15].

The routinely collected PHQ-9 scores were used as an estimate for real-world effectiveness. As an estimate of symptom change, the mean difference (delta) of PHQ-9 scores at registration and after 6-9 weeks was calculated for all patients with available entries in the category after 6-9 weeks. This time span was used based on experience from a previous study [8], according to which effects of the intervention were the largest after the sixth week. If patients had filled in PHQ-9 more than once 6-9 weeks after their registration, a mean value was used. Since this difference score fulfilled the criteria of normal distribution, it was used as a dependent variable for a linear regression model.

A multiple linear regression model predicting delta-PHQ was specified, including the following variables as independent variables: baseline PHQ-9, current psychotherapy (yes versus no), current antidepressant medication (yes versus no), diagnosed depression (yes versus no), age, gender, guidance (guided versus unguided), and minimal dose (achieved versus not achieved), as well as the interaction of guidance and minimal dose. This interaction coefficient is of special interest, since differences in reductions of symptoms of depression that depend both on minimal dose and group can be regarded as an estimate for a differential treatment effect between guided and unguided use. The fit of this model was compared to a reduced version without guidance and minimal dose using analysis of variance. This allows us to test if the reduction in the residual sum of squares due to the additional variables is statistically significantly different from zero. This statistical approach was chosen to control for the influence of the available baseline variables that might differ between the two groups and yield the best possible estimate for the interaction of guidance and minimal dose.

All statistical analyses were performed using R (version 3.5.1) [16] and the level of statistical significance was set at α =.05.

Results

Sample

On October 16, 2020, data were extracted for 9730 participants, of whom 2181 (22.42%) had been invited to use iFD by a guiding health care professional and 7549 (77.58%) had received access through unguided accounts during the first nationwide lockdown in Germany during the COVID-19 pandemic. In total, 483 (22.15%) people in the guided sample and 940 (12.45%) people in the unguided sample provided PHQ-9 data after 6-9 weeks and were included in the current analysis. Sociodemographic data broken up for guidance (yes versus no) and achieved minimal dose (yes versus no) are displayed in Table 1. The proportion of users achieving minimal dose did not significantly differ between guided and unguided users $(X^2_{1423}=2.8846, P=.09)$.

Table 1. Overview of sociodemographic characteristics. *P* values correspond to the comparison of participants who used iFightDepression with and without guidance.

Variables	Total (n=1423) Guided (n=483) Unguided (n=940)		40)	<i>P</i> value, comparison of guided versus unguided sample (false discovery rate–adjusted <i>P</i> value)		
		Minimal dose achieved (n=66)	No minimal dose (n=417)	Minimal dose achieved (n=158)	No minimal dose (n=782)	
Female, n (%)	946 (66.45)	42 (63.64)	266 (63.79)	106 (67.09)	533 (68.16)	.11 (.13)
Age in years, mean (SD)	40.15 (13.35)	38.77 (13.16)	39.77 (14.13)	39.79 (12.31)	40.54 (13.14)	.26 (.26)
Baseline Patient Health Questionnaire score, mean (SD)	14.11 (4.89)	14.68 (4.91)	14.65 (4.93)	13.29 (4.65)	13.94 (4.88)	.003 (.006)
Diagnosed depression, n (%)	1093 (76.81)	58 (87.88)	375 (89.93)	108 (68.35)	552 (70.59)	<.001 (<.001)
Current psychotherapy, n (%)	660 (46.38)	43 (65.15)	263 (63.07)	58 (36.71)	296 (37.85)	<.001 (<.001)
Current antidepressant treatment, n (%)	582 (40.90)	31 (46.97)	221 (53.00)	47 (26.75)	283 (36.19)	<.001 (<.001)
Past psychotherapy, n (%)	620 (43.57)	20 (30.30)	147 (35.25)	74 (46.84)	379 (48.47)	<.001 (<.001)
Past antidepressant treatment, n (%)	471 (33.10)	17 (25.76)	127 (30.46)	52 (32.91)	275 (35.17)	.07 (.09)

Results of the multiple linear regression predicting delta-PHQ indicated a statistically significant interaction of guidance and minimal dose (β =-1.75, *t*=-2.37, *P*=.02; Figure 1), while the main effects of guidance (β =-.53, *t*=-1.78, *P*=.08; Table 2) and minimal dose (β =.51, *t*=1.27, *P*=.21) did not reach significance.

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A larger reduction in symptoms of depression was also associated with a greater PHQ-9 score at baseline (β =-.42, *t*=-15.84, *P*<.001), being younger (β =-.02, *t*=-2.31, *P*=.02), and not reporting being diagnosed with depression (β =.94, *t*=2.76, *P*=.006). The model estimates for nonsignificant

predictors were as follows: gender (β =.12, *t*=0.45, *P*=.65), current psychotherapy (β =-.02, *t*=-0.08, *P*=.94), and current antidepressant medication (β =-.536, *t*=-1.88, *P*=.06). The full

model led to R^2 =0.168 and explained significantly more variance than a basic model without guidance and minimal dose ($F_{3,1414}$ =4.60, P=.003).

Figure 1. Boxes indicate the 25th to 75th percentile, while the bold line in the box indicates the mean delta-PHQ. Whiskers mark the largest value within 1.5 times interquartile range above the 75th percentile and below the 25th percentile. Values further out are marked as points and are potential outliers. Delta-PHQ refers to the change in participant score on the Patient Health Questionnaire.

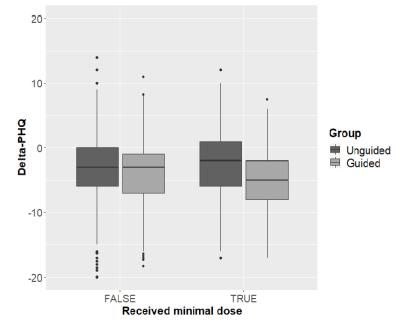


Table 2. Differences in Patient Health Questionnaire scores at baseline and after 6-9 weeks of program use.

Sample	Patient Health Questionnaire score at start of intervention, mean (SD)	Patient Health Questionnaire score after 6-9 weeks intervention, mean (SD)	Within-group effect size, <i>d</i> (95% CI)
Guided sample (n=483)	14.65 (4.92)	10.49 (5.26)	0.82 (0.69-0.95)
Unguided sample (n=940)	13.83 (4.85)	10.72 (5.66)	0.59 (0.50-0.68)

Discussion

Principal Findings

This retrospective analysis of a convenience sample provides a new perspective on the importance of guidance in IMIs. While both guided and unguided users reported a reduction in symptoms of depression, the differences varied depending on the use of the intervention. Those patients who did not interact with the intervention material (ie, completed less than two workshops) and just filled in the symptom questionnaire reported a similar reduction in symptoms of depression, independent of receiving guidance or not. On the other hand, when patients did engage with the intervention material, the reduction in symptoms of depression was superior in the guided group, as indicated by the significant interaction in the linear model. This effect was stable when other covariates that influenced delta-PHQ were taken into account (eg, baseline PHQ-9, age, and reporting being diagnosed with depression).

It needs to be mentioned that contrary to earlier results that associate adherence with effectiveness [17], in the current data set, there was no significant main effect of minimal dose. In the current sample, minimal dose was only predictive through its interaction with guidance.

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One interpretation of this interaction could be that the role of guidance goes beyond just facilitating adherence. It might be that the guided version of iFD was perceived as more credible or that guides could help in correcting misinterpretations concerning the exercises. A further possible explanation is that patients working through the program might take the tasks more seriously when they know that a professional is guiding them and taking care of them. Both would enhance the use of CBT techniques and might create a greater positive expectation, strengthening the placebo effect. Still, it is also possible that patients with more persistent symptoms during the 6-9 weeks of data collection had a harder time motivating themselves to engage with the intervention when unguided and therefore achieved the minimal dose less often.

Concerning the covariates, the current results only partly replicate existing knowledge. Higher symptom scores before the intervention have been regularly associated with greater reductions during treatment [18], possibly because of regression to the mean as well as floor effects for patients with initially mild symptoms.

Although results concerning both age and gender as predictors for adherence/effectiveness have been inconclusive in a meta-analysis [19], another trial of a large sample of community

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users in Australia showed higher engagement with an intervention for younger users [20] and thus points in a similar direction as the current analysis.

Finally, the association of not being diagnosed with depression with greater improvement might be a sign that (especially in the unguided group) some patients might have had symptoms of depression caused by acute stressors without fulfilling the criteria of major depression. That could lead to a faster decline in symptoms of depression in this group but this is only speculative at this stage.

It is noteworthy that the amount of variance in delta-PHQ that can be explained by the current model is rather low (16.8%). Although changes in symptoms of depression will naturally depend on many situational and intrapersonal variables, it is possible there might be other relevant variables influencing the changes in delta-PHQ that were not assessed in the current analysis (eg, attitudes toward online interventions, expectations of success).

Limitations

When interpreting these results, it needs to be kept in mind that no randomization was applied and the selection process between guided and unguided samples clearly differed. In order to assess the impact of the limitations described above on the validity of the study, it is useful to examine where exactly the risks lie. Although the guided group had been invited by their treating health care professional, the unguided group was self-selected. Self-selection occurred during the first weeks of the COVID-19 pandemic. This might covary with participant characteristics (eg, depressive symptoms) in view of acute stress due to lockdown measures versus participants with depressive disorders treated in care as usual by the guides. Although the current analysis controlled for baseline differences in the variables that were available, there might be differences between the two samples in other areas. It is possible that the unguided sample had more comorbid disorders and was therefore less likely to benefit from a CBT intervention for depression or that the pandemic situation made it more difficult to actually use the CBT techniques and therefore the minimal dose was still not effective. In addition, the amount or content of guidance is not documented or known in this context, so it is possible that there was a large variance in this. Finally, the mean number of days between first and last login for the current sample was 27, so the percentage of people who provided data after 6-9 weeks was low. This analysis therefore only considers those users who for some reason logged into the tool again after that time span and filled in the PHQ-9; it cannot be known if this subgroup was representative for all users (for details, see Multimedia Appendix 1). This finding underscores the need to design interventions in a way that supports adherence and user engagement [21,22]. The results on the interaction of guidance and minimal dose should therefore be regarded as preliminary and should be followed up on in randomized trials.

Conclusions

This analysis yields some further evidence that guidance is an essential part of IMIs targeting depression. It is known from past research that guidance has a positive effect on adherence; in the current data set, it is associated with greater improvements in symptoms of depression. This underscores the importance of creating conditions in the health care system to provide IMIs with professional guidance. Although many patients spontaneously provided feedback of being very grateful for this low-threshold intervention, based on this analysis, the strategy seems less appropriate. In comparable situations where regular care pathways are not available, unguided digital interventions for depression should therefore not be the preferred and only option.

Acknowledgments

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Conflicts of Interest

The iFD tool was developed by the European Alliance against Depression (EAAD), of which UH is chairman of the board. In Germany, iFD is operated, continuously developed, and evaluated by the Stiftung Deutsche Depressionshilfe, a member organization of the EAAD. The Stiftung Deutsche Depressionshilfe is an independent nonprofit foundation under civil law, financed primarily by donations, endowments, grants, and third-party funding for projects and research. It also receives income from its business operations but works independently of the pharmacological industry. UH is a member of the advisory board for Janssen Pharmaceutica and has received travel costs and an honorarium as a speaker, a research grant from Medice for an investigator-initiated trial, and travel costs and an honorarium as a speaker for Servier. The other authors declare no conflicts of interest.

Multimedia Appendix 1

Overview of sociodemographic characteristics. <italic>P</italic> values correspond to the comparison of participants who did versus did not provide Patient Health Questionnaire data after 6-9 weeks. [PDF File (Adobe PDF File), 103 KB - mental_v8i7e28321_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy EAAD: European Alliance Against Depression iFD: iFightDepression IMI: internet- and mobile-based intervention PHQ-9: Patient Health Questionnaire

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Original Paper

A Gamified Smartphone-Based Intervention for Depression: Randomized Controlled Pilot Trial

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Abstract

Background: Available smartphone-based interventions for depression predominantly use evidence-based strategies from cognitive-behavioral therapy (CBT), but patient engagement and reported effect sizes are small. Recently, studies have demonstrated that smartphone-based interventions combining CBT with gamified approach-avoidance bias modification training (AAMT) can foster patient engagement and reduce symptoms of several mental health problems.

Objective: Based on these findings, we developed a gamified smartphone-based intervention, mentalis Phoenix (MT-Phoenix), and hypothesized the program would both engage patients and produce preliminary evidence for the reduction of depressive symptoms.

Methods: To test this hypothesis, we evaluated MT-Phoenix in a randomized controlled pilot trial including 77 individuals with elevated depression scores (Patient Health Questionnaire-9 scores \geq 5). Participants were either instructed to train for 14 days with MT-Phoenix or assigned to a waitlist control condition. Engagement with the intervention was measured by assessing usage data. The primary outcome was reduction in depressive symptom severity at postassessment.

Results: Data from this pilot trial shows that participants in the intervention group used the smartphone-based intervention for 46% of all days (6.4/14) and reported a significantly greater reduction of depressive symptoms than did participants in the control condition ($F_{1,74}$ =19.34; P=.001), with a large effect size (d=1.02). Effects were sustained at a 3-month follow-up.

Conclusions: A gamified smartphone-based intervention combining CBT with AAMT may foster patient engagement and effectively target depressive symptoms. Future studies should evaluate the effectiveness of this intervention in a phase 3 trial using clinical samples. Moreover, the intervention should be compared to active control conditions.

Trial Registration: German Clinical Trial Registry DRKS00012769; https://tinyurl.com/47mw8du7

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KEYWORDS

smartphone technology; depression; cognitive behavioral therapy; approach/avoidance; gamification

Introduction

Depression is one of the most common mental disorders in the world [1] and is associated with severe impairments for afflicted individuals [2]. Fortunately, there is ample evidence for the efficacy of psychotherapeutic treatments for depression [3]. However, in spite of costly attempts to provide evidence-based

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treatment for all patients, a large number of individuals remain untreated [4,5] or respond to psychotherapy only partially [6].

In the past decade, many attempts have been made to use the internet to improve access and response to depression treatments. Due to the dramatic increase in smartphone use in the past years [7], these attempts have recently started to focus on smartphone-based interventions for mental health [8]. This focus can be explained by the advantages of smartphones such as their

widespread use [9], their resulting potential for dissemination [10], and their constant availability, which allows for the integration of therapy-relevant competencies into the patient's daily life [11].

Available research shows that smartphone-based interventions using strategies from cognitive-behavioral therapy (CBT) have the potential to effectively reduce depressive symptoms. For example, a study [12] showed that a smartphone-based intervention offering 6 weeks of self-guided CBT for adults with mild-to-moderate depression led to significant reductions of depressive symptoms when compared to a control condition with access to internet-based psychoeducation for depression (d=1.03). Significant effects were also found on measures of behavioral activation and work-related outcomes such as productivity, absence rates, and workplace distress. In another trial [13], participants from a community sample with mild-to-moderate symptoms of depression received 7 weeks of training with a CBT-based self-help smartphone-based intervention. At postassessment, participants in the intervention group showed significantly greater reductions of depressive symptoms than both an attention control group (d=0.36) and a waitlist control condition (d=0.46).

However, results for the effectiveness of CBT-based smartphone-based interventions for depression are inconsistent. For example, a three-armed trial [14] compared 4 weeks of treatment with a gamified smartphone-based intervention that targets cognitive control abilities to a smartphone-based intervention based on problem-solving therapy and an information control smartphone-based intervention in a sample of participants with mild-to-moderate symptoms of depression. Although depression symptoms decreased in the total sample, no significant differences were found between the two active smartphone-based interventions and the information control condition at both 4-week and 12-week follow-up assessment. Moreover, meta-analysis results suggest that heterogeneous smartphone-based interventions for depression are moderately effective when compared to inactive controls (g=0.56), but that effects are small when compared to active control conditions (g=0.22) [15]. In the meta-analysis, a subgroup analysis showed that the use of CBT techniques did not influence study effect sizes significantly when compared to smartphone-based interventions that did not use CBT.

In addition to smartphone apps using techniques from CBT, smartphone-based interventions using cognitive bias modification (CBM) paradigms have recently been discussed as potentially useful for the reduction of symptoms in various psychological domains. For depression, available CBM interventions have focused primarily on the modification of attention biases [16] and interpretation biases [17]. Regarding their effectiveness, a meta-analysis study reported a moderate effect of attention bias modification and interpretation bias modification trainings on biases (g=0.49), but only a small effect on anxiety and depression symptoms (g=0.13) [18]. Lately, approach-avoidance biases have been shown to play an important role in the development and maintenance of depression. For example, one study showed that depressed individuals have a stronger avoidance tendency toward angry faces when compared to healthy controls (d=0.26) [19]. In

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another study [20], the authors found reduced approach motivation toward positive pictures compared to neutral pictures in individuals with depressive symptoms when compared to nondepressed controls (d=0.55). In trainings aiming at the modification of approach-avoidance biases (approach-avoidance modification training [AAMT]), participants are asked to approach functional disorder-specific stimulus material (pictures and/or statements) and to avoid dysfunctional material. Prominent examples for the clinical utilization of computer-based AAMT can be found in the domain of alcohol dependency. Here, two studies demonstrated that the combination of 3 months of inpatient CBT and computer-based AAMT effectively reduced relapse rate in alcohol-dependent individuals after a 12-month follow-up by 10% [21] to 13% [22] when compared to CBT-only controls. In the domain of depression, a recent study used computerized AAMT as an add-on to treatment-as-usual [23]. In a sample of clinically depressed individuals, this blended intervention was shown to successfully reduce depressive symptoms when compared to a sham control condition. Another study included patients with various diagnoses and tested AAMT as an adjunct to inpatient treatment [24]. Here, results showed that AAMT reduced depressive symptoms compared to a sham control group. Interestingly, approach tendencies and symptom reductions were moderated by depression severity at baseline, such that only participants with higher initial depressive symptoms benefited from this intervention.

With regard to smartphone-based interventions facilitating a similar blended approach, pilot studies yielded promising results for the efficacy of gamified smartphone-based interventions combining AAMT with face-to-face CBT in various psychological domains. In one of these studies, the combination of 14 days of gamified AAMT with a brief face-to-face counseling session led to significant reductions in body dissatisfaction in individuals at risk for eating disorders when compared to waitlist controls (d=0.62) [25]. In another study, two brief face-to-face group counseling sessions and 14 days of gamified AAMT significantly reduced procrastination when compared to a waitlist control condition (d=0.84) [26]. A third study tested the aforementioned rationale in the domain of alexithymia and showed the intervention significantly reduced alexithymia (d=1.14) and improved emotion recognition skills (d=0.97) when compared to an active control condition [27].

Aside from the utilization of psychotherapeutic techniques, some studies have suggested that low adherence rates to smartphone-based interventions and the lack of engagement features used by apps may be partly responsible for the limited effectiveness of available interventions [28]. In search of ways to improve patient engagement, several studies [29,30] have discussed the use of gamification elements as a particularly promising tool to increase engagement in nongaming contexts. Gamification refers to the use of game elements and design features such as points, badges, levels, progress, and challenges in nongaming software [31]. Regarding the use of gamification strategies to increase engagement with online interventions, a systematic review demonstrated that gamification has the potential to increase engagement parameters such as time spent in a program, number of completed assignments, and total

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number of views [32]. In depression research, a meta-analysis that analyzed gamified interventions targeting depression found a moderate effect size for depression therapy at posttreatment (d=0.47) [33].

Addressing the important role of CBT and approach-avoidance biases in depression as described above and following up on the promising findings for smartphone-based interventions that combine gamified AAMT with face-to-face CBT in other we developed an automated, gamified domains, smartphone-based intervention for depression combining AAMT with CBT (mentalis Phoenix [MT-Phoenix]). To provide a scalable and possibly cost-effective intervention, we developed MT-Phoenix as a standalone smartphone-based intervention. The aim of this study was to test MT-Phoenix in a phase 2 randomized controlled pilot trial to explore the effectiveness of this novel intervention in a cohort of individuals with elevated depressive symptoms. We hypothesized MT-Phoenix would reduce depressive symptoms and improve well-being. Treatment effects were expected to be stable at a 3-month follow-up.

Methods

Recruitment

Participant recruitment started in May 2017 through announcements published on the internet (ie, across several social media channels and local notice boards). Interested individuals were asked to scan a QR code or click a link provided in the announcements that led to a survey tool (Unipark) providing a screening questionnaire that assessed participants for study inclusion based on the following criteria: heightened depression scores with values ≥ 5 on the Patient Health Questionnaire-9 (PHQ-9) [34], sufficient German language skills, aged ≥ 18 years, access to a smartphone using iOS (Apple iPhone 5 or above), and ability to provide informed consent. Eligible individuals were sent written information about study procedures and an informed consent form via email. Participants that returned a signed copy of the informed consent form were randomly assigned to either the intervention or a waitlist control condition. We used block randomization with a fixed block size of two to ensure similar sample sizes across conditions. Randomization was conducted by a master's degree student (not otherwise involved in the study) using a randomization website. Participants received an email with a link to the survey tool reminding them to complete both the primary and secondary outcome measures. Posttreatment assessment was conducted 2 weeks after baseline, follow-up assessment was conducted 12 weeks after posttreatment assessment. The treatment was free of charge. Student participants received course credit for participation and every participant automatically took part in a draw for a shopping gift card. All data were assessed with the help of the survey tool. After baseline completion, participants in the intervention group received an email inviting them to download MT-Phoenix in the App Store and to train over a 14-day period. Given the heterogeneity of studies in this emerging field, no standardized recommendations on the use of smartphone-based interventions have come to the authors' attention. Thus, participants did not receive any recommendations regarding duration or frequency

of use of the intervention in this pilot trial. Participants in the waitlist condition were given access to the intervention after completing the follow-up assessment. All study procedures complied with the human research guidelines of the Declaration of Helsinki and were approved by the ethics committee of the German Psychological Society.

Intervention

Overview

MT-Phoenix was developed by a graduate psychologist (CAL) and a professor in clinical psychology (MB). MT-Phoenix is a gamified intervention that provides the trainings for 13 module-based competencies important for managing depressive symptoms. Multimedia Appendix 1 shows screenshots of the app. The 13 competencies in MT-Phoenix are presented in this order to the participants: functional thoughts, positive activities, daily routines, experiencing pleasure, relaxation, reconnect socially, self-support, self-comfort, problem-solving, acceptance, grieving, gratitude, and self-care. Gamification is used by arranging the modules sequentially, having participants earn points for completion of certain activities, using a level system in the AAMT, and providing illustrated feedback components. The competencies consist of the elements described below.

Psychoeducation

At the start of each competency module, MT-Phoenix provides information on the relevance of the respective competency for depression. Consistent with typical smartphone use, educative information is provided by simulating a fictional group chat in which a coach and four users affected by depression communicate with each other via made-up SMS text messages. In the fictional conversations, the coach makes use of two conventional therapeutic techniques: guided discovery and Socratic dialogue.

AAMT/Audio Instructions

In 10 of the 13 competencies, MT-Phoenix uses four different types of gamified AAMT in which participants are asked to systematically approach functional stimulus material and avoid dysfunctional stimulus material. Approach-avoidance is achieved by making use of the smartphone's several input channels. Three consecutive levels of AAMT are provided in each of the 10 competencies containing AAMT. Before the start of a new level, MT-Phoenix provides a short tutorial on how the respective level is played. Made-up stimulus material was provided for each competency. The stimuli used in the AAMT are competency-specific pictures (faces, scenes, etc) with text statements (negative thoughts, dysfunctional beliefs, etc) written on them. Examples of stimuli can be found in Multimedia Appendix 2. In the first level (SWIPE), approach-avoidance is trained by asking participants to wipe away dysfunctional stimuli and to pull functional stimuli toward themselves by moving the stimulus either to the top or the bottom of their smartphone screen with their finger. In the second level (COMMAND), participants can control the stimuli with voice commands (eg, saying the words "future" or "friend" to a functional stimulus, making it move toward oneself, and the words "past" or "foe" to a dysfunctional stimulus, making it disappear from the smartphone display) by making use of the smartphone's

microphone. In the third level (DRAW), participants are asked to approach or avoid stimuli by drawing meaningful gestures (eg, by drawing a check mark on a functional stimulus or by "crossing out" a dysfunctional stimulus) on the smartphone display. Here, approach-avoidance is reinforced by making checkmarks appear in green and crosses in red. In the fourth level (MAZE), the stimuli are placed in the center of different labyrinths and participants are instructed to maneuver stimuli through the labyrinths before pulling functional stimuli toward themselves or wiping away dysfunctional stimuli. Upon correct and incorrect reactions, MT-Phoenix provides feedback (positive feedback: showing illustrated thumbs-up pictures and the word "Correct!"; negative feedback: illustrated thumbs-down pictures, the words "That's wrong!" and a short vibration of the smartphone) to the participants. For three competencies (relaxation, experiencing pleasure, and self-support), MT-Phoenix provides audio instructions instead of AAMT.

Tasks

At the end of each competency module, participants are asked to complete a series of competency-related short tasks. Short tasks are exercises designed to foster motivation and behavioral activation (eg, "Go for a 15-min walk today," "Try to think of three things you liked today and write them down in the app"). Studies have found behavioral activation tasks in smartphone apps for depression to be particularly helpful [35]. Participants have to complete a minimum of three short tasks to successfully "play through" a competency and to continue to the subsequent module in the training.

Measures

Primary Outcome

Depressive symptoms were assessed using the PHQ-9 [34]. The PHQ-9 is a 9-item self-report questionnaire that evaluates the presence of depressive symptoms during the last 14 days based on the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnostic criteria for major depression. Each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day) so that scores can range from 0 (absence of depressive symptoms) to 27 (severe depressive symptoms). The German version of the PHQ-9 used in this study has been shown to have high sensitivity (95%) and specificity (86%) in the detection of depression [36]. In previous studies, the internal consistency of the PHQ-9 has been demonstrated as good, with an α score ranging from .86 to .89. In this study, the α for the PHQ-9 was .86.

Secondary Outcomes

Presence of emotional, motivational, cognitive, somatic, and interactional aspects of depression during the last 7 days was assessed with the German 20-item version of the Center for Epidemiological Studies Depression Scale (Allgemeine Depressions-Skala [ADS]) [37]. Higher values indicate more severe depressive symptoms. Internal consistency has been demonstrated as good, with α scores ranging from .89 to .92. In this study, the internal consistency was .91.

Well-being was assessed using the 5-item World Health Organization Well-being Index (WHO-5) [38]. On a 5-point Likert-type scale ranging from 0 (none of the time) to 5 (all of the time), the WHO-5 asks respondents to rate how the following statements applied to them during the last 14 days: "I have felt cheerful and in good spirits," "I have felt calm and relaxed," "I have felt active and vigorous," "I woke up feeling fresh and rested," and "My daily life has been filled with things that interest me." Internal validity has been shown to be excellent (Cronbach α =.92) in a German-speaking sample. The α for this study was .89.

Statistical Analysis

Possible intervention effects were evaluated using an intention-to-treat approach. Missing data were shown to be missing completely at random (nonsignificant Little test), imputed with the help of Markov chain Monte Carlo multivariate imputation algorithm with 10 estimations per missing value [39]. We conducted analyses of covariance (ANCOVAs) on post and follow-up outcome scores to evaluate possible intervention effects and included the outcomes' baseline values as covariates to control for a potentially confounding influence of these scores. As for effect sizes, we calculated Cohen *d* based on [40] and followed commonly used conventions [40] by defining 0.20, 0.50, and 0.80 as small, moderate, and large effects, respectively.

Results

Participants

Multimedia Appendix 3 illustrates the flow of participants through the study. In the final sample of 77 participants, the mean age was 29.93 (SD 11.61) years. Participants were predominately female (56/77, 82%) and 34% (26/77) of participants reported they were receiving therapeutic treatment at the time. Significant baseline differences between the intervention and the control condition were found with regard to depression measured with the PHQ-9, age, and occupation. Table 1 displays sociodemographic and clinical characteristics at baseline.



Variable	Intervention group (n=40)	Control group (n=37)	Test type	P value	
Age, mean (SD)	35.05 (13.64)	24.25 (4.31)	Wilcoxon rank-sum test	.001	
Gender (female), n (%)	31 (82)	25 (86)	Fisher exact test	.74	
Country of origin, n (%)					
Germany	38 (95)	37 (100)	Fisher exact test	>.99	
Austria	1 (5)	0 (0)			
Occupation, n (%)					
Student	14 (35)	27 (73)	Fisher exact test	.02	
Employed	19 (48)	4 (11)			
Unemployed	2 (5)	1 (3)			
Other	5 (12)	5 (14)			
Education, n (%)					
<10 years	8 (20)	5 (14)	Fisher exact test	.54	
>10 years	32 (80)	32 (86)	Fisher exact test	.53	
Psychotherapy (no), n (%)	22 (55)	29 (78)	Fisher exact test	.048	

Intervention Effects

ANCOVA results on depressive symptoms as assessed with the PHQ-9 revealed significant differences between the intervention and the waitlist control condition at postintervention assessment ($F_{1,74}$ =19.34; P=.001) with a large effect (d=1.02). Of all treated participants, 63% (25/40) achieved clinically significant improvement on the primary outcome measure as defined by a reduction \geq 5 points on the PHQ-9. Regarding depressive

symptoms as assessed with the ADS, the ANCOVA yielded significant differences between the intervention and the waitlist control condition after the intervention ($F_{1,74}$ =36.68; P=.001) with a large effect (d=1.41). With regard to well-being, ANCOVA results showed significant differences between the intervention and the waitlist control condition at postintervention assessment ($F_{1,74}$ =15.34; P=.001) with a large effect (d=0.91). Empirical means and standard deviations are displayed in Table 2.

Table 2. Means and standard deviations for primary and secondary outcomes.

Outcomes	Intervention group (n=40)			Control group (n=37)		
	Pretreatment, mean (SD)	Posttreatment, mean (SD)	Follow-up, mean (SD)	Pretreatment, mean (SD)	Posttreatment, mean (SD)	Follow-up, mean (SD)
Primary outcome: Patient Health Questionnaire (PHQ-9)	11.65 (5.27)	8.11 (4.07)	9.55 (4.64)	14.87 (4.43)	13.48 (4.69)	13.79 (4.85)
Secondary outcome: General Depression Scale (ADS)	48.35 (10.88)	39.91 (7.95)	43.39 (11.87)	51.47 (7.79)	50.88 (8.65)	50.40 (9.74)
Secondary outcome: World Health Organization Well-being Index (WHO-5)	7.77 (4.50)	10.76 (4.25)	10.57 (4.09)	7.67 (3.09)	7.75 (3.37)	7.91 (3.57)

Maintenance of Effects

Regarding the maintenance of treatment effects, ANCOVA results showed that intervention effects persisted through follow-up for the PHQ-9 ($F_{1,74}$ =6.35; P=.014), the ADS ($F_{1,74}$ =5.85; P=.018), and the WHO-5 ($F_{1,74}$ =14.72; P=.001).

Intervention Engagement and Evaluation

With regard to intervention engagement, 13 participants did not initiate training with the intervention over the intervention period. The 27 participants that did initiate training with MT-Phoenix used the app for an average of 6.38 days (SD 2.83) and spent 62.39 minutes in the app (SD 68.17). During the training, participants completed 5.89 (SD 4.43) modules and

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an average of 25.89 (SD 23.43) tasks and played 2.28 (SD 3.10) levels of the AAMT per module. The average error rate (incorrect responses) in the AAMT was 2.4%, suggesting that participants understood the training instructions. Participants spent 20.39 (SD 12.97) minutes playing the AAMT, representing 33% of the total time spent in the app. Regarding the intervention evaluation, participants in the intervention group were asked to evaluate the three major components of MT-Phoenix for their perceived helpfulness at postassessment using a Likert scale from 0 to 4. Evaluation results were above average, with high ratings for psychoeducation (mean 3.17, SD 0.72), the AAMT (mean 3.00, SD 0.53), and behavioral activation tasks (mean 3.17, SD 0.55).

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Discussion

This phase 2 pilot trial evaluated the preliminary effectiveness of a standalone gamified smartphone-based intervention combining AAMT and CBT principles in a sample of adults with elevated depression scores. Study results indicate a greater reduction of depressive symptom severity over the course of the intervention in the intervention group when compared to waitlist controls at posttreatment. Follow-up analyses indicate that effects were maintained over a period of 3 months after the completion of the intervention. In addition, the intervention group exhibited a significant increase in well-being at postassessment when compared to the control condition. These effects were also sustained through follow-up.

To the best of our knowledge, this is the first study to evaluate the effectiveness of a gamified intervention that combines CBT and AAMT techniques for the reduction of depressive symptoms. With regard to patient engagement, data analyses show a considerably high retention rate for MT-Phoenix (25/27, 93%, representing the percentage of participants that reused the app after the first use) when compared to studies showing that about 30% of individuals stop using smartphone-based interventions after the initial use [41]. Comparisons of adherence to smartphone-based depression interventions across studies indicate that participants trained with MT-Phoenix almost every other day (6.4/14 days, 46%), while intervention adherence was lower (39%) in a study that evaluated three smartphone-based interventions targeting depression [14]. However, comparisons are limited as smartphone-based interventions tend to differ on various parameters that have been shown to influence adherence such as interventional content, design, gamification elements, and use of reminders and notifications. Comparisons are further limited by varying study designs such as intervention periods, target populations, and use instructions. Moreover, the current study design did not include an experimental manipulation that tested the gamified smartphone-based intervention against a nongamified version. Thus, it cannot be concluded that the gamification elements used in MT-Phoenix were responsible for the engagement rates observed in this study. On the contrary, engagement with the intervention may have been influenced by participants with mild depression scores as such individuals have been shown to be more willing and able to use a self-directed intervention like MT-Phoenix [42].

To the best of our knowledge, this study is the first to evaluate the effectiveness of a gamified smartphone-based intervention targeting depressive symptoms using AAMT and principles of CBT. The observed effect sizes (*d*) were 1.02-1.41 for depression and 0.91 for well-being. Comparisons of effect sizes suggest that MT-Phoenix yields similar (well-being) and larger (depression) effects compared to smartphone-based interventions using gamified AAMT in combination with face-to-face CBT. Moreover, preliminary effects found in this pilot trial are superior to other standalone smartphone-based interventions for depression (g=0.56), as demonstrated in a meta-analysis [15]. Thus, MT-Phoenix is a promising low-threshold intervention for individuals with heightened depressive symptoms.

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The findings presented in this paper have important theoretical and clinical implications. First, they provide evidence that a gamified smartphone-based intervention combining AAMT with CBT principles can reduce depressive symptoms. Second, this study is the first to show that a blended approach (smartphone-based intervention combined with face-to-face CBT) can be automated and delivered by a standalone smartphone-based intervention without any face-to-face contact with a mental health professional. Study results add to the growing body of literature suggesting that smartphone-based interventions have the potential to change the provision of mental health services profoundly, especially when interventions are scalable and easy to disseminate like the program under investigation. Third, this study demonstrates that a smartphone-based intervention targeting depression can engage participants to adhere to the intervention frequently. This finding is corroborated when comparing training data from this study with usage rates in other studies that tested smartphone-based interventions for depression.

Regardless of its merits, results from this study are subject to several limitations that need closer consideration. First, although similar interventions have been positively evaluated in pilot studies on body dissatisfaction [25], procrastination [26], and alexithymia [27], findings from this study provide preliminary evidence only for the particular program under investigation and thus cannot be easily generalized to other interventions combining AAMT and CBT. Hence, future studies should replicate these findings in other disorders or psychological problems. Second, as 30% of all participants received psychotherapy while participating in this study, results may have been influenced by factors other than the intervention under investigation. Further studies are needed to examine whether MT-Phoenix may be more appropriate as an adjunct to treatment-as-usual instead of a standalone intervention. Third, generalization of study results is limited as the smartphone-based intervention was made accessible for iPhone owners exclusively, the statistical power was low due to the rather small sample size, and the sample was homogeneous with regard to several sociodemographic variables. Thus, future studies should make MT-Phoenix available for other operating systems as well and should further examine the intervention in larger and more diverse samples. Fourth, inclusion of participants was performed on the basis of heightened depression scores rather than on the basis of a systematic diagnosis (eg, by using the Structured Clinical Interview for DSM-IV Axis I Disorders) [43]. We included participants who reported PHQ-9 depression scores of ≥ 5 to ensure testing of the intervention in individuals with a range of symptom severity and to allow for comparison between studies on smartphone-based interventions for depression that have focused predominately on participants with mild and moderate depressive symptoms. However, as we did not include an upper cutoff for study inclusion, participants with severe depressive symptoms were also included in the study. Approximately 30% of the study sample reported being in therapeutic treatment, thus hinting at the inclusion of patients with diagnosed depression. Future studies should try to replicate the findings in samples of patients that are more distinct with regard to depressive symptom severity. To this end, we are currently conducting a large multicenter clinical study that

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compares a gamified version of MT-Phoenix with a nongamified version in patients with a major depressive disorder diagnosis after release from inpatient treatment. Fifth, although the majority of participants in the treatment condition achieved clinically significant improvement, the intervention should be further improved to ensure positive outcomes for an even larger number of individuals. Sixth, future studies should attempt to further improve both study and intervention adherence. To this end, qualitative analyses of user data may be helpful to systematically identify and improve flaws in both the technology and content of the 1.1 version of the intervention used in this study. Seventh, the use of a nonactive waitlist control group may have led to an overestimation of treatment effects as waitlist designs have been discussed as possible nocebo conditions in the literature [44]. Despite the acknowledged limitations of research designs using nonactive control conditions, we decided to use an economic waitlist design in this pilot trial. Eighth, the high dropout rate before initiation of the intervention in the intervention group is another factor that has to be regarded with

caution when interpreting the results of this study, especially in terms of the use of an intention-to-treat approach. Although uptake of automated online-based interventions with no personal contact between participants and study personnel is commonly observed as low in the literature [45], allocation to the control group and older age usually predict low uptake rates. Further observations are needed to identify possible reasons for this phenomenon beyond the aforementioned. Ninth, this pilot trial did not include an a priori power analysis to determine the sample size necessary for meaningful comparisons between treatment arms. Finally, despite the important role of approach-avoidance biases in depression, the current design prohibits assigning intervention effects to the AAMT. Further dismantling or comparison studies are needed to ascribe intervention effects to distinct techniques used in MT-Phoenix. Another possible solution to this limitation is to systematically measure approach and avoidance tendencies at both pre- and posttraining.

Acknowledgments

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Conflicts of Interest

CAL and MB report stock ownership of a company commercially disseminating digital mental health products. BE declares no conflicts of interest.

Multimedia Appendix 1 App screenshots. [PNG File, 335 KB - mental_v8i7e16643_app1.png]

Multimedia Appendix 2 Stimuli examples. [PNG File, 1024 KB - mental_v8i7e16643_app2.png]

Multimedia Appendix 3 CONSORT flow diagram. [PDF File (Adobe PDF File), 84 KB - mental_v8i7e16643_app3.pdf]

Multimedia Appendix 4 CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 359 KB - mental_v8i7e16643_app4.pdf]

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Abbreviations

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AAMT: approach-avoidance modification training ADS: Allgemeine Depressions-Skala ANCOVA: analysis of covariance CBM: cognitive bias modification CBT: cognitive-behavioral therapy MT-Phoenix: mentalis Phoenix

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PHQ-9: Patient Health Questionnaire-9 **WHO-5:** 5-item World Health Organization Well-being Index

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Original Paper

Usability and Acceptability of Two Smartphone Apps for Smoking Cessation Among Young Adults With Serious Mental Illness: Mixed Methods Study

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Abstract

Background: Young adults with serious mental illness (SMI) have higher smoking rates and lower cessation rates than young adults without SMI. Scalable interventions such as smartphone apps with evidence-based content (eg, the National Cancer Institute's [NCI's] QuitGuide and quitSTART) could increase access to potentially appealing and effective treatment for this group but have yet to be tested in this population.

Objective: The goal of this user-centered design study is to determine the user experience (including usability and acceptability) of 2 widely available apps developed by the NCI—QuitGuide and quitSTART—among young adult tobacco users with SMI.

Methods: We conducted usability and acceptability testing of QuitGuide and quitSTART among participants with SMI aged between 18 and 35 years who were stable in community mental health treatment between 2019 and 2020. Participants were randomly assigned to use QuitGuide or quitSTART on their smartphones. App usability was evaluated at baseline and following a 2-week field test of independent use via a video-recorded task completion protocol. Using a mixed method approach, we triangulated 4 data sources: nonparticipant observation, open-ended interviews, structured interviews (including the System Usability Scale [SUS]), and backend app use data obtained from the NCI. Quantitative data were analyzed using descriptive statistics, and qualitative data were analyzed using thematic analysis.

Results: Participants were 17 smokers who were not interested in quitting, with a mean age of 29 (SD 4) years; 41% (n=7) presented with psychotic disorders. Participants smoked an average of 15 (SD 7) cigarettes per day. The mean SUS scores for QuitGuide were similar at visits one and two (mean 64, SD 18 and mean 66, SD 18, respectively). The mean SUS scores for quitSTART numerically increased from visit one (mean 55, SD 20) to visit two (mean 64, SD 16). Acceptability scores followed the same pattern. Observed task completion rates were at least 75% (7/9 for QuitGuide, 6/8 for quitSTART) for both apps at both visits for all but 2 tasks. During the 13-day trial period, QuitGuide and quitSTART users interacted with their assigned app on an average of 4.6 (SD 2.8) days versus 10.8 (SD 3.5) days, for a mean total of 5.6 (SD 3.8) interactions versus 41 (SD 26) interactions, and responded to a median of 1 notification (range 0-8) versus 18.5 notifications (range 0-37), respectively. Qualitative comments indicated moderate to high satisfaction overall but also included concerns about the accuracy of the apps' feedback.

Conclusions: Both QuitGuide and quitSTART had acceptable levels of usability and mixed levels of acceptability among young adults with SMI. The higher level of engagement with quitSTART suggests that quitSTART may be a favorable tool for young adult smokers with SMI. However, clinical support or coaching may be needed to overcome initial usability issues.

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KEYWORDS

smoking cessation; mHealth; serious mental illness; smartphone application; digital health; psychiatric illness; tobacco treatment; mobile phone

Introduction

People with a serious mental illness (SMI), such as schizophrenia and severe mood or anxiety disorders, are more likely to smoke and less likely to quit than the general population [1-3]. Quitting before the age of 35 years may reverse the early mortality associated with smoking [4,5], providing an important rationale for engaging young smokers in cessation attempts. Although many studies have tested smoking cessation treatments in young adults in the general population [6,7], few studies have examined smoking cessation interventions in young adults with SMI [8,9].

Because of their widespread use and unique features, smartphone apps are a promising vehicle for smoking cessation interventions in people with SMI. Recent data demonstrate that nearly 80% of young adults with SMI use smartphones, and more than two-thirds are interested in using smartphones for health and wellness interventions [10]. Potential advantages of app interventions include the user's ability to tailor their experience by entering personal data, access content on demand, be cued to practice a behavioral change skill, and receive personalized feedback on their progress [11]. Recent findings demonstrate that young adults with SMI value these and other app features, suggesting that apps may be well suited to deliver smoking cessation support to this population [12]. Although hundreds of smartphone apps are available for smoking cessation, they vary widely in their content and features [11,13-17]. To our knowledge, none have been evaluated for usability, appeal, or effectiveness in young adults with SMI.

The National Cancer Institute (NCI) provides 2 smoking cessation apps based on behavioral change theories and clinical practice guidelines [11,14-16,18,19]—one designed for adults (QuitGuide) and the other designed for teens (quitSTART). These apps vary considerably in their content, layout, and design. Research on previous versions of these apps (2013-2015) indicated superior content quality than most other available smoking cessation apps [14,16,19]. In addition to their content, the design and usability of digital tools affect their use with time and thus require considerable attention to ensure that an app will be accessed as intended by a user group. In particular, people with SMI have greater difficulty understanding abstract labels, navigating complex content configurations, and understanding content organization, which may deter the use of standard apps [14,20,21]. Testing of QuitGuide (and its precursor QuitPal) among middle-aged adults with SMI resulted in mixed usability reviews [14,22]. However, neither QuitGuide nor quitSTART has been tested in youth or young adults with SMI who grew up in an era of widespread mobile technology.

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As young adults generally report greater confidence and ease of use with technology than middle-aged adults [23], young adults with SMI may have a reasonable ability to use standard apps, despite cognitive limitations and other impediments.

Although there is increasing interest in using smartphone technology for behavioral smoking cessation interventions, early phase assessment of this technology offers crucial data in preparation for an efficacy trial [13]. Usability ("how well users can learn and use a product to achieve their goals") and acceptability (which includes perceived value, usefulness, and desirability) are important components of user experience [24], and increased user engagement is associated with improved outcomes [25-27]. Given that the NCI's apps are easily available and free, contain high-quality content, and provide numerous features of interest to young adults with SMI [12], we seek to evaluate the apps' potential role for cessation interventions in this population by assessing their usability and appeal among young adults with SMI. We tested QuitGuide because we believe its simple design could be highly usable among young people with SMI, and we tested quitSTART because we believe its content and features could be more appealing than QuitGuide among young people with SMI.

Methods

Participants and Recruitment

Potentially eligible participants were recruited from a single large community mental health center in New England, United States, between May 2019 and February 2020 via flyers posted in waiting rooms and clinician invitations. Eligible participants were aged between 18 and 35 years, English speaking, stable in outpatient mental health treatment for SMI (ie, no hospitalization in the past 30 days per chart review), self-reported regular tobacco smokers (daily and nondaily) confirmed by breath carbon monoxide (CO)>7 parts per million (ppm) [28], and smartphone users (either Apple or Android). The desire to quit smoking was not required. We excluded patients who were pregnant or had a current, unstable substance use disorder per chart review or the patient's mental health center clinician. We aimed to recruit 5 participants with psychotic disorders and 5 with other SMI diagnoses per app, as prior usability research has demonstrated that more than 80% of usability issues can be identified after the first 5 participants [29].

Interventions

The QuitGuide and quitSTART apps are available free of charge on Smokefree.gov via the Apple Store or Google Play. Both apps encourage the user to set a quit date within 14 days, provide

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information through text with minimal graphics. Users can type

journal entries and can read a text-only guide on how to quit

smoking. In contrast, quitSTART utilizes a more complex layout

with bright colors and informal language that results in a cheery

tone and prominently displays relatively large symbols and few

words within the icons. Information in quitSTART is displayed

on swipeable cards, each with a different color background and

5 or fewer sentences. quitSTART provides a selection of 7

games for distraction that can be played within the app. Both apps allow users to set notifications based on time or location,

and quitSTART also automatically sends check-in notifications

that ask users how many cigarettes they have smoked since the

last check-in (QuitGuide does not have an analogous check-in

information about quitting, and allow users to enter personal data, such as how many cigarettes they smoked per day, what times of day they tend to smoke, and how much they spend per pack of cigarettes. They allow users to track cigarette cravings, slips (defined as cigarettes smoked for this study), and moods and provide information regarding coping with these experiences. They also provide information on users' progress, such as cigarettes avoided and dollars saved by not smoking. In addition, users can connect to social media through the apps.

Although QuitGuide and quitSTART offer many similar features, their design and content differ in a number of ways (Figure 1). QuitGuide offers a relatively linear layout, utilizes darker colors that convey a serious tone, and provides

Figure 1. Selected screenshots from QuitGuide (A-C) and quitSTART (D-F).

В А С Kack Staying Smokefree Jul. = **Ouit** Guide .Iıl 1. Keep Your Guard Up **0** DAYS SMOKEFREE MY QUIT DATE: Your body has changed since you began to 12/03/2020 smoke. Your brain has learned to crave okefree I Slipped nicotine. So certain people, places, things, and 0 DAYS SMOKEFREE situations can trigger a strong urge to smoke, 0 8 even years after quitting. That's why you should never take a puff again, no matter how **0 CIGARETTES NOT SMOKED** long it has been since you quit. MY REASON FOR QUITTING After you've quit, the urge to smoke often hits at the same times. For many people, the Write a message here that will re you what your reason is for quitti YOU SAVED \$0.00! hardest place to resist the urge is at home. And many urges hit when someone else is smoking YOU SAVED YOURSELF nearby. Identify your smoking triggers so you can be prepared for a temptation. If a craving 0 MINUTES! hits, use the skills you've learned. Share 2. Fight the Urge Manage My Mood It might be tempting to give in a smoke when a craving hits, but the longer you go without smoking the more these urges will fade. Resist Learn To Quit the urge to smoke. Having one or two go-to D E F **auitSTART** quit START quitSTART 0 days, 0 hr 0 m 10 s 0 days, 0 hr 0 m 4 s Inspirations Challenge Tips Quit Date You're not alone if you What's Up? continue to have cravings for a long time after you . auit. oops Many ex-smokers report Thursday, December 3 thinking about cigarettes long after physical addiction and withdrawal ends. These cravings may be set off by reminders of smoking, but with time they fade. When a craving strikes think of all the quit benefits you've gained! oacts others in ways beyond

feature).

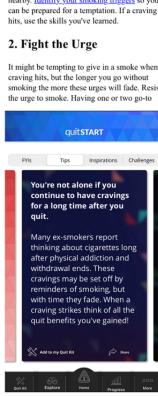
Procedures

Potentially eligible participants completed an informed consent process and proceeded with the study procedures once eligibility was confirmed. The first 12 participants received a US \$30 gift card to a retail store after completing each of the 2 study visits

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(for a total of US \$60). To improve recruitment, we increased compensation to US \$60 per visit (for a total of US \$120) for the last 5 participants. The New Hampshire State Institutional Review Board approved and monitored all study activities.

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Participation in the study lasted for 2 weeks. A trained researcher obtained demographics and diagnoses from record reviews and conducted structured interview assessments using a standardized procedure in which measures were administered aloud and answers were recorded on paper forms and then entered immediately into a computerized database. To assist with answering multiple-choice questions, answer choices were provided as visual cues on paper. A component of the assessment included a semistructured, open-ended interview, which was audio-recorded. Usability tasks were video-recorded.

At the first study visit (visit 1), participants completed a structured interview assessing demographics, tobacco use, and technology use. Participants were then randomly assigned to 1 of the 2 apps (QuitGuide or quitSTART) in groups of 4 blocked by age group [30]. They were asked to download the app on their smartphones. Researchers oriented the participants to the *think-aloud* method [31] and video-recorded participants as they completed a set of 9 predefined tasks without researcher guidance. Researchers then assessed participants' perceived acceptability and ease of use of their assigned app using the measures described below.

At the conclusion of the first study visit, we provided participants with a brief in-person tutorial on using their assigned app. The tutorial focused on helping users obtain skills for 3 tasks within the app: setting a quit date, logging and viewing logged moods, and logging and viewing logged *slips*; these tasks were chosen based on guideline-recommended interventions [32], the importance of mental health symptoms to smoking in this population [33], and our prior findings that young adults with SMI want to track cigarettes [12], respectively. We instructed participants to use the app independently over the following two-week period. We recommended that they try to skip cigarettes using their assigned app, but we did not advise participants to quit smoking for this study.

Following this period of independent use, participants returned for a second study visit (visit 2) and were assessed for smoking, perceptions of acceptability and usability, and task performance within the usability task protocol.

Measures

Demographics, Technology Use, and Diagnosis

Using a structured interview, researchers obtained participants' demographics at visit 1 and history of technology use (eg, frequency of internet use and app use) at visits 1 and 2. Psychiatric diagnosis and stability—as determined by mental health center clinicians—as well as insurance information were obtained via medical chart review at visit 1.

Tobacco History and Smoking

Researchers obtained participants' history of tobacco use (eg, duration and frequency of smoking, product use, and prior quit attempts) with a structured interview at visit 1. At visits 1 and 2, we assessed tobacco dependence using the Fagerström test for nicotine dependence [34], a 6-item scale shown to be reliable and valid among smokers with SMI [35]. We obtained smoking

status (yes or no) and confirmed this via exhaled breath CO>7 ppm (measured with a Covita Smokerlyzer) at both visits [28].

App Feature Preferences

Before performing the usability protocol, participants were asked to rate 15 app features on a 5-point Likert-type scale according to how important they believed the features were to help someone quit or reduce their smoking (Multimedia Appendix 1). The researchers chose the features included in this task based on clinical practice guidelines as well as prior studies reporting users' preferences within smoking cessation apps [32,36,37].

Observed App Usability

The following usability protocol was developed and administered following a user-centered design methodology [24,38]. Participants were oriented to the *think-aloud* procedure [31], after which they were given up to 5 minutes to freely explore the app while practicing thinking aloud. Participants were then asked to complete 9 specified tasks within the app (Multimedia Appendix 2) while thinking aloud and were provided as much time as they felt necessary to complete each task before moving on to the next task. Tasks included setting a quit date (Quitdate), reporting how many cigarettes they smoke per day (CigsperDay), logging a good mood (FeelingGood), logging a craving (Craving), finding information on how to quit smoking (HowtoQuit), logging a *slip* (smoked cigarette; Slipped), finding the progress page (Progress), connecting to social media (SocialMedia), and uploading a photo (Photo). Tasks were chosen based on US Clinical Practice Guidelines [32] as well as prior studies that evaluated frequently used features, desired app features, and features that have been correlated with point prevalence abstinence [12,36,37]. The participants' phone screens and hand motions were video-recorded as they completed the tasks.

The video recordings were scored as follows: a task was designated *completed* if the participant was able to reach the requested end point, regardless of whether they encountered difficulties along the way. A task was designated as *not completed* if the participant requested to skip the task or indicated that they had completed the task but did not reach the requested end point. *Usability challenges* were defined either as actions performed in the app that could not be used to reach the requested end point or difficulty reaching the requested end point verbalization during the task.

App Perceptions Qualitative Interview

At each visit, we conducted and audio recorded a brief, semistructured, open-ended qualitative interview to assess perceived ease of use and acceptability of the apps. During the first visit, interview questions assessed participants' general feedback about their assigned app, including likes and dislikes, and recommendations for changes to the apps' features, graphics, or layout. During the second visit, these questions were repeated with additional questions regarding app features, such as cigarette tracking and notifications.

System Usability Scale

The System Usability Scale (SUS) [39] is a validated questionnaire widely used to assess the usability of various technologies [22,40,41]. Scores range from 0 to 100, with values between 68 and 70 representing the average usability [42,43].

Perceived Ease of Use and Acceptability Questionnaire

A 14-item questionnaire assessed perceived ease of use and general acceptability of the apps, comprising a subset of questions derived from the Post-Study System Usability Questionnaire [44] and the Usefulness, Satisfaction, and Ease of Use Questionnaire [45]. We chose a subset of questions from these scales that have been previously used in people with SMI [46] and used a 5-point Likert-type scale for consistency among our study questions.

App Utilization

The NCI provided backend app usage data, including date and time of app use, features activated in the apps, and responses to notifications [47]. An app interaction was defined as the user opening the app and activating at least one feature (whether or not a notification from the app prompted this), with interaction instances separated by at least 25 minutes. A cutoff of 25 minutes was chosen to avoid interpreting prolonged interaction with one feature (such as reading the *How to Quit* section in QuitGuide or playing a game in quitSTART) before engaging with another feature as more than one episode of engagement with the app.

Participant Flow

We identified 98 potential candidates for inclusion in this study. Overall, 35% (34/98) potential candidates were ineligible based on prescreening criteria, 7% (7/98) were unable to participate because of time constraints related to work or childcare responsibilities, 1% (1/98) was in the process of moving to another location, 10% (10/98) did not have working smartphones, and 28% (27/98) declined to participate. The remaining 19% (19/98) individuals provided informed consent. Of these, 2% (2/98) were ultimately deemed ineligible because of breath CO below the cutoff for inclusion. Thus, 17% (17/98) participants were included in the study. All 17 participants completed visits 1 and 2 (100% retention). Backend app usage data from the 2-week trial period were available for 15 out of 17 participants (88%; home app use data were not available for 2 quitSTART participants because of issues with the participants' phones, and these participants were excluded from the app utilization analyses).

Data Analysis

Quantitative Analyses

Descriptive statistics were used for all quantitative analyses; 1 usability task was missing for 1 participant at visit 1. These data were omitted from the analysis. For the 15 participants with available backend app usage data, we analyzed home app use on days 2 to 14 (full days with the opportunity for app use during the entire day). The first and last days of app use were excluded because participants completed the usability tasks on those days. Complete data were available for all 15 participants on all days except day 14 as a participant was assessed a day earlier.

Video recordings from the usability task completion protocol were reviewed to assess the participants' ability to reach the prespecified end point for each task and identify difficulties encountered during task completion. Participant navigation through the apps was compared with maps of each app created by the research team to determine task completion rates and usability challenges. Researchers also included participants' comments during the session regarding their intended navigation through the apps to further assess usability challenges. During the initial coding of the videos, definitions regarding usability challenges were refined until a final set of definitions was reached. The final coding of the video recordings was performed using this set of definitions.

Qualitative Analyses

Audio recordings of the qualitative responses to the semistructured interview questions were transcribed and compared with the original audio files to ensure accuracy. The transcripts were analyzed using thematic analytical techniques [48]. After conducting an immersive review of the data set, 3 researchers (MAG, NJK, and AEM) independently applied structural and inductive coding methodologies [49] to each of the interview transcripts using either Microsoft Word (Microsoft Corporation) or the qualitative data analysis program, Atlas.ti (Version 8, ATLAS.ti Scientific Software Development GmbH). Because of the descriptive nature of the data, themes naturally emerged during the initial coding process, and researchers reached a consensus regarding these themes after a single discussion. Negative case analysis was used to ensure that the entire data set was represented in the emerging themes.

Results

Participant Characteristics

As shown in Table 1, participants were 17 daily smokers with a mean age of 29 (SD 4) years, 41% (7/17) were diagnosed with psychotic disorders, and 94% (16/17) were Medicare or Medicaid beneficiaries (Table 1). Participants smoked an average of 15 (SD 7) cigarettes per day and were moderately dependent on tobacco (mean Fagerström score 4.4, SD 1.8). More than 90% (16/17) of participants reported using smartphone apps on a daily basis, and more than 75% (13/17) had previously downloaded an app related to health and wellness. Of the 17 participants, only 4 (24%) endorsed previously trying a smartphone app to aid in a quit smoking attempt; of the remaining 13 participants, 11 (85%) were unaware that smartphone apps were available to help people quit smoking.



Table 1. Participant characteristics (N=17).

Characteristic	Values
Demographic and clinical characteristics	
Age (years), mean (SD)	29 (4)
Female, n (%)	7 (41)
White, n (%)	16 (94)
High school diploma, n (%)	14 (82)
Psychotic disorder, n (%)	7 (41)
Currently employed (part-time or full-time), n (%)	8 (47)
Medicaid or Medicare beneficiary, n (%)	16 (94)
Tobacco use characteristics	
Cigarettes per day, mean (SD)	15 (7)
Baseline breath carbon monoxide, mean (SD)	26 (11)
Fagerström score, mean (SD)	4.4 (1.8)
Age started smoking, mean (SD)	13 (3.5)
Previous quit attempt, n (%)	15 (88)
Smartphone use characteristics, n (%)	
Use smartphone ≥twice daily	16 (94)
Use apps at least once per day	16 (94)
Ever downloaded a health app	13 (77)
Would try app if recommended by a doctor	14 (82)

Appeal of App Features

A majority of participants agreed or strongly agreed at both visits that most of the proposed app features were important to help someone quit smoking (Multimedia Appendix 3). The importance of location tracking increased from 35% (6/17) of participants at visit 1 to 59% (10/17) at visit 2, whereas the importance of tracking smoking triggers decreased from 71% (12/17) to 47% (8/17). Less than half of the participants indicated that sharing progress on social media was important: 41% (7/17) at both visits.

Usability

The mean SUS scores for QuitGuide were similar at visits 1 and 2 (64; range 30-77.5, SD 18, and 66; range 25-85, SD 18, respectively). In contrast, mean SUS scores for quitSTART

numerically increased from visit 1 (55; range 25-82.5, SD 20) to visit 2 (64; range 35-85, SD 16). Responses to the ease of use questions followed a similar pattern (Table 2). By the second visit, at least three-quarters of both QuitGuide and quitSTART users reported feeling satisfied with their app's ease of use. In general, QuitGuide's ease of use question responses were similar at visits 1 and 2, whereas affirmative responses to most questions regarding quitSTART's ease of use increased between visits 1 and 2.

The observed usability task completion rates for both apps were high at both visits (Figures 2 and 3). At the first study visit, all 9 tasks were successfully completed by at least 75% of participants assigned to QuitGuide (7/9 for the first 8 tasks and 6/8 for the final task); similarly, 8 of the 9 tasks were successfully completed at the first study visit by at least 75% (6/8) of participants assigned to quitSTART.



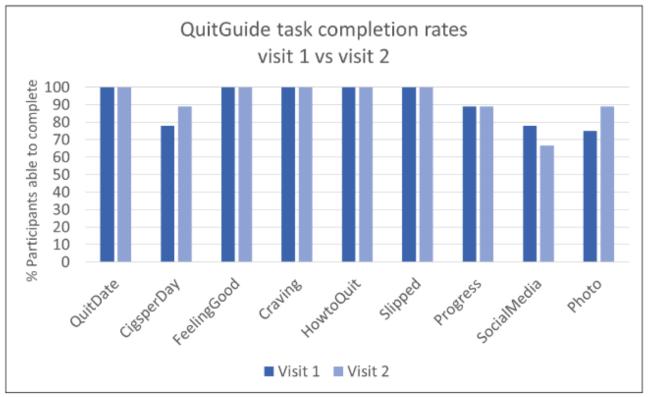
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Table 2. Ease of use and acceptability questionnaire results.

Statement ^a	QuitGuide (n=9)		quitSTART (n=8)	
	Visit 1, n (%)	Visit 2, n (%)	Visit 1, n (%)	Visit 2, n (%)
Ease of use	•			
Overall, I am satisfied with how easy it is to use the app	7 (78)	7 (78)	4 (50)	6 (75)
I felt comfortable using the app	5 (56)	6 (67)	4 (50)	6 (75)
It was easy to learn to use the app	7 (78)	8 (89)	2 (25)	5 (63)
Whenever I made a mistake using the app, I could recover quickly and easily	8 (89)	6 (67)	5 (63)	4 (50)
It was easy to find the information I needed	6 (67)	7 (78)	1 (13)	5 (63)
How things appeared on the screen was clear	7 (78)	7 (78)	4 (50)	5 (63)
Acceptability				
Overall, I am satisfied with the app	6 (67)	5 (56)	4 (50)	5 (63)
I liked using the app	5 (56)	5 (56)	2 (25)	5 (63)
The app has all the functions and capabilities I expect it to have	6 (67)	4 (44)	3 (38)	2 (25)
I would recommend the app to a friend	5 (56)	7 (78)	3 (38)	5 (63)
The app is fun to use	4 (44)	4 (44)	3 (38)	2 (25)
The app works the way I want it to	4 (44)	4 (44)	2 (25)	1 (13)
The app can help me quit smoking	5 (56)	6 (67)	2 (25)	5 (63)
The app was interactive enough	6 (67)	5 (56)	4 (50)	5 (63)

^aPercentage of participants who agree or strongly agree with the corresponding statements.

Figure 2. QuitGuide task completion rates.



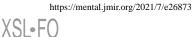
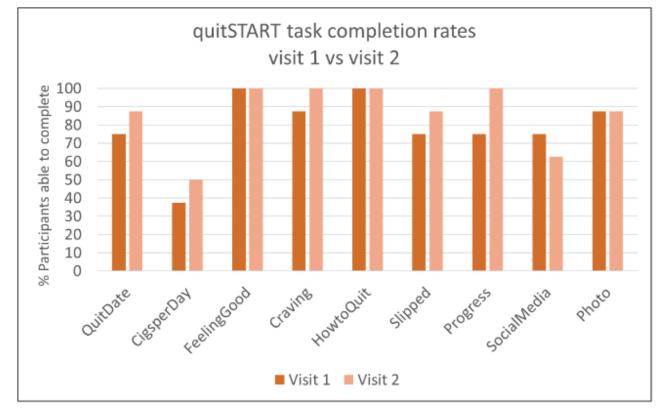


Figure 3. quitSTART task completion rates.



The most common usability challenges occurred during attempts at 4 tasks: entering the number of cigarettes smoked per day, setting a quit date, connecting to social media, and uploading a photo. The first 3 of these tasks required navigation through menus, whereas the remaining tasks we assessed could be reached with a single click from the home screen, suggesting that menu navigation was associated with lower usability. The photo feature in QuitGuide (but not quitSTART) could also be accessed from the home screen but was uniquely challenging in that it only intermittently opened when users clicked on it because of a bug in the app (which has since been fixed).

Some feature locations were not intuitive to the participants. Users could enter their quit date during the initial app setup and later in their Quit Plan (QuitGuide) or Profile (quitSTART). Additionally, the apps were not designed to track cigarettes smoked on a daily basis but asked users to enter the average cigarettes smoked per day in the same locations (ie, Quit Plan or Profile). Many participants tried to enter cigarettes smoked or change their quit dates on the progress pages, but these pages were designed only for viewing information and not entering information. This sometimes led to participant frustration after repeated attempts to click on the pages' inactive icons. Although some participants struggled with this issue, others were able to complete these tasks by accessing their Quit Plan in QuitGuide or their Profile in quitSTART.

Notably, setting a quit date required the user to set a date within the next 14 days. Although most users were ultimately able to find where to set a quit date, they were not planning to quit during this time frame, and the apps did not allow them to enter a later date (although quitSTART did include a *not ready* option). Both apps recommended users to choose a quit date

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within the next 14 days; however, most participants did not see this explanation located above the date selection field, and many users became confused when the apps defaulted to 14 days from the current date. They allowed the app to choose a quit date for them, even though they verbalized that the selected date was an unrealistic goal that they could not achieve.

Common menu navigation challenges involved misunderstanding menu labels and expecting to find features in certain locations in the app based on prior experience with other apps. A commonly misunderstood menu label was My tags for both apps. Although the intended meaning was to identify (ie, tag) the times and locations when participants were at a higher risk of smoking, many participants interpreted this label to indicate a connection to social media. Other tasks, such as uploading a photo in QuitGuide, proved problematic when participants tried to use their experience with other apps to guide them. For example, many participants expected to find this option in the Settings feature of the app, though the Settings feature does not contain this option. Instead, the photo feature could be accessed within the Quit Plan under Reasons to Be Smokefree. In contrast, quitSTART users were able to upload a photo in the Profile section of the app (QuitGuide does not have a Profile feature).

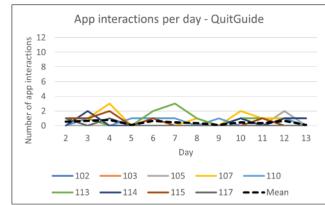
Finally, participants often used personal information (data) entry pathways to complete tasks unrelated to logging or tracking personal information in the app, potentially leading to inaccurate feedback to the user if the app tailors feedback based on these features. For example, users can obtain information about quitting in both apps by touching the *slip* button on the home page, and both apps provide a tally of the user's entered slips on the Progress page. Participants in both groups frequently

used the slip feature to obtain information about quitting, often favoring it over alternate pathways that involved more complicated menu navigation (which did not involve data entry). Although they were ultimately able to reach the desired end point, using these pathways when not planning to log information influences feedback on the Progress page, which users perceive as being inaccurate as discussed below.

Acceptability

Responses to the acceptability questions are presented in Table 2. Notably, more than half (5/9, 56%) of QuitGuide users indicated that they liked using the app at both visits, whereas the proportion of users who liked using quitSTART increased from 25% (2/8) at visit 1 to 63% (5/8) at visit 2. About

Figure 4. App interactions per day by participant for QuitGuide and quitSTART.



Tobacco Use at Follow-Up

At visit 2, 78% (7/9) QuitGuide users reported that they had tried to quit or cut back during the 2-week trial period (mean CO for all QuitGuide users 25, SD 12); no participants quit. Similarly, 75% (6/8) of quitSTART users reported trying to quit or cut back during the study (mean CO for all quitSTART users 25, SD 16). In fact, 25% (2/8) of quitSTART users reported that they no longer smoked at visit 2 (both confirmed with breath CO < 7 ppm), having instead switched completely to e-cigarettes.

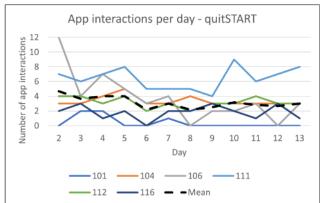
Qualitative Feedback and User Experience

Themes resulting from qualitative data analysis of QuitGuide interview data conveyed a mildly positive view of the app. In contrast, the themes among quitSTART users included stronger reactions that were both positive and negative. A major theme among QuitGuide users at both visits was that the app was easy to use; although a minor theme, participants found some aspects of navigation confusing. Among quitSTART users, difficult navigation was a theme during the first visit, but ease of use was a stronger theme during the second visit.

The most prominent theme at visit 1 was the same for both apps: participants liked that the apps used a positive and supportive tone and provided motivational quotes and feedback on money saved. They thought that the apps could track cigarettes smoked on a daily basis and liked the idea of that feature. Most quitSTART users also expressed interest in the games included within the quitSTART app at visit 1 (QuitGuide does not offer games). two-thirds of users thought each app would help them quit smoking at the second study visit, although fewer participants in each group felt that their assigned app had all the functions they expected it to have at visit 2 compared with visit 1.

App Utilization

In contrast to the SUS scores, app use patterns demonstrated dramatically greater engagement with quitSTART than QuitGuide (Figure 4). Compared with QuitGuide users, quitSTART users demonstrated greater mean days of use (10.8, SD 3.5, vs 4.6, SD 2.8), greater mean total app interactions (41, SD 26, vs 5.6, SD 3.8), and greater median responses to notifications (18.5, range 0-37, vs 1, range 0-8) during the 13-day period.



At visit 2, many participants continued to perceive both apps as positive and supportive and noted that this was a strength of the apps. Many participants voiced a general concern that a negative tone or repeated reminders of a lack of progress would evoke feelings of guilt and failure, which could undermine their quit attempts. Although some participants worried that calling a smoked cigarette a *slip* in these apps could evoke negative emotions, most participants in both groups commented on the overall positive tone of the apps and how this was a necessary attribute to maintain their engagement over time. In addition, a strong theme was feeling cared for by the apps. A quitSTART user, who was initially very skeptical about using a smartphone app to quit smoking, commented on quitSTART's check-ins at visit 2:

You know, it's nice. Like 'Oh, okay, maybe someone cares out there'. [Participant 108]

Similarly, a QuitGuide user noted:

And it's good to have something looking out for you and asking you how you feel. It makes you feel, like, a little better. [Participant 105]

Another strong theme for users of both apps was the importance of notifications at the second study visit. QuitGuide users wished that they had received more notifications, as they often forgot to open the app. quitSTART users often mentioned that the *check-in* notification feature was one of the most valued app features because it reminded them to use the app and increased their awareness of their smoking and because they appreciated the caring tone of these notifications. In fact, many quitSTART

users (who received multiple notifications per day) indicated that they wished that they had received more.

In addition to noting the strengths of the apps at visit 2, a strong theme among participants in both groups was frustration at how the feedback features ultimately functioned for them. A quitSTART participant noted:

It kept giving me badges that I didn't do...It gave me one at seven days smoke free, which I wasn't, even though I was trying not to smoke. [Participant 106]

Similar sentiments were expressed by QuitGuide users:

...I believe it says there's, like, 14 days without a cigarette, but I was writing that I slipped up like it said, and it wasn't correcting it. [Participant 103]

Some of this app feedback relied on the users' entered quit dates and could be updated by choosing a new quit date. However, only some user data reset when a new quit date is chosen, which further confuses some participants. In addition, some of the calculations were mathematically incorrect, possibly because of a bug in the app.

Many participants in both groups also expressed a desire for a cigarette tracking feature that enabled them to track cutting down, which they felt was important to frame their progress positively. Instead of tracking *slips* or smoke-free days, they expressed a desire for a daily cigarette tally, so they could track incremental progress toward quitting. A QuitGuide user stated:

You know, this day I'm only gonna smoke this many cigarettes and track each cigarette I smoked. Because I felt like that would be less of me failing, and more like the app helping me be able to see, like, 'Hey today you smoked twenty. Yesterday you smoked twenty-five. Good job, you cut a couple out.' [Participant 102]

Participants in both groups also wished that there were more sections in the apps where they could enter free-text responses to prompts (such as their moods or their triggers for smoking) instead of choosing from a prepopulated menu. As a participant noted:

There's gotta be, like, a write your own response of why you slipped if you slipped. You know, if you wanna try to track what's causing you to smoke, you can't have just ten preset answers. There's so much more to life than that. [Participant 102]

Notably, most participants had little desire to connect with others on social media about their quit attempts. They worried that sharing information about quitting on social media could be detrimental if they were not successful in their quit attempts. In contrast, many suggested that the apps include a chat feature to connect with other app users. They felt that social support from others who were working on quitting, and therefore understood the challenge of quitting, could be helpful.

Participants provided opposing opinions regarding many of the remaining app features, highlighting the importance of a personalized experience for each user. Some participants planned to use only 1 or 2 app features, whereas others indicated their intention to explore all of the different features within their assigned app. Although many participants stated that they would

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not use certain app features, they also commonly recommended against removing these features from the apps because they thought other users might find them helpful. For example, in describing the games in quitSTART, a user stated:

...like, I would hate for them not to be there, but I just didn't play them. [Participant 106]

These young adult users of quitSTART made no comments indicating that they thought it was designed for teens and not for them.

Discussion

Principal Findings

In this user-centered design study, we used a mixed methods approach and triangulated multiple measures to assess usability and appeal. We found that QuitGuide demonstrated greater initial ease of use and acceptability, which remained stable over time. In contrast, quitSTART demonstrated lower initial usability and acceptability, which improved over time to a level similar to that of QuitGuide. Although SUS scores indicated below average usability for both apps (average score between 68 and 70 [42,43]), the objective quantitative and qualitative usability measures provided positive indications of usability. First, objective task completion demonstrated that at least three-quarters of participants were able to complete all but one task upon first downloading the apps. Second, during the open-ended qualitative interviews, participants stated that the apps were easy to use (at both visits for QuitGuide, and primarily at the follow-up visit for quitSTART). Several other measures also suggested that quitSTART performed well and provided value to users. First, the backend administrative data analyses showed that although user engagement with QuitGuide remained low during the trial period, quitSTART users sustained a substantially higher level of engagement (discussed in detail below). Second, although none of the users were required to engage in a quit attempt during this study, 2 of the 8 quitSTART users had biologically confirmed abstinence from smoking at follow-up compared with none of the QuitGuide users. Notably, although quitSTART was designed for teens, by Visit 2 it was perceived positively based on the qualitative feedback and a high level of engagement among these young adults with SMI. Given the acceptable perceived usability at the second visit, the much higher level of engagement with quitSTART, and previous work demonstrating the importance of engagement to cessation outcomes [25-27], our findings suggest that quitSTART may be a reasonable choice for use among young adult smokers with SMI, particularly if support and coaching facilitate initial use of the app.

A strong behavioral indicator of usability and acceptability is engagement over time. One of the most striking differences we found between the apps was the participants' engagement, or frequency of use, during the 2-week trial period. Engagement with quitSTART, 2 to 4 interactions per day that persisted steadily over the 2 weeks, was much more favorable than engagement with QuitGuide (less than 1 per day). On the basis of participant feedback, app notifications played an important role in the different use patterns of the apps. Although some participants initially voiced concern about receiving too many

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notifications, many ultimately felt that notifications were positive and important to their engagement with the apps. Because our participants were not required to wish to quit smoking and were not engaged in a cessation program, the level of engagement here is likely lower than what would be seen among smokers trying to quit.

Notably, although both apps contain content and features that participants deemed important and desirable during a quit attempt, the overall appeal of the apps was influenced by perceptions of the app's tone and data tracking. Previous work [50-53] has documented the importance of positive message framing to engage tobacco users in considering a quit or reduction attempt, and our findings further support this. In addition, our participants noted the importance of a positive tone within the apps to support ongoing motivation and indicated that a negative tone could undermine their quit or reduction attempts. Users in both groups felt that the apps were overall positive and motivating and indicated that this was a key factor in their interest in using the apps.

Not surprisingly, the perceived inaccuracy of the feedback (such as the number of slips or money saved) had a significant impact on users' overall perceptions of the apps. Some of the perceived inaccuracy was because of the apps' reliance on the entered quit date to calculate money saved and cigarettes avoided. Our participants were not required to engage in a quit attempt for this study, and some of the perceived data inaccuracy was likely because of choosing a default date without intending to quit on that day. Although the apps may be intended for users who plan to quit abruptly, our participants expressed interest in using the apps within a reduction-to-quit framework [54]. Incorporation of features within the app to support initial smoking reduction followed by cessation may be beneficial for this population. In addition, our findings indicate that entering personal information to track progress should be unlinked from other app features such as viewing inspirational quotes; otherwise, accessing these other features could also affect the accuracy of the users' feedback.

Comparison With Previous Work

Compared with recently reported data among middle-aged adults with SMI who were trying to quit smoking, QuitGuide usability scores were lower among these young adult participants [41]. Among middle-aged adults with SMI, the mean SUS score for young adults was 78.4 (SD 16.5), compared with 64 (SD 18) in this study. We are not aware of other published usability studies of the QuitGuide app among young adults with SMI.

Comparison of user engagement data among studies can be challenging because of different durations of follow-up, varied measurements of app engagement (eg, app openings, days of use, and specific actions within the app), and previously demonstrated decay in the use of eHealth interventions over time [25]. Nevertheless, our QuitGuide findings appear similar to those from other studies. In the study of middle-aged adults with SMI by Vilardaga et al [41], participants used the app on 32 (SD 24.5) days during the 120-day trial period, whereas the young adults in this study used the app on 4.6 days during our 13-day study period. Bricker et al [55,56] have previously assessed QuitGuide as a comparator app for evaluating novel

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cessation apps among middle-aged general population smokers trying to quit. In one trial [55], QuitGuide users self-reported opening the app an average of 15 times during an 8-week study period (days of use not reported). In another study [56], backend app usage data demonstrated that QuitGuide users opened the app 9.9 times on 7.1 days during a 12-month trial period. Satisfaction with QuitGuide ranged from 45%-70% in these trials. Hebert et al [57] have also assessed QuitGuide as a comparator for a just-in-time adaptive intervention. In this pilot study, QuitGuide users opened the app an average of 9.9 times on an average of 10.6 days during a 5-week trial period. Satisfaction scores for QuitGuide were lower than for the just-in-time intervention or usual care (in-person and/or telephone counseling), with QuitGuide averaging 3.64/5 for the survey item "I believe that my treatment will help me quit smoking and stay quit."

Although we were unable to identify other studies that assessed the acceptability, usability, or user engagement of quitSTART, our findings regarding user engagement and satisfaction with quitSTART are promising compared with those of other apps in the general population of adult tobacco users. This includes studies of SmartQuit [55], in which users opened the app an average of 37 times during the 8-week trial period (days of use not reported), and of whom 59% were satisfied with SmartQuit overall; iCanQuit [56], in which users opened the app an average of 37.5 times on an average of 24.3 days during the 12 month trial period, and more than 80% of iCanQuit users found their app useful for quitting; and Clickotine [58], in which users opened the app an average of 100.6 times during the 8-week study period (days of use not reported).

Our qualitative usability findings are similar to those of Ferron et al [14], which found that middle-aged adults with SMI noted text-heavy apps to be unappealing, had difficulty navigating more engaging apps because of abstract symbols and one-word menu labels, and had difficulty following subtle directions to use various app features. Notably, our young adult participants rapidly overcame most challenges with these design features in quitSTART after a brief coaching session and 2 weeks of independent use.

Our acceptability findings are similar to those of other evaluations of middle-aged adults with SMI [40,59]. The evaluation of an earlier version of QuitGuide (QuitPal) by Vilardaga et al [40] highlighted participants' desire for finer-grained cigarette tracking and interactive and motivating features, as well as the importance of seeing incremental progress. Klein et al [59] found that middle-aged participants with SMI expressed the importance of social support within the app, the role of caring and positivity from the app, and concern for negative emotions related to relapse. Our findings also significantly overlap with the assessment of Struik et al [60] among general population young adult tobacco users who assessed the Crush the Crave app, including the importance of positive message framing, preference for lighter colors, and frustration that progress feedback based on the user's quit date was not accurate.

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Limitations

Our study has several limitations. First, we included a small number of participants because prior research has demonstrated the adequacy of this number for identifying most usability issues [29], but our acceptability findings should be interpreted with caution. Second, participants were not required to be interested in quitting or engaging in a quit attempt for this study. App preferences may differ during planned quit attempts when engagement is likely to be higher. Although more than three-quarters of our participants reported attempting to quit or reduce their smoking during the trial period, they had not committed to cessation treatment. This may have contributed to the frustration with inaccurate feedback, which was based on the entered quit date. In addition, engagement may differ in the context of a study compared with the use outside of the study context. However, the consistency between our findings and those of previous research supports the validity of our usability and acceptability findings. Finally, our 2-week follow-up period was relatively short, and user engagement has been shown to decay with time. However, users of quitSTART sustained their use for these 2 weeks, indicating a promising level of initial usability and acceptability during that period.

Conclusions

Overall, we found that both NCI's smoking cessation apps (QuitGuide and quitSTART) were usable and appealing among young adults with SMI. However, engagement with quitSTART was high, and ratings of its usability improved with time, indicating that quitSTART may be a more favorable tool than QuitGuide for young adult smokers with SMI. Our findings suggest a possible role for quitSTART during quit attempts in this group; however, clinical support or coaching may be needed to overcome initial usability issues. These findings may assist with the development and adaptation of interventions for young adults with SMI.

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Authors' Contributions

MAG and MFB designed the study with qualitative expertise provided by MRL and usability testing expertise provided by RV. MAG collected the data and performed quantitative data analysis. MAG, NJK, and AEM performed qualitative data analysis with an overview of the activities provided by MFB, MRL, and RV. MAG and MFB prepared the original draft of the manuscript. MFB, MRL, RV, NJK, and AEM reviewed and provided comments on the manuscript before submission.

Conflicts of Interest

MFB received research funding support from Alkermes. The other authors have no competing interests to declare.

Multimedia Appendix 1 Features included in the feature preference task. [DOCX File , 16 KB - mental_v8i7e26873_app1.docx]

Multimedia Appendix 2 Usability tasks. [DOCX File, 16 KB - mental_v8i7e26873_app2.docx]

Multimedia Appendix 3 App feature preferences. [DOCX File , 20 KB - mental_v8i7e26873_app3.docx]

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Abbreviations

CO: carbon monoxide NCI: National Cancer Institute ppm: parts per million SMI: serious mental illness SUS: System Usability Scale

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Review

Acceptability of Computerized Cognitive Behavioral Therapy for Adults: Umbrella Review

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Abstract

Background: Mental ill-health presents a major public health problem. A potential part solution that is receiving increasing attention is computer-delivered psychological therapy, particularly during the COVID-19 pandemic as health care systems moved to remote service delivery. However, computerized cognitive behavioral therapy (cCBT) requires active engagement by service users, and low adherence may minimize treatment effectiveness. Therefore, it is important to investigate the acceptability of cCBT to understand implementation issues and maximize potential benefits.

Objective: This study aimed to produce a critical appraisal of published reviews about the acceptability of cCBT for adults.

Methods: An umbrella review informed by the Joanna Briggs Institute (JBI) methodology identified systematic reviews about the acceptability of cCBT for common adult mental disorders. Acceptability was operationalized in terms of uptake of, dropping out from, or completion of cCBT treatment; factors that facilitated or impeded adherence; and reports about user, carer, and health care professional experience and satisfaction with cCBT. Databases were searched using search terms informed by relevant published research. Review selection and quality appraisal were guided by the JBI methodology and the AMSTAR tool and undertaken independently by 2 reviewers.

Results: The systematic searches of databases identified 234 titles, and 9 reviews (covering 151 unique studies) met the criteria. Most studies were comprised of service users with depression, anxiety, or specifically, panic disorder or phobia. Operationalization of acceptability varied across reviews, thereby making it difficult to synthesize results. There was a similar number of guided and unguided cCBT programs; 34% of guided and 36% of unguided users dropped out; and guidance included email, telephone, face-to-face, and discussion forum support. Guided cCBT was completed in full by 8%-74% of the participants, while 94% completed one module and 67%-84% completed some modules. Unguided cCBT was completed in full by 16%-66% of participants, while 95% completed one module and 54%-93% completed some modules. Guided cCBT appeared to be associated with adherence (sustained via telephone). A preference for face-to-face CBT compared to cCBT, low motivation, too busy or not having enough time, and personal circumstances were stated as reasons for dropping out. Yet, some users favored the anonymous nature of cCBT, and the capacity to undertake cCBT in one's own time was deemed beneficial but also led to avoidance of cCBT. There was inconclusive evidence for an association between sociodemographic variables, mental health, and recommended cCBT. Overall, the results indicated that service users' preferences were important considerations regarding the use of cCBT.

Conclusions: The review indicated that "one size did not fit all" regarding the acceptability of cCBT and that individual tailoring of cCBT is required in order to increase population reach, uptake, and adherence and therefore, deliver treatment benefits and improve mental health.

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KEYWORDS

computerized/internet cognitive behavioral therapy; cCBT; iCBT; acceptability; mental health; umbrella review

Introduction

Globally, mental health problems and mental disorders are a major public health concern [1]. Collectively, the results of multiple studies and systematic reviews over the last few decades appear to point to the overall effectiveness of cognitive behavioral therapy (CBT) [2,3]. CBT aims to help individuals overcome, change, and challenge aberrant thought processes and behaviors [4]. The advent of the internet and surge in the use of computer technology led to the delivery of CBT via computer- or web-based platforms, with demonstrable effectiveness to treat and manage mental health conditions and symptoms [5-7]. Computerized delivery of CBT (cCBT) is a generic term that encompasses web-based or internet-delivered CBT (iCBT). It can be delivered in the community, at home, or in a health care setting and can be self-directed or self-guided by the user or is guided via telephone or email by a health care professional or practitioner [8]. There is evidence to suggest that cCBT may be as effective as face-to-face delivered CBT [9,10], and, for example, the UK National Institute for Health and Clinical Excellence (NICE) recommends the use of cCBT for specific conditions such as mild depression [11]. Compared to face-to-face CBT, cCBT may remove or minimize barriers associated with uptake and be more accessible (eg, for rural dwellers and individuals who have mobility issues) and affordable; thereby, it may reduce waiting times and be more cost-effective [12,13]. In addition, the absence of in-person contact with cCBT delivery may reduce stigma associated with mental health service use for some individuals even though perceptions towards help-seeking for mental health in many countries have taken a positive step over recent years [14].

The onset of a global pandemic of the SARS-CoV-2 virus occurred during the conduct of this umbrella review. Government-directed measures designed to control the transmission of the virus such as social distancing, quarantine, and self-isolation were implemented widely. These measures necessitated a move to remote-delivered therapies [15].

Mental health interventions such as CBT require active engagement from participants in order to affect therapeutic change. Adherence and the degree to which an individual engages with, and completes, a web-based intervention is a potential limitation. Poor adherence limits exposure to a web or computerized program, and an insufficient "dose" may impact treatment effectiveness and reduce the likelihood of an improved outcome for people with mental health problems, particularly if they drop out of a program. It is important to enhance understanding about acceptability and adherence in order to gain insights about the implementation of cCBT and to increase its effectiveness [16]. Improving understanding about acceptability is even more important now given that mental disorders and mental health problems appear to be increasing due to the direct and indirect effects of COVID-19 and the possibility that remotely delivered psychological therapies may become the norm in the context of strategies designed to minimize virus transmission [17]. The results of our initial scoping activity indicated that there has been an exponential increase in the number of systematic reviews and there are international collaborations that specialize in systematic reviews and maintain databases of systematic reviews. Therefore, we decided to synthesize the evidence from existing systematic reviews regarding the acceptability of cCBT by undertaking a review of reviews or an "umbrella" review [18]. We used cCBT to encompass also iCBT, as some programs are delivered without the internet (eg, CD-ROMs), and our focus was on mental health generally to encompass experiences with both psychological symptoms and clinically diagnosed disorders. Acceptability [19] was defined broadly as encompassing factors that facilitate or impede uptake, adherence, and completion or that contribute to attrition (including reported reasons for dropping out) and satisfaction. This review also captured service users' and therapists' or clinicians' views of cCBT [19].

Methods

The search strategy for the umbrella review [18] was informed by the use of the following key concepts from published reviews: "systematic reviews," "cCBT," "iCBT," "barriers," "facilitators," and "common mental disorders and symptoms" [20-22]. The Boolean operators "AND" and "OR" were used to combine search terms between and within concepts, respectively. The PubMed, EMBASE, MEDLINE, PsycINFO, and CINAHL databases were searched from inception until December 18, 2019 (see Textbox 1). Titles and abstracts were imported into an Excel spreadsheet, and duplicates were removed by CT. MD and CT independently assessed each title and abstract against the eligibility criteria and independently applied the Joanne Briggs Institute critical appraisal checklist for systematic reviews [18], supplemented with one item from the AMSTAR (A Measurement Tool to Assess Systematic Reviews) checklist [23]. Any disagreements regarding inclusion of articles were resolved through discussion. Results of the quality appraisal checklist are reported in Multimedia Appendix 1. Review papers were included in the umbrella review if they met the criteria that are detailed in the following sections.



Textbox 1. MEDLINE search strategy (adapted for other databases).

#1 ((internet or web or online) adj3 (cognitive or behavio*)).ti,ab,kf. OR (iCBT or i-CBT or ePsych* or e-Psych or cCBT).ti,ab,kf

#2 computer communication networks/ or internet/ or blogging/ or social media/ OR cell phones/ or smartphone/ or text messaging/ or videoconferencing/ or webcasts as topic/ or wireless technology/ OR Telemedicine/ OR (eLearning or blended learning).ti,kf. OR (videoconferenc* or video conferenc*).ti,kf OR (synchronous or asynchronous or (electronic adj2 deliver*)).ti,kf. OR android.ti,ab,kf. OR (app or apps or blog*).ti,ab,kf. OR (cell phone or cellphone or chat room or computer* or cyber* or digital or technology based or DVD).ti,ab,kf. OR CD-ROM.ti,ab,kf. OR (eHealth or electronic health or email*).ti,ab,kf. OR (ePortal or eTherap* or forum* or gaming or information technolog* or instant messag* or messaging or internet* or ipad or iphone or ipod or podcast or smart phone or smartphone or social network* site* or social networking or mHealth or mobile or multimedia or online* or personal digital assistant or PDA or SMS or social medi* or software or telecomm* or telehealth* or telemed* or telemonitor* or telepsych* or teletherap* or text messag* or texting or virtual* or web* or WWW).ti,ab,kf.hw.

#3 (behavio* or cognitive).ti. OR ((cognitive or behavio*) adj2 (activat* or component? or defusion or modif* or restructur* or technique* or intervention or treatment* or therap* or train*)).mp. OR (psychotherap* or psychological therap* or cognitive behavio*).mp. OR ((acceptance* or commitment*) adj3 therap*).mp. OR (rational emotive or RET or problem sol* or PST or problem focus* or solution focus* or trauma focus* or psychoeducat* or psychodrama or mindfulness* or third wave or self control).mp. OR (self* adj3 (control or efficacy)).mp. OR (stress manage* or exposure or reality therap*).mp. OR (anxiety adj3 (management or therap* or train*)).mp. OR (relaxation or guided imagery or present cent* or person cent* or person* construct* or therapeutic process* or schema?) or schemata).mp. OR (thought* adj3 suppress*).mp. OR rumination.mp.

#4 #2 AND #3

#5 #1 OR #4

#6 "Systematic Review"/ OR systematic review.ti,ab,kf.

#7 #5 AND #6

#8 program evaluation.mp. OR program evaluation/ OR process evaluation.mp. OR "process assessment (health care)"/ OR (process evaluation* OR qualitative component* OR qualitative aspect* OR qualitative approach* OR systematic evaluation* OR participant observation OR simulation OR implementation audit).mp. OR (audit OR feedback).tw. OR qualitative research/ OR qualitative.mp. OR qualitative research.mp.

#9 #7 AND #8

#10 depression/ OR depression.mp. OR anxiety/ OR anxiety.mp. OR Obsessive-Compulsive Disorder/ OR obsessive compulsive disorder.mp. OR Mental Disorders/ OR common mental disorders.mp. OR Occupational Stress/ OR Stress Disorders, Post-Traumatic/ OR stress.mp. OR Stress, Psychological/ OR mental health.ti OR mental illness.ti. OR psychiatric.ti OR mood disorder.tw OR neurotic disorder.sh

#11 #9 AND #10

Population and Focus of the Review

The target population was people with common mental disorders or experiencing an increase in psychological symptoms (eg, depression, anxiety, and distress) [1]. Systematic reviews of studies of mixed populations and interventions were included if it was possible to disaggregate data in relation to the use of cCBT to target psychological symptoms or mental disorders. Reviews that addressed the topic of acceptability including reviews of quantitative and qualitative studies were included, and reviews that assessed effectiveness only were excluded unless they investigated one or more aspects of acceptability. Systematic reviews only were included as, usually, they include a focused research question with defined parameters and follow an a priori agreed methodology. Other review types such as scoping reviews were excluded because, typically, they tend to address a broad review question and, often, are limited due to time and scoping restraints [24].

Intervention

Reports of interventions had to indicate that that they were grounded in CBT in terms of, for example, aiming to improve or maintain mental health outcomes by changing aberrant thought patterns and behaviors. CBT interventions delivered via the internet or via computer only were included [4]. Interventions were included if they were guided (by email, telephone, or online therapist support) or self-directed/unguided (no therapist support) and accessed in a clinical, community, or home-based setting. The duration of an intervention or the

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intensity with which it was delivered was not used as a criterion for excluding a review.

Outcomes

The scoping activity and the review team discussions identified the following key outcomes or indicators of acceptability: percentage of uptake or refusal following invitation to cCBT; adherence (number of completed intervention sessions or components); proportion of "drop-outs" (including reasons for, time of, and factors associated with dropping out); satisfaction with intervention components or mode of delivery; and user, carer, or health care professional reports about their views of cCBT.

There were no language nor year restrictions. Three non-English language papers were identified, but from examining available English abstracts, they did not meet the review criteria. Double counting of primary studies across reviews is an inherent bias of an umbrella review, and where present, efforts have been made to indicate study overlap. Some reviews included physical health conditions and non-cCBT interventions, and these findings were excluded from the umbrella review.

Data Extraction

We followed best guidance on the conduct of umbrella reviews [18] and studied examples of the methodological approach that were reported in other umbrella reviews [25]. Data were extracted by CT and checked by MD. The following data were extracted into tabular format: first author, publication year,

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study design, research question, searches, type of study and setting, participant details, type of intervention, quality appraisal method and scores, and research synthesis method. Thus, data were synthesized narratively at review level and under the following headings: uptake or refusal, adherence or cCBT completion, proportion and timing of "drop-outs," satisfaction or acceptability of cCBT, and users' views of cCBT (including therapists' views).

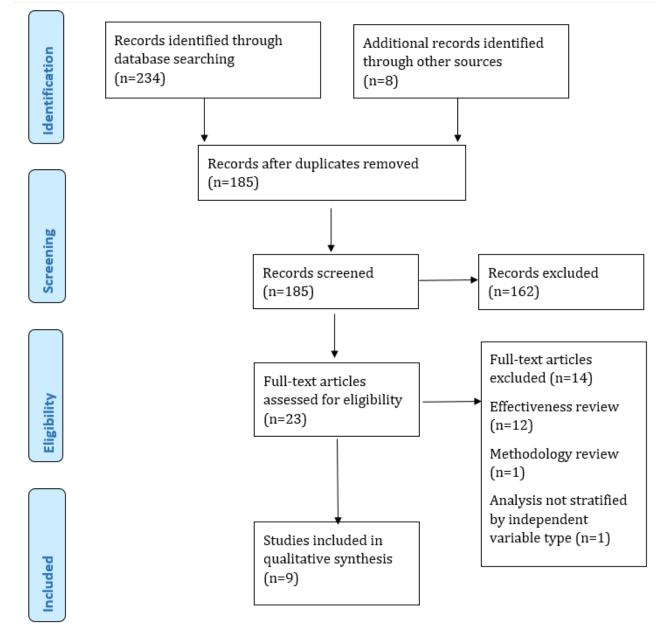
Results

The database searches identified 234 titles: 23 full-text papers remained following duplicate removal and abstract screening, and a further 8 titles were identified through citation lists of the 23 reviews. Of the 31 papers, 9 met the eligibility criteria for inclusion in the umbrella review (see Figure 1 for the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA] flowchart). The 9 reviews covered 151 unique studies, with 27 of the 151 studies reported in more than one review. Individual studies varied in terms of study design including experimental design (n=111), qualitative studies (n=15), mixed methods (n=8), feasibility studies (n=7), cohort or survey design (n=4), and a systematic review (n=1). This systematic review was not identified during the electronic searches because it did not meet one or more of the concepts that informed the search strategy and it focused on the effectiveness of online mental health programs rather than

directly addressing the umbrella review question. Regarding reviews that included intervention studies, most control groups were waitlist (n=21), were attention controls (n=13), received no treatment (n=12), or received treatment as usual (n=10).

Most review studies focused on adult populations (n=119), while a smaller number examined adolescent populations (n=8) and one study included both adults and adolescents [26]. One review [27] did not report the target population, and so, 7 of the 16 primary studies in this review were examined (9/16 studies were not accessible because of paywall restrictions). Studies covered a range of mental disorders and symptoms including depression (n=80), anxiety (n=24), panic disorder or phobia (n=26), stress or distress (n=9), insomnia (n=6), posttraumatic stress disorder (n=4), eating disorders (n=4), alcohol misuse disorders (n=3), grief (n=2), body image issues (n=1), bipolar disorder (n=1), and unspecified or nondefined "public health mental disorders" (n=1). Some studies covered more than one mental health condition. Reviews focused on individuals with clinically diagnosed disorders [26,28-30], experiencing psychological symptoms [31,32], or both [27,33,34]. We refer throughout the review, where possible, to whether findings relate to mental disorders or symptoms. Individuals with physical conditions or other populations (eg, cancer caregivers, survivors of natural disasters) were the focus of 9 studies, and details about the populations in 5 studies were not provided (see Multimedia Appendix 2).

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



Intervention Characteristics

We examined 178 cCBT interventions across the reviews, with 23 studies examining more than one cCBT condition. Two reviews were not focused only on cCBT and included a small number of non-cCBT interventions (n=1) or did not specify the type of therapeutic intervention (n=2). Detailed descriptions about interventions including their content, format, and delivery were reported infrequently. It was possible to discern, where this information was reported, that there were 53 guided and 50 unguided interventions; guidance included email support (n=11), telephone support (n=9), face-to-face contact (n=9), and a discussion forum (n=3). Technical support was provided in 25 studies (see Multimedia Appendix 2).

Uptake or Refusal

Data on the proportion of people in each study who availed of the use of a cCBT intervention were provided in 5 reviews. Definitions of uptake varied widely and referred to qualitatively different types of individuals; for example, 1 review included the proportion of eligible individuals who were randomized and spontaneous users who accessed cCBT websites [26]. A very wide range of uptake proportions (1%-97%) was reported across reviews [26-29,34]. Only 1 review reported the proportion of people who refused (9%-24%) [26]. In 2 reviews, the proportions who enrolled to receive cCBT and take part in its evaluation but then did not take up cCBT varied widely from 1% to 63% [26,29] (see Tables 1 and 2). Rates of uptake, refusal, or not starting were not separated by type of cCBT (eg, self-guided or guided) in reviews, and often this information was not reported by reviews for individual cCBT programs. All 5 reviews included studies of people with depression or anxiety.

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Table 1. Adherence definitions and rates.

Study	Adherence definition	Rates of uptake	Proportion completing treat- ment ^a	Drop-outs
Kaltenthaler et al (2008) [34] ^b	Patient recruitment; number of patients who accessed website and agreed to take part in study; drop-outs; number of patients who dropped out of the study	25% agreed to take part	Type of program (% partici- pants did not complete com- ponents, number of studies): Beating the Blues (26%- 45%, 5 studies); MoodGym (17%-75%, 2 studies) web- site mass recruitment; ODIN (34%, 2 studies); COPE (29%-32%, 2 studies); Re- covery Road (32%, 1 study); Five Areas Approach (30%, 1 study); BALANCE (11%, 1 study); two unnamed inter- ventions (0%, 37%)	Mean 31.75% (SD 16.52%); range 0%-75%
Waller and Gilbody (2009) [27] ^c	Invited: those who received information about the study; recruited: those specifically asked to take part in the study; finished study: % of those who started and com- pleted the study; finished modules: % of those who completed all modules	Median 38%; range 4%- 84%	Started and subsequently completed: median 83%, range 26%-100%; overall completion: median 56%, range 12%-100%	Individuals in cCBT were twice as likely to drop-out than control groups (OR 2.03, 95% CI 0.81-5.09)
Melville et al (2010) [30] ^d	Drop-out: "leaving treat- ment before its comple- tionat one of a number of points throughout treat- ment"; pretreatment drop- out: before beginning of treatment; treatment dropout: prior to completion of treatment sessions; fol- low-up drop-out: prior to completing follow-up assess- ments; rates of drop-out; number of eligible partici- pants (denominator) and the number of individuals who terminated at any point from registering the treatment and completing follow-up ques- tionnaires (numerator)	Not reported	Not reported	Pretreatment drop-out: 4%- 52% (median 10%; weight- ed median ^e 21%); treatment dropout: 0%-78% (median 10%; weighted median 21%); follow-up drop-out: 0%-18% (median 4%; weighted median 8%)
Vallury et al (2015) [26] ^f	Rates of uptake and rates of adherence	Uptake rate: 44%-86%; re- fusal rate: 9%-24%; did not start: 7%	Completed treatment: 33%- 100%; completed follow-up at 3 months: 63%	Not reported



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Study	Adherence definition	Rates of uptake	Proportion completing treat- ment ^a	Drop-outs
Beatty and Binnion (2016) [29] ^g	Quantitative studies: adher- ers were those who complet- ed program or completed the postreatment assessment; nonadherers were those who did not complete program or did not complete the post- treatment assessment; num- bers of modules/sessions/as- sessments completed, dura- tion of logins, time using program, number of logins, number of homework assign- ments completed, accessing the program; qualitative studies: those who do not complete treatment, barriers to adherence	Uptake rate: 41.3%; did not start: 1%-63%	Completed all sessions: 16.9%-83.0%, 35.8%-66.0% for unguided or unsupported interventions, 58.0%-74.4% for guided or supported inter- ventions; completed only one session or module: 27%- 90%, 94% for guided, 95% for unguided; completed some but not all sessions or modules: 10%-99%, 67%- 84% for guided interven- tions, 54.4%-93.0% for un- guided interventions; com- pleted all assessments: 26.0%-90.8%	Early drop-out (during first sessions): 10.0%-56.9%, 37.1% for the treatment group, 32.1% for the control group; drop-outs at end of study: 4.25%-38.00%, 56.3%-75.0% for the treat- ment group, 29%-48% for the control group, 35.9% for guided, 33.7% for unguided, 56% of those who immedi- ately accessed, 80% of those who delayed access
Rost et al (2017) [28] ^h	Uptake, drop-out, or comple- tion rates as a means of as- sessing user acceptance	39%-97%	Mean 67.17% (SD 20.29%), range 26.7%-100%; 8.1%, 56% guided intervention; 16.28%, 36% unguided inter- vention	Mean 31.5% (SD 19.49%), range 0%-63%
Twomey and O'Reilly 2017 [32] ⁱ	Proportion of participants withdrawing before final data collection, proportion of individuals who complet- ed intervention	Not reported	10%-100%	Withdrew before posttreat- ment data collection: 0%- 64%

^aThis was defined differently across reviews; in some cases, this included proportions of those who started and subsequently completed treatment or follow-up assessments.

^bOf the 16 studies, 10 were overlapping.

^cOf the 36 studies, 15 were overlapping.

^dOf the 19 studies, 6 were overlapping.

^eWeighted for study sample size.

^fOf the 11 studies, 1 was overlapping; 4 studies included adolescent populations.

^gOf the 36 studies, 6 were overlapping; 6 studies included populations with physical health or other conditions and thus were excluded.

^hOf the 29 studies, 6 were overlapping; 2 studies included adolescents.

ⁱOf the 11 studies, 5 were overlapping.



Table 2. Findings from quantitative studies (as categorized by review) referring to factors associated with adherence or dropping out.

Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a
Demographic variable	es (not specified)			
	Internet-based cognitive be- havioral therapy (CBT; sub- threshold depression)	8 studies	No difference between com- pleters and noncompleters [31] ^b	No association
Gender				
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	No association (1); men more likely to drop-out (1) [30] ^c	Mixed results
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	15 studies	Women more likely to adhere (7), men more likely to adhere (1), no association with gender (7) [29] ^b	Not reported
Age				
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	No association (1) ^d , younger age associated with drop-out (1) [30] ^c	Mixed results
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	14 studies	No association $(6)^d$, older age associated with adherence (4), younger age associated with adherence (3), mixed findings (1) [29] ^b	Not reported
Education level				
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	No association (2 [1] ^d) [30] ^c	No association
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	13 studies	No association (8) ^d , higher edu- cation associated with higher adherence (4), lower education associated with higher adher- ence (1) [29] ^b	Not reported
Ethnicity				
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	1 study	No association [29] ^b	Not enough evidence
Being partnered				
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	1 study	Being partnered associated with drop-out (1) [30] ^c	No association
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	8 studies	No association with having a partner (6), being partnered associated with adherence (2) [29] ^b	No association
Employment status				
	Computerized CBT (cCBT; mild or moderate depres- sion)	1 study	Getting a job provided as reason for dropping out (2) [34] ^c	No association

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Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a	
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	7 studies	No association (7) [29] ^b	Not reported	
Geographical location					
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	1 study	Oceania or Europe residency associated with higher comple- tion of modules than residency in North America, South America, and Africa (1) [29] ^b	Not enough evidence	
Residency (urban/rural))				
	cCBT (prevention of anxiety and depression)	2 studies	Adherence and/or attrition among rural compared to urban participants, rurality had no ef- fect (1) or negative effect (1) on retention to cCBT [26] ^{b,c}	Not enough evidence	
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	2 studies	Within Ireland and Australia, no association (2) [29] ^b	Not reported	
Personal circumstances					
	cCBT (mild or moderate depression)	2 studies	Family reasons (3) or change in circumstances (15%) or moving house (10%) provided as reasons for dropping out [34] ^c	Limited evidence	
	cCBT, (common mental health disorders)	9 studies (126 participants)	Personal circumstances were stated as a reason for declining ^d [27] ^c	Not reported	
Time commitments					
	cCBT (mild or moderate de- pression)	2 studies	Being too busy (8) provided as reason for dropping out [34] ^c	Limited evidence	
	cCBT (depression)	6 studies	Lack of time reported (6) as reason for dropping out [28] ^c	Not reported	
Physical health					
	cCBT (mild or moderate de- pression)	1 study	Ill-health (15%) provided as reason for dropping out of study [34] ^c	Not enough evidence	
Mental health status var	riables (unspecified)				
	Internet-based CBT (sub- threshold depression)	8 studies	No difference between com- pleters and noncompleters [31] ^b	Not enough evidence	
Symptom severity					
- •	cCBT (mild or moderate de- pression)	1 study	Improvement in symptoms was reported as a reason for drop- ping out (2) ^e [34] ^c	Mixed evidence	
	cCBT (common mental health disorders)	2 studies (2 participants)	Perceived increased risk (poten- tial increase in symptoms) re- ported as reasons for drop-out ^d [27] ^c	Mixed evidence	



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Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a
	Internet-based treatment (psychological dysfunction	3 studies	Lower symptom severity asso- ciated with dropping out of	Not reported
	or distress related to psychi- atric conditions)		study $(3 [1]^d) [30]^c$	
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	20 studies	At baseline: no association (10), lower symptom severity associated with increased adher- ence (6) and increased module completion (1); higher symp- tom severity associated with higher adherence (3) [29] ^b	Not reported
Duration of problem			ingher autorence (3) [23]	
	cCBT (mild or moderate de- pression)	1 study	Improvement in condition (10%) provided as reason for	Mixed evidence
			dropping out of study [34] ^c	
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	No association (2) [30] ^c	Not reported
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	3 studies	Longer duration associated with higher adherence (2), no association (1) [29] ^b	Not reported
Psychiatric diagnosis				
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	Comorbid depression and anxi- ety no association (2) [30] ^c	Not enough evidenc
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	4 studies	Diagnosis of anxiety or depres- sion associated with higher ad- herence (3), and alcohol depen- dency associated with higher adherence among waitlist con- trol group (1) [29] ^b	Not enough evidenc
Medication or alcohol u	Ise			
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	2 studies	No association (2; studies not targeting alcohol dependency) [29] ^b	Not enough evidence
Treatment credibility of	r expectation			
	cCBT (mild or moderate depression)	4 studies	Perception that intervention is not useful (11), unhelpful (10), didn't like treatment (n not re- ported), inappropriate for needs (1) provided as reason for dropping out of study ^e [34] ^c	Mixed evidence
	cCBT (common mental health disorders)	11 studies (101 participants)	Therapy was reported as a rea- son for dropping out, but it is not clear what this meant or	Not reported
			which group it referred to [27] ^c	
	Internet-based treatment (psychological dysfunction or distress related to psychi- atric conditions)	2 studies	No association (2) [30] ^c	Not reported



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Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a
	cCBT (prevention of anxiety and depression)	1 study	Treatment preference fulfilment was associated with adherence to the study for rural residing participants [26] ^b	Not reported
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	9 studies	Positively associated with higher adherence (7), no association (2) [29] ^b	Not reported
	cCBT (depression)	6 studies	Treatment being perceived as inconvenient (4) was reported as a reason to drop out [28] ^c	Not reported
Motivation and rea	diness to change			
	cCBT (mild or moderate depression)	2 studies	Low motivation (8), inability to commit (n not reported), and no desire to continue (n not re- ported) provided as reasons for dropping out [34] ^c	Limited evidence
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	4 studies	Treatment readiness associated with higher adherence (2), and intention to complete treatment associated with higher adher- ence (1); intention to complete treatment no association (1) [29] ^b	Not reported
Self-efficacy or self	-confidence			
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	3 studies	No association (2), taking re- sponsibility for one's own choices was associated with higher adherence to a bulimia self-guided program (1) [29] ^b	Not enough evidence
Computer-related i	icenoc		sen-guided program (1) [2)]	
	cCBT (mild or moderate de- pression)	2 studies	Internet-related issues (5), changed mind about PC deliv- ery (1) provided as reasons for dropping out [34] ^c	Mixed evidence
	cCBT (common mental health disorders)	5 studies (14 participants)	Information technology issues were not commonly reported as	Not reported
			a reason for dropping out [27] ^c	
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	4 studies	Higher adherence was associat- ed with website usability (1) and a positive attitude to a computerized self-guided for- mat (1), no association between adherence and computer litera- cy level (2) [29] ^b	Not reported
	cCBT (depression)	4 studies	Computer or technical issues (4) were reported as reasons for dropping out of the study [28] ^c	Not reported
Guidance or theraj	pist support			
	cCBT (mild or moderate depression)	1 study	Preference for face-to-face help (8) provided as reason for dropping out [34] ^c	Guided intervention associated with higher adherence



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Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	8 studies	Guided interventions were asso- ciated with higher adherence than unguided interventions (4), phone support was associated with higher adherence than email support (1), no difference in adherence between guided and unguided interventions (3) [29] ^b	Not reported
Referral source				
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	3 studies	General practitioner referral (2) or the media (1) associated with higher adherence [29] ^b	Not enough evidence
Program content				
	cCBT (mild or moderate depression)	2 studies	Other help sought provided as reason for dropping out (2), treatment not demanding (n not reported) [34] ^c	Not enough evidence
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	2 studies	Gratitude intervention group was twice as likely to complete treatment than a monitoring and restructuring intervention group (1); tailored feedback to in- crease self-efficacy, personaliza- tion of intervention team (eg, photo with "we") increased ad- herence for participants who accessed all intervention com- ponents (1) [29] ^b	Not reported
Setting				
	cCBT (mild or moderate de- pression)	2 studies	Hard to attend (13) or journey too long (3) provided as reasons	Not enough evidence
Duration of intervention	ND		for dropping out [34] ^c	
	cCBT (mild or moderate depression)	16 studies	Duration influenced drop-out (direction of effect not reported in review); duration of interven- tions ranged from 1-33 ses- sions; the authors note that it is di cult to make comparisons between cCBT programs regard- ing drop-out rates because of di erences in study design, populations, and methods for defining drop-outs and level of detail provided in a study [34] ^c	Duration associated with adherence
Group membership				
	cCBT (mild or moderate depression)	1 study	Intervention group had higher drop-outs compared to partici- pants in the information web- site group [34] ^c	Control groups more likely to adhere than intervention groups
	cCBT (common mental health disorders)	9 studies	Participants in cCBT were twice as likely to drop out than participants in the control group (OR 2.03, 95% CI 0.81-5.09) [27] ^c	Not reported



Factor	Intervention (population)	Number of studies or participants	Results or findings (number of studies)	Heterogeneity ^a
	Self-directed psychological intervention (psychological outcomes for mental and physical disorders)	4 studies	Control (waitlist) group mem- bership predicted higher adher- ence than intervention group membership (1), intervention group membership associated with adherence (1), no associa- tion with group membership (2) [29] ^b	Not reported

^aAt least 50% of studies needed to provide evidence of or absence of an association; there was not enough evidence if <5 studies available. ^bAssociation with adherence.

^cAssociation with drop-out.

^dOverlapping studies.

^eNumber of participants (where reported in reviews).

Adherence to or Completion of One or More Intervention Sessions or Components

The definitions of adherence varied between and within reviews. For example, some reviews included studies that defined adherence in terms of "completers" or individuals who completed an outcome assessment at the end of receipt of cCBT while other studies defined "treatment completers" as individuals who completed all "modules" or a specified "dose" of cCBT even if they did not undertake a research outcome assessment [29]. The proportion of participants who completed an entire cCBT program ranged from 10% to 100% [26-29,32]. Only 1 review [29] provided more detailed data about adherence — the proportion of individuals who discontinued after 1 session or module fluctuated between 27% and 90%, and completion of more than 1 session or module ranged from 10% to 99%.

Heterogeneity in terms of the proportion of individuals who completed cCBT was present for guided and unguided cCBT (guided cCBT: completed full program, 8%-74%; completed 1 module only, 94%; completed some modules, 67%-84%; and unguided cCBT: completed full program, 16%-66%; completed 1 module only, 95%; completed some modules, 54%-93%) [28,29]. The proportions of cCBT users who remained in studies after completion of cCBT and until follow-up assessments were infrequently reported [26,29] and probably provide more evidence for the acceptability of research participation rather than cCBT acceptability.

Dropping Out or Discontinuing Use of cCBT

Two reviews reported (without providing details about timing) that, on average, around one-third of users "dropped out" [28,34]. According to 2 reviews, service users dropped out pretreatment, before cCBT started (range 4%-52%) [30], during cCBT treatment (range 0%-78%) [30], "early" within the first few sessions (10%-57%) [29], and during posttreatment (0%-38%) [29,30]. A wide range of cCBT participants (0%-64%) did not remain in cCBT studies for posttreatment data collection [32].

The proportion of service users who dropped out of guided (36%) and unguided (34%) cCBT programs was similar [29]. One review reported that cCBT participants in a treatment group were twice as likely to drop out than active attention control

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XSL•F() RenderX participants [27]. However, this finding was neither significant nor supported by a second review [29], which compared "early" drop-outs within the first few sessions (treatment group, 37% vs control group, 32%) to individuals who dropped out at the end of cCBT (treatment group, range 56%-75% vs control group, range 29%-48%).

Sociodemographic Factors and Adherence

Across 2 reviews, 7 of 16 studies (and 1 overlapping study) reported the absence of an association between age and adherence [29,30]. The remaining 9 studies in the 2 reviews found mixed evidence (1/16) or that older age (5/16) or younger age (3/16) was associated with cCBT adherence or dropping out. Regarding gender across the same 2 reviews [29,30], there was a positive association between being female and adherence (8/16 studies) or no association (8/16 studies), and 1 study concluded that men were more likely to adhere than female participants. Overall, the evidence from the reviews indicated that there was no association between education [29,30], having a significant other [29,30], or employment status [29,34] with adherence or dropping out. One review [31] stated (without providing supporting data) that there were no sociodemographic differences between people who completed or did not complete cCBT. The limited available evidence did not indicate that ethnicity [29], geography [29], or urban or rural residency [26,29] played a role in adherence (see Table 2).

Mental Health Status–Related Factors and Adherence

The association between mental health symptom severity and adherence was unclear [27,29,30,34]. Across 4 reviews, 10 of 26 studies reported no association between symptom severity and adherence; 9 studies observed that adherence was sustained when fewer and less severe symptoms were experienced while 7 studies reported an association between experiencing more symptoms and adherence. The relationship between duration of symptoms and adherence across 3 reviews [29,30,34] was inconsistent (no association: 3/6 studies; shorter duration association: 1/6 studies; and longer duration association: 2/6 studies). In 1 review [29], 2 studies found no association between adherence and medication or alcohol use, respectively; an examination of attrition bias (as part of risk of bias assessment) indicated that there were no mental health differences between people who completed and did not complete

cCBT [31]. The relationship between physical health status and adherence is unknown (see Table 2).

cCBT Features and Adherence

cCBT features and adherence were examined in 4 reviews. Guided compared to unguided cCBT was associated with higher adherence (4/7 studies), or there was no association (3/7) [29]. Adherence was better sustained via telephone compared to email support, though only 1 review addressed the type of support [29]. A preference for face-to-face therapy compared to cCBT was stated as a reason for dropping out for 8/60 participants (only 39 participants stated reasons) in 1 study [34]. Internet or computerized delivery problems were cited as reasons for dropping out in 2 of 3 reviews [28,34]. There was no association between computer literacy and adherence (2 studies), though cCBT website competency (1 study) and a positive attitude towards computerized delivery of CBT (1 study) were associated with higher adherence [29]. There was wide variation in the duration of cCBT programs (range 1-33 sessions). Only 1 review tested the relationship between cCBT duration and adherence, reporting that duration of cCBT was a factor in dropping out [34]. Higher adherence (or fewer drop-outs) was observed in control groups compared with cCBT programs [27,29,34]. A meta-analysis of 9 studies [27] reported that controls may be twice as likely as cCBT participants to drop out of studies (OR 2.03, 95% CI 0.81-5.09). The reviews did not investigate other factors such as the role of referral source, specific program content, delivery setting, access, and adherence (see Table 2). Most were narrative reviews and did not include or included only minimal statistical results.

Behavioral Factors and Adherence

Behavioral factors and adherence were examined in 6 reviews. Negative perceptions about cCBT (eg, as unhelpful or inappropriate) were associated with dropping out [28,34], while positive expectations were associated with good adherence [26,29]. The direction of the relationship between cCBT expectancies and adherence was uncertain or absent in 2 reviews [27,29,30]. Low motivation was a reason for dropping out in 1 review (2 studies) [34], and a second review [29] found that intending or being ready to participate in cCBT was associated with higher adherence (3/4 studies). Several studies across 3 reviews reported that being too busy or not having enough time (8 studies) [28,34] and "personal circumstances" (10 studies) [27,34] were reasons for dropping out. The role of self-efficacy and adherence was investigated by a limited number of studies [29] (see Table 2).

Service Users' Views

Generally, users appeared to be highly satisfied [26-28,34] and would recommend cCBT [27,34]; mixed reports of satisfaction were infrequently reported by individual review studies [28]. Rural-dwelling participants were more likely than urban participants to report that cCBT improved their depression or substance misuse and were more likely to report that they were satisfied with cCBT support and liked the autonomy, confidentiality, and privacy that it afforded [26]. The anonymous nature of remotely delivered cCBT was preferred compared to face-to-face therapies [28], though some users reported feelings

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of increased isolation [28] and uncertainty about the privacy of cCBT [29]. The capacity to undertake cCBT in your own time was perceived to be beneficial [27-29] but also led to avoidance of cCBT [27,28]. Similarly, being too busy or unable to find the time to undertake cCBT was reported in several studies [29]. Users experienced difficulties finding a quiet, private space to access a computer to undertake cCBT [30]. The computerized format (and associated technical aspects) was reported to be easy to use, particularly when training was provided [27,34]. User perceptions of their information technology (IT) skills or openness to using computers impeded adherence [27-30], and the additional time that older participants required due to lower technical competency appeared to be off-putting [27].

Predominantly based on qualitative data (with the exception of quantitative data in 1 review [34]), guided cCBT programs appeared to lead to greater adherence [27,28,34]. Studies that compared guided and unguided cCBT were mixed or unclear regarding satisfaction and perceived helpfulness [28]. There was a preference for face-to-face CBT [27,30], and generally users who had experience with both modes perceived cCBT as more beneficial [27], though some studies reported criticisms by users in terms of cCBT lacking human contact and sufficient guidance [29]. The role that therapists played in guided cCBT or face-to-face CBT was perceived positively because they had particular skills (eg, promoting understanding of condition or therapy) or characteristics (eg, more tolerant) or were considered more helpful for particular patient groups (eg, complex mental health cases) [27]. A small number of reviews reported service users' views about some aspects of cCBT programs. The use of a booklet, multimedia design, and program structure [34] and program design [27] were noted positively by users. There was a positive association between adherence and when cCBT programs were viewed as helpful versus when programs were perceived as impersonal or irrelevant [28,29]. One review [27] reported that particular user groups had different levels of motivation and adherence levels (eg, self-referrals [higher] and mental health referrals [lower]), and delivery of cCBT in a primary care setting was viewed positively (see Multimedia Appendix 3).

A qualitative review containing a meta-synthesis identified 2 "core constructs" to explain factors that impeded or facilitated participation in cCBT: "sensitivity of self and identity" and "the dialectical nature of user experience." First, the preferences, needs, and challenges that an individual with mental ill-health faces (eg, reduced motivation and concentration) need to be considered before deciding that cCBT is an appropriate option or to inform how to tailor the delivery of cCBT. Second, the delivery of cCBT needs to take into account the contradictory presence of perceived benefits and drawbacks (eg, the option to self-select modules may be empowering and burdensome, and cCBT may be perceived as enhancing confidentiality and privacy or as an obstacle to meeting the need for face-to-face support from therapists and peers) [33]. Lack of motivation related to depression was a barrier to cCBT adherence, and feeling that cCBT was not helping was related to poor adherence [27]. Some users appeared to drop out of cCBT programs because they were perceived to be too general, limited, or intensive or they had negative experiences with particular cCBT

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components [29]. Therapists' views about cCBT were captured by 1 study in 1 review only [27]. Their views revolved around the following factors: the availability of resources (the need for training, computer suite, and costs); institutional support to provide resources; "culturally tailored" cCBT; cCBT as an adjunct to, rather than a replacement for, face-to-face therapy; concerns about security; and data protection. Finally, therapists rated face-to-face therapy as safer and more effective [27] (see Multimedia Appendix 4).

Discussion

Principal Findings

This umbrella review investigated the acceptability of cCBT, in terms of the proportion of people who availed of, adhered to, or dropped out of cCBT as well as with reference to qualitative reports of the reasons for dropping out and users' and therapists' views. Nine reviews provided relevant data, though the aforementioned indicators of acceptability were defined and operationalized heterogeneously across reviews. The extent of this variation made it difficult to "sum up" the results from the 9 reviews and to compare acceptability across populations, conditions, programs, and settings. Several reviews reported that cCBT retention proportions (eg, face-to-face CBT drop-out range, 5%-38% and cCBT mean drop-out, 33%) were comparable and as variable as psychological therapy delivered face-to-face [27,28,30,34], thereby suggesting that acceptability of cCBT may be on par with face-to-face therapies and unrelated to features of computerized delivery.

Often, reasons were not given for dropping out of studies, so it is difficult to draw firm conclusions regarding why adherence to cCBT was difficult for some individuals. It is important to understand the reasons for dropping out and whether they vary at different stages. For example, did individuals withdraw because cCBT was not what they expected, treatment was too intensive, symptoms improved (whether or not improvement was attributed to cCBT), or for other reasons separately or in combination. Included reviews did not present data regarding why individuals chose not to take up cCBT at all or that illuminated a deeper understanding about reasons for dropping out. Developing strategies to increase uptake, adherence, and retention with respect to cCBT requires a clear understanding about the factors associated with adherence or reasons for dropping out. Most reviews gathered quantitative data, and it is likely that a mixed methods research approach would help to advance our understanding about the reasons for problems and challenges. Indeed, the quantitative results were inconsistent regarding sociodemographic variables, health status, cCBT characteristics, and behavioral factors and their association with cCBT adherence.

The qualitative synthesis presented by Knowles et al [33] stressed the importance of taking into account individuals' preferences and captured the contradictory nuances related to user acceptability of cCBT. The results from the quantitative studies indicated that guided cCBT was associated with better adherence, whereas qualitative findings indicated that there were favorable and unfavorable aspects to guided and unguided cCBT formats. Very few reviews directly compared guided and

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unguided formats, and like-with-like comparisons were not prominent. There is a need for future research to consider whether there are issues that are specific to particular types of cCBT. Targeted training may help to ease apprehensions about IT, and improving computer literacy may overcome reluctance to participate in cCBT.

There is a need for further research to improve understanding about "dosage" and dropping out. The review points clearly to the conclusion that "one size does not fit all" and that cCBT even in relatively small "doses" may work well for some patients including patients who drop out at various stages, whereas a "full dose" and perhaps even more again is needed by other patients. For example, a recent randomized controlled trial and intention-to-treat analysis found a beneficial effect for the cCBT treatment of insomnia despite a high drop-out rate and increasingly lower adherence to modules over the course of the study. It is important to note that the study was comprised of a student population and most students experienced subclinical insomnia [35,36]. It was not possible to discern from our umbrella review which types of patients benefited from different "doses" of cCBT, and there are similar unanswered questions for "brief" face-to-face CBT and its variants.

Only limited attention was given to the potential for theory to illuminate understanding about the acceptability of cCBT [28,30] such as diffusion of innovations theory [37] and the Technology Acceptance Model [38], particularly concepts around perceptions about the ease of use and the effectiveness of cCBT. The use of theories of implementation science (eg, the Consolidated Framework for Implementation Research [39]) may also facilitate understanding about acceptability and the implementation of cCBT within a health care system, particularly if health care professionals or therapists are resistant to delivering cCBT. The limited evidence in the umbrella review regarding therapist acceptability found fewer positive views about cCBT. Acceptability and implementation may be achieved if cCBT is delivered within a "stepped care model" in which individuals begin with face-to-face therapy and then transfer to a cCBT "step," though there may be complex cases that require ongoing individual face-to-face therapy [27]. There may be ethical concerns that require consideration (eg, avoiding the transfer of burden from health care professionals to service users [27] and possibly creating inequalities around internet access [40-42] or due to education level).

Limitations

Though a protocol was developed for this review, it was not registered on a registry such as Prospero. However, this umbrella review was informed by an established rigorous methodology for the "summing" of the increasing number of systematic reviews about a given topic and involves independent screening, appraisal, and data extraction. There was a consensus among review authors that study or program heterogeneity and variability and inadequate reporting of details in primary studies restricted meaningful analytical comparisons between cCBT programs, and we relied upon authors' reports of study and data type (eg, qualitative or quantitative) and use of validated outcome measures of acceptability or satisfaction. Moreover, there is a lot of variance in terms of the labels and descriptions

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used to describe internet or computerized interventions such as cCBT, and this lack of consensus may contribute to difficulties in research synthesis [43]. This limitation of umbrella review methodology was compounded further due to the reliance on reviews as a secondary data source rather than searching through primary studies to try to identify missing details. It is important to remain cognizant that self-selection of participants to primary research studies (eg, more women) may influence adherence and reports of cCBT experience. This review did not apply any language restrictions, though only English-language reviews met the review criteria. Primary studies published in other languages could provide information about the acceptability of translated versions of cCBT or perhaps for migrant populations where language barriers may exist. The use of a reporting guideline such as the Template for Intervention Description and Replication (TIDieR) Checklist [44] or even use of relevant

parts (eg, Part 5 – Interventions) of the CONSORT (Consolidated Standards of Reporting Trials) extension for reporting studies of social and psychological interventions [45] would be a major advance towards achieving a reliable synthesis and furthering our understanding about the acceptability of cCBT.

Conclusions

Collectively, the results of the reviews indicate that "one size does not fit all" regarding the acceptability of cCBT and that individual patient and service user group tailoring of cCBT are required to increase the population reach and uptake of cCBT and adherence and so, deliver treatment benefits and improve mental health. In turn, tailoring to create as close a patient-treatment match as possible is likely to involve a blending process involving a human guide or therapist.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Supplementary table 1: quality appraisal. [DOCX File , 16 KB - mental_v8i7e23091_app1.docx]

Multimedia Appendix 2 Supplementary table 2: included review characteristics. [DOCX File , 35 KB - mental_v8i7e23091_app2.docx]

Multimedia Appendix 3 Supplementary table 3: satisfaction and acceptability. [DOCX File , 29 KB - mental v8i7e23091 app3.docx]

Multimedia Appendix 4 Supplementary table 4: qualitative findings. [DOCX File , 16 KB - mental_v8i7e23091_app4.docx]

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Abbreviations

AMSTAR: A Measurement Tool to Assess Systematic Reviews CBT: cognitive behavioral therapy cCBT: computerized cognitive behavioral therapy CONSORT: Consolidated Standards of Reporting Trials iCBT: internet-delivered cognitive behavioral therapy IT: information technology NICE: National Institute for Health and Clinical Excellence PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses TIDIER: Template for Intervention Description and Replication



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Original Paper

Empowering Anxious Parents to Manage Child Avoidance Behaviors: Randomized Control Trial of a Single-Session Intervention for Parental Accommodation

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Abstract

Background: A majority of youth who need anxiety treatment never access support. This disparity reflects a need for more accessible, scalable interventions—particularly those that may prevent anxiety in high-risk children, mitigating future need for higher-intensity care. Self-guided single-session interventions (SSIs) may offer a promising path toward this goal, given their demonstrated clinical utility, potential for disseminability, and low cost. However, existing self-guided SSIs have been designed for completion by adolescents already experiencing symptoms, and their potential for preventing anxiety in children—for instance, by mitigating known anxiety risk factors—remains unexplored.

Objective: This trial evaluated the acceptability and proximal effects of project EMPOWER: a web-based, self-guided SSI designed to reduce parental accommodation, a parenting behavior known to increase the risk of anxiety in offspring.

Methods: In total, 301 parents who reported elevated anxiety symptoms with children aged 4-10 years received either project EMPOWER or an informational control (containing psychoeducational materials and resources); parents self-reported their accommodation of child anxiety and overall distress tolerance at baseline and 2-week follow-up.

Results: Relative to control-group parents, those who received the intervention outlined in project EMPOWER reported significant reductions in their accommodation of child anxiety (d_s =0.61; P<.001) and significant increases in their distress tolerance (d_s =0.43; P<.001) from baseline to 2-week follow-up. Additionally, parents rated project EMPOWER as highly acceptable (ie, easy to use, helpful, and engaging) in accordance with preregistered benchmarks.

Conclusions: Project EMPOWER is an acceptable self-guided SSI for parents of children at-risk for anxiety, which yields proximal reductions in clinically relevant targets.

Trial Registration: ClinicalTrials.gov NCT04453865; https://tinyurl.com/4h84j8t9

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KEYWORDS

acceptability; adolescent mental health; adolescent; anxiety; avoidance; behavior; child mental health; children; digital mental health; intervention; mental health; parent; prevention; young adult

Introduction

Background

Anxiety disorders are among the most common, debilitating forms of childhood psychopathology, affecting 8.3%-27.0% of

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youth aged less than 18 years [1,2]. Child anxiety increases the risk for psychiatric comorbidities across the lifespan [3], creates significant burdens for caregivers [4], and carries stark societal costs [5,6]. Although numerous interventions have been developed to treat anxiety disorders in the youth, up to 82.2%

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of the youth in the United States, who have anxiety do not receive adequate care [7]. Several factors may explain this discrepancy, including the length and cost of existing treatments and limited accessibility for families in need. Together, these factors create a pressing need for accessible, brief preventive programs to decrease the odds of the onset of anxiety disorder in at-risk youth.

Single-session interventions (SSIs) may offer a potential solution to bridge this gap in care. SSIs include core components of comprehensive evidence-based interventions delivered succinctly to improve the odds of access and completion [8]. In a meta-analysis of 50 randomized trials, SSIs reduced youth psychopathology across multiple disorders, with SSIs that target child anxiety producing especially large effects (mean g=0.58) [8]. Thus, well-targeted SSIs may offer cost-effective additions or alternatives to traditional care for anxiety in the youth. However, most existing SSIs for child anxiety target populations already experiencing clinical distress, highlighting the requirement of options that may prevent anxiety in vulnerable children. Given that family factors play a crucial role in the etiology of child anxiety [1], SSIs targeting parents and their interactions with offspring may be a promising approach to preventing anxiety in the youth [9]. Thus, this trial examined the acceptability and short-term effects of a novel, web-based, self-guided SSI targeting parental accommodation: a well-established, potentially modifiable risk factor for child anxiety [10-13].

Parental Accommodation as a Modifiable Intervention Target

Parental accommodation refers to changes in caregiver behaviors that facilitate or maintain their child's anxiety-driven avoidance behaviors [14,15]. Examples of such behaviors include modifying family routines (ie, staying home from work to mitigate a child's separation fears) or directly participating in a child's avoidance strategies (ie, keeping a child home from school). Parental accommodation reduces children's immediate distress but maintains their long-term avoidance of feared stimuli or situations, and high levels of parental accommodation are associated with more severe anxiety symptoms in offspring [15-17]. Parental accommodation may be further maintained by caregiver-level factors, including elevated parental anxiety symptoms and low distress tolerance. For instance, accommodation behaviors are more frequent among parents who report higher distress about their child's anxiety symptoms [18] and perceptions that experiencing anxiety is harmful to the youth [19].

Parental accommodation can also be systematically reduced through psychosocial intervention. For instance, in trials of the 12-week, parent-directed, therapist-delivered Supportive Parenting for Anxious Childhood Emotions program, which targets parents' accommodation, has helped mitigate anxiety in children with subclinically and clinically elevated anxiety symptoms [15,20]; recent studies even suggest that parent-directed, accommodation-focused treatments may be noninferior to exposure therapy for treating child anxiety [21]. Translating core components of existing multisession interventions for parental accommodation into briefer,

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self-guided SSIs (ie, those that do not involve a trained therapist) may improve families' access to empirically driven supports. Thus, we developed and tested a web-based, self-guided SSI for parents—project EMPOWER—to provide psychoeducation and teach skills to reduce parents' accommodation of avoidance behaviors in their school-aged children. Within an enhanced waitlist-control design, parents were randomized to either Online Resources and Referrals (ORR) and project EMPOWER (ORR+EMPOWER group) or ORR and delayed Project EMPOWER access (2 weeks after study conclusion) (ORR+waitlist group). We predicted that parents would report larger declines in self-reported accommodation behaviors (primary outcome) and larger increases in distress tolerance (secondary outcome) in the ORR+EMPOWER group, relative to the ORR+waitlist group, from baseline to 2-week follow-up. We also predicted that parents completing project EMPOWER would subjectively perceive larger pre-SSI to immediate post-SSI increases in their ability to help their child manage distressing situations, relative to control-group parents. Finally, we predicted that parents completing project EMPOWER would rate the intervention as acceptable (enjoyable, worth recommending to other parents, and personally helpful).

Notably, because this trial constituted the first formal test of project EMPOWER, the study's primary goal was to assess the program's potential to engage its intended mechanistic target: parental accommodation of avoidance and anxiety in their young children. If project EMPOWER can systematically improve this target in parents of children with or without clinically elevated anxiety, this study may lay the foundation for future trials on project EMPOWER's capacity to prevent child anxiety symptoms in the longer term.

Methods

Ethical Considerations

Study procedures were reviewed and approved by the institutional review board of the university, and informed consent was obtained from each participant via the internet prior to participation. The trial and all methods were prospectively preregistered on in ClincialTrials.gov prior to participant enrollment (NCT04453865).

Recruitment and the Resulting Sample

In total, 301 parents of children aged 4-10 years were recruited through Facebook advertisements, following established ethics guidelines for passive, social media-based study recruitment [22]. Participants were eligible for the study if they (1) reported subclinical or greater anxiety symptoms (a score of >40 on the Penn State Worry Questionnaire [PSWQ]) because children whose parents have high levels of anxiety are at an elevated risk for developing anxiety themselves, and parents with high levels of anxiety report engaging in more accommodation than do those with lower levels of anxiety [17]; (2) had at least 1 child aged 4-10 years; and (3) displayed comfort with English (intervention materials were available in English only). This specific child age range was selected because it encompasses the age of onset for common child anxiety disorders [23]; it also matches the age-range for which parent-focused interventions are often designed [24]. Study recruitment began in July 2020

and ended in August 2020 once the target number of participants was achieved.

Procedures

After clicking on a social media advertisement, parents were directed to an informational study webpage that invited them to complete a web-based eligibility screener. Eligible parents then reviewed a web-based consent form that invited them to participate. Parents could initiate the study at any time and location, using any internet-equipped device (smartphone, laptop, or tablet device). After starting the study, participants first completed preintervention self-report questionnaires, which are detailed below. Within the same survey, participants were randomized via Qualtrics (1:1 allocation ratio) to receive either ORR and immediate access to project EMPOWER (intervention condition) or ORR and delayed access to project EMPOWER after the 2-week follow-up (control condition). Those in the intervention condition also completed the Program Feedback Scale, along with other postintervention surveys, immediately following the completion of project EMPOWER. Two weeks later, all parents-regardless of condition-were invited to complete follow-up questionnaires. Parents in the control condition were then invited to complete project EMPOWER, if they were interested (completion of project EMPOWER subsequent to follow-up questionnaires was optional and was not part of the study). Thus, all participants were able to complete project EMPOWER, either immediately or after a 2-week delay.

Intervention

Project EMPOWER (freely available for anonymous completion on the project's website [25]) is a web-based, self-guided SSI for parents, which takes 20-30 minutes to complete. The program includes 5 main elements, which are based on current recommended practices in SSI design [26] and existing, therapist-delivered interventions targeting parental accommodation [15,21]:

- 1. Psychoeducation on child anxiety and avoidance, along with how parental accommodation can inadvertently foster child anxiety;
- Information on how parents can better identify children's patterns of avoidance and encourage "brave behavior," instead;
- 3. An exercise that guides parents in creating a personalized, step-by-step "action plan" for promoting brave, approach-oriented behaviors (rather than anxiety-driven avoidance) in their own child;
- 4. A segment intended to normalize parent distress responses in response to anxiety in offspring, including a rationale for why encouraging "brave behaviors"—despite being emotionally challenging for caregivers—ultimately bolsters children's well-being and resilience; and
- 5. A vignette exercise in which parents read about another family's difficulty managing child anxiety; parents identify various elements of the "anxiety cycle" (in accordance with psychoeducation provided previously) and generate possible solutions for the parents described in the vignette, which are based on their newfound knowledge of promoting "brave behavior" in the youth.

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Control Condition

ORR included an information sheet containing a list of web-based psychoeducational resources (videos, books, web-based toolkits, etc) on anxiety, hotlines, and resources on finding mental health treatment around the United States. ORR did not include any psychoeducational components explicitly designed to reduce parental accommodation of child anxiety. The full content of ORR is provided in Multimedia Appendix 1.

Measures

Other measures not detailed here were included in the study for exploratory purposes. The full battery of measures included in the study can be found on the registration page on ClinicalTrials.gov.

Demographics

Parents self-reported the gender, biological sex, ethnicity, country of origin, education level, and age for themselves and their children.

Parental Accommodation of Child Anxiety (Primary Outcome)

Using the Family Accommodation Scale—Anxiety (FASA) [10], parents rated agreement with 9 items, which reflected the extent to which they accommodate their child's anxiety symptoms or avoidance behaviors. Higher mean scores indicate more frequent parental accommodation. As a primary outcome measure, the FASA was administered at baseline and 2-week follow up to all participants. The FASA has demonstrated excellent psychometric properties across numerous studies [10]. Here we used α values of .87 and .85 at baseline and 2-week follow-up, respectively.

Parent Distress Tolerance (Secondary Outcome)

Using the 16-item Distress Tolerance Scale (DTS) [27]—a valid, reliable measure of overall distress tolerance in adults—parents rated their perceived ability to experience and withstand distressing emotional states on a 5-point scale. Higher mean DTS scores reflect lower levels of distress tolerance. As a secondary outcome measure, DTS was administered at baseline and 2-week follow to all study participants. Here we used α values of .86 and .88 at baseline and 2-week follow-up, respectively.

Child Anxiety Symptoms

Parents completed Revised Children's Anxiety and Depression Scale-Parent Report (RCADS-25-P) [28]: a well-validated, 25-item measure that assesses child internalizing symptoms. Parents endorsed the presence (or absence) of 25 different anxiety and depressive symptoms in children, each on a 4-point scale. Higher scores reflect more severe child internalizing symptomatology. The RCADS-25-P was completed at baseline only to characterize the level of anxiety experienced by children of participating parents. Here we used an α value of .85. Notably, we did not assess child anxiety at 2-week follow-up in this study, because the trial's objective was to establish whether project EMPOWER could successfully engage its intended target (parental accommodation behaviors).

Parent Anxiety Symptoms

Parents completed the PSWQ [29]—a well-validated 16-item self-report questionnaire that asks respondents to rate their perceived experience of worry- and anxiety-related problems using a 5-point scale. Higher sum scores indicate more severe worry. Parents completed the PSWQ at baseline to screen for subclinical or higher parental anxiety levels (an inclusion criterion) and to characterize the participating parent sample by anxiety severity. The PSWQ has demonstrated high internal consistency and good test-retest reliability [29]. Here we used an α value of .88.

Perceived Change in Preparedness to Help Children Manage Distress

A single-item measure that gauges participants' perceived changes in their ability to help their children manage distressing situations was adapted for this study [26]. All participants were asked to rate their agreement with a single-item statement on a 5-point scale, either immediately after completing project EMPOWER (intervention condition) or immediately after being presented with psychoeducational materials (informational waitlist condition): "Compared to before you started this survey, how prepared do you feel to help your child manage distressing situations?" This item was administered immediately post SSI only for the intervention group as a secondary exploratory outcome.

Intervention Acceptability

Parents in the intervention condition completed the Program Feedback Scale (PFS) [30]—a reliable and valid measure routinely used to assess acceptability and user perceptions of web-based, self-guided SSIs. The PFS asks participants to rate 7 statements on a 5-point scale (scores ranging 1-5) and share what they liked and what they would change about the SSI, in an open-response format. A mean score of \geq 3 indicates acceptability and positive program evaluation. The PFS was administered post SSI to parents assigned to the intervention condition to assess program acceptability.

Power Analysis

Using G*Power (version 3.1, Heinrich-Heine-Universität Düsseldorf), sample sizes needed to detect group differences in the primary outcome (changes in accommodation from baseline to follow-up) between the intervention and control groups of small (.2), medium (.5), and large effects (.8) based on an *F*-test, linear multiple regression with α =.05, and power=0.80, were 395, 55, and 25, respectively. Thus, our sample (n=301) offered sufficient power to detect a small-to-medium between-groups effects (consistent with effect sizes observed in previous randomized trials on web-based SSIs) [31].

Missing Data

We imputed missing data using the expectation maximization and bootstrapping algorithms implemented with Amelia II in R, as no evidence emerged for unequal drop-out by condition. These imputed data sets allowed for more conservative intent-to-treat analyses than listwise deletion or last-observation carried forward and allowed us to retain high power even considering missing data. We imputed 60 data sets in accordance with the proportion of missing data for our primary outcome measure (using FASA) at 2-week follow-up.

Analysis Plan

The entire preregistration can be found on ClinicalTrials.gov (NCT04453865). Deidentified data and code for all preregistered analyses are available on the Open Science Framework [32].

Effects of Project EMPOWER on Primary and Secondary Outcomes

To assess the effects of the intervention on parent's accommodation levels and distress tolerance from baseline to 2-week follow up, we used a multiple linear regression approach with the intervention condition (1=ORR+EMPOWER; 0=ORR+waitlist), baseline accommodation levels, and parental distress as predictor variables to examine whether participants in each condition saw a differential reduction in outcome variables. Using the MOTE R Package, we also reported the Cohen *d* effect sizes and 95% CIs for within-group (*d*_av; reflecting intervention effects for changes before the intervention up to follow-up) and between-group (*d*_s; reflecting changes in outcome before the intervention up to follow-up in the 2 groups) differences in both accommodation and distress tolerance levels [33].

Perceived Change in Preparedness to Manage Child Anxiety Before and After the Intervention

A 2-sample *t* test was performed to determine whether the overall, subjectively detectable pre-to-post changes in "preparedness to help their child manage anxiety" significantly differed between parents who completed project EMPOWER immediately, compared to control-group parents.

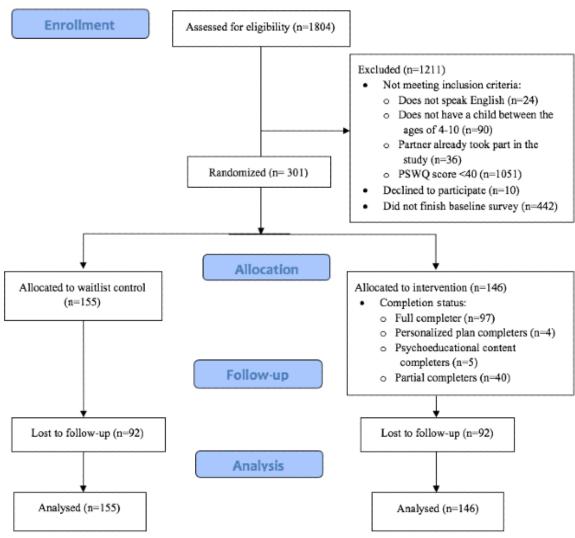
Project EMPOWER Acceptability

We examined overall and item-level mean PFS scores among parents who completed project EMPOWER. Mean and item-level scores of >3 or higher on any item (on a 5-point scale) reflected the endorsement of the program's acceptability (eg, positive feedback), either for that specific item or overall.

Project EMPOWER Completion Rates

Operational definitions of differential "program completer" status among parents assigned to the project EMPOWER condition were preregistered prior to data analysis. Full completers were those who reached the final page of the intervention, thus receiving the full "dose" of intended materials (approximate completion time: 25-30 minutes); personalized plan completers completed all psychoeducational content in project EMPOWER and finished their personalized plan for promoting brave behavior in their child (approximate completion time: 20-25 minutes); psychoeducational content completers completed all psychoeducational content, but not a personalized plan (approximate completion time: 10-15 minutes); and partial completers began the intervention but did not reach any of the above-mentioned program benchmarks. We report completion rates at each level, among parents assigned to the project EMPOWER condition, in the CONSORT diagram (Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram. PSWQ: Penn State Worry Questionnaire.



Results

Sample Characteristics

Characteristics of the 301 participating parents and their children are shown in Table 1. Parents were predominantly female (98.00%), 67.77% were White, 9.63% were Asian, 9.63% were of other racial backgrounds, 6.31% were Hispanic/Latino/a, 2.33% were American Indian/Alaska native, 1.99% were of more than 1 ethnicity, 1.66% were Black/African American, and 0.66% were native Hawaiian/Pacific Islanders; 52.82% had a received a graduate or professional degree. Consistent with our goal to recruit parents with elevated levels of anxiety, participants reported a mean score of 60.74 (SD 9.84) on the PSWQ, immediately below the clinical cut-off score of 62, in line with Behar et al [34]. Parents indicated a broad range of difficulties facing their child (raw RCADS score 18.83, SD 9.95), which included the following: clinically significant anxiety symptoms (76.74%), mood problems (17.94%), behavioral problems (33.89%), attention problems (33.89%), developmental delay (6.31%), learning disabilities (7.31%), peer relationships (35.55%), family relationship problems (21.93%), and trauma (15.28%).



Table 1. Sample characteristics.

Variable	Project EMPOWER (n=146)	Waitlist control (n=155)
Parents' score on the Penn State Worry Questionnaire, mean (SD)	60.30 (9.81)	61.18 (9.89)
Youths' score on the Revised Children's Anxiety and Depression Scale-Parent Report, mean (SD)	18.08 (9.64)	19.53 (10.22)
Age of the youths (years), mean (SD)	6.77 (1.93)	6.73 (2.03)
Female youths, n (%)	75 (51.02)	67 (43.51)
Race and ethnicity of the youths, n (%)		
American Indian/Alaska Native	5 (3.42)	5 (3.23)
Asian	11 (7.53)	11 (7.10)
Black/African American	4 (2.74)	1 (0.65)
Hispanic/Latino/a	6 (4.11)	8 (5.16)
White/Non-Hispanic	87 (59.59)	101 (65.16)
>1 Race	14 (9.59)	19 (12.26)
Other	19 (13.01)	10 (6.45)
Annual family income (US \$), n (%)		
0-19,000	9 (6.16)	8 (5.16)
20,000-39,000	16 (10.96)	20 (12.90)
40,000-59,000	18 (12.33)	12 (7.74)
60,000-79,000	16 (10.96)	18 (11.61)
80,000-99,000	16 (10.96)	15 (9.68)
100,000-119,000	11 (7.53)	14 (9.03)
120,000-140,000	15 (10.27)	13 (8.39)
>140,000	27 (18.49)	31 (20.00)
Marital status, n (%)		
Married	104 (71.23)	118 (76.13)
Living with partner	14 (9.59)	12 (7.74)
Never married	13 (8.90)	10 (6.45)
Divorced	9 (6.16)	8 (5.16)
Separated	4 (2.74)	6 (3.87)
Widowed	2 (1.37)	1 (0.65)
Single parent	32 (21.92)	32 (20.65)
Number of children, mean (SD)	2.02 (1.00)	2.19 (1.20)
Female parents, n (%)	143 (97.95)	152 (98.06)

Did Project EMPOWER Reduce Parental Accommodation of Anxiety and Improve Parent Distress Tolerance?

Parents assigned to the project EMPOWER condition reported significantly greater reductions in the accommodation of their children's anxiety (between-group d_s =0.61; *P*<.001), as well as significantly greater improvements in distress tolerance (d_{av} =0.17; between-group d_s =0.43; *P*<.001) from baseline to 2-week follow-up, relative to control-group parents. Table 2 provides additional details regarding the multiple linear regression approach.

Regarding within-group effects, parents who participated in project EMPOWER reported significant 2-week reductions in accommodation of child anxiety (project EMPOWER within-group d_{av} =0.67), whereas those who were assigned to the control condition did not (control within-group d_{av} =0.17). Between- and within-group effect sizes (d_{av} and d_s) and 95% CIs are reported in Table 3.

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Table 2. Results of multiple linear regression analysis in predicting intervention effects on parental accommodation (using FASA^a) and distress tolerance (using DTS^b) at 2-week follow-up.

Parameter	Parent-reported accommodation		Parent-reported distress tolerance		
	Coefficient (SE)	P value	Coefficient (SE)	P value	
FASA score at baseline	0.53 (0.07)	<.001	N/A ^c	N/A	
DTS score at baseline	N/A	N/A	0.77 (0.07)	<.001	
Intercept	0.79 (0.15)	<.001	0.75 (0.20)	<.001	
Condition	-0.48 (0.11)	<.001	-0.24 (0.09)	.008	

^aFASA: Family Accommodation Scale—Anxiety.

^bDTS: Distress Tolerance Scale.

^cN/A: not applicable.

Table 3. Means, standard deviations, and effect sizes of outcome variables by condition.

Outcome variable	Project EMPOWER		Cohen d_av ^a	Control group		Cohen d_av	Cohen d_s ^b
	Mean (SD) at baseline	Mean (SD) at 2- week follow-up	(95% CI)	Mean (SD) at baseline	Mean (SD) at 2- week follow-up	(95% CI)	(95% CI)
Score on the Family Accommodation Scale—Anxiety	1.83 (0.91)	1.29 (0.71)	0.67 (0.49-0.85)	1.88 (0.90)	1.79 (0.81)	0.11 (-0.05- 0.26)	0.61 (0.38-0.84)
Score on the Distress Tolerance Scale	2.77 (0.76)	2.64 (0.73)	0.17 (0.01-0.34)	2.73 (0.72)	2.85 (0.76)	-0.16 (-0.32- 0.00)	0.43 (0.20-0.66)

^aCohen d_{av} reflects within-group changes in each outcome variable.

^bCohen *d_s* reflects between-group changes in each outcome variable.

Did Parents who Completed Project EMPOWER Perceive Improvements in Their Preparedness to Manage Child Distress?

Immediately following the completion of either the control condition or project EMPOWER, participants were asked the following question: "Compared to before you started this survey, how prepared do you feel to help your child manage distressing situations?" On a scale of 1 ("much less prepared to help my child") to 5 ("a lot more prepared to help my child"), parents who completed project EMPOWER reported feeling significantly more prepared to help their child than those in the control group ($t_{155.27}$ =8.66; P<.001). Among parents who received immediate access to project EMPOWER and completed the intervention, 54.28% reported feeling "a little more prepared to help my child," 30.00% reported feeling "a lot more prepared," and 15.71% reported feeling "the same amount prepared." No participant reported feeling less prepared to help their child.

Was Project EMPOWER Acceptable?

Among parents who were assigned to the intervention condition, the majority (n=97, 66.44%) fully completed project EMPOWER, 4 (2.74%) qualified as personalized plan completers, 5 (3.42%) were psychoeducation content completers, 32 (21.92%) were partial completers, and the remaining parents (5.48%) did not begin project EMPOWER after randomization. Parents who completed project EMPOWER rated the intervention as acceptable in accordance with a mean PFS score of 4.25 of 5.00 (higher than the preregistered cut-off score of

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3.00). More specifically, parents rated the intervention as easy to understand (4.41 of 5.00), easy to use (4.31 of 5.00), likely to help other parents (4.31 of 5.00), enjoyable (3.92 of 5.00), worth recommending to other parents (4.20 of 5.00), and endorsed agreement with the program's message (4.56 of 5.00).

Discussion

Principal Findings

Our results support the short-term efficacy and acceptability of project EMPOWER: a self-guided, web-based SSI designed to reduce parental accommodation of child anxiety. Compared to a psychoeducational control, project EMPOWER yielded significant reductions in clinically relevant outcomes-parental accommodation and distress tolerance-across a 2-week follow-up period. Additionally, participating parents viewed project EMPOWER as highly acceptable and subjectively helpful for managing their child's distress relative to the psychoeducational control. Moreover, parents who began project EMPOWER completed the program at a relatively high rate (66.44%), both when compared to a prior naturalistic program evaluation of web-based, self-guided SSIs (eg, 34.32% completion rates for 3 other web-based SSIs) [26] and compared to completion rates reported for similar self-guided, digital mental health support tools (0.5%-28.6%) [35]. This retention level within a self-guided program suggests project EMPOWER's strong acceptability among its users. Together, our results suggest the promise of project EMPOWER to mitigate known risk factors for anxiety in children, and specifically those with parents who have high levels of anxiety.

Notably, the between-group effects of project EMPOWER on parental accommodation (d_{FASA} =0.61) compared favorably to the effects observed in separate trials of treatments targeting parental accommodation-including those observed in a trial of a 12-week, parent-directed, therapist-guided intervention (the Supportive Parenting for Anxious Childhood Emotions program [15], postintervention $d_{FASA} = 0.22$ vs child-directed exposure therapy). The effect sizes in project EMPOWER also compare favorably to previously reported effects of SSIs that directly target anxiety in the youth (post-SSI $d_{child anxiety}$ =0.56) [8]. These previously observed effects serve as approximate benchmarks for the impact of project EMPOWER, rather than direct comparisons, owing to variation in the methods (eg, more vs less active comparison groups), follow-up duration, and intervention intensity. Nonetheless, our results are the first to suggest that a 30-minute, fully self-guided, parent-directed intervention may help reduce parental accommodation, potentially helping to mitigate anxiety in their children. Frequently cited benefits of self-guided, web-based SSIs-including their potential for rapid scalability, their free availability to users, and the ability to complete them at any time and location [26,31]—highlight the high potential public health impact of project EMPOWER, catering to individuals and populations who may otherwise be unable to access support.

Limitations

Several limitations of this trial warrant discussion and suggest directions for future studies. First, although the completely web-based study design allowed for a large sample size and rapid, low-cost recruitment through social media, the lack of monetary compensation likely contributed to substantial attrition at follow-up (61.13%), despite scheduled email reminders. However, it is worth noting that offering greater monetary compensation may have introduced additional bias to the sample selection. This limitation was addressed via a rigorous missing data approach, which has shown utility with high rates of missing data, including those observed in this trial [36]. Second, similar to the limitations noted in much of the literature on parenting interventions, the homogeneity in sex (98% mothers), race and ethnicity, and education status in our sample limited the generalizability of our results across diverse groups of parents. This may be due to the selection bias introduced by recruitment through social media as Facebook likely distributed the advertisements to users who are interested in the study topic. As the study team did not have control over the algorithms that are used to distribute the advertisement, it limited our ability to reach a more diverse population. Moving forward, it will be critical to test the acceptability and effects of project EMPOWER and other self-guided SSIs among members of marginalized and minoritized communities of individuals who are systematically least likely to access traditional, face-to-face mental health treatments owing to financial, logistic, and stigma-related barriers.

Given that non-English-speaking parents were unable to take part in the study (project EMPOWER is currently available only in English), efforts to translate project EMPOWER into various languages may greatly facilitate tests of its acceptability and utility among more diverse caregivers. Third, because this trial was the first to assess the acceptability and proximal effects of project EMPOWER, we included a relatively brief 2-week follow-up period. Thus, results address only the short-term effects of the intervention on known risk factors for child anxiety. Given that some trials of self-guided SSIs have demonstrated clinical benefits for youth up to 9 months after the intervention [31,37], the longer-term effects of project EMPOWER remain important to explore. Such studies may investigate whether the intervention can prevent the emergence of child anxiety symptoms and evaluate improvements in parental accommodation and distress tolerance as possible change mechanisms.

Future Directions

Future studies should examine whether and how project EMPOWER may be useful as both a standalone intervention (as assessed here) and as a possible adjunctive support in the context of longer-term, child-directed anxiety treatment, for families in need of more intensive clinical support. For example, clinicians may assign project EMPOWER as "homework" to augment traditional psychoeducation about the nature and maintenance of anxiety; alternatively, therapists might deploy project EMPOWER as a relapse prevention tool, which would be introduced upon termination of child-focused treatment or as an interim support for families on waiting lists for treatment. Future studies should gauge the potential of project EMPOWER as a therapy-augmenting tool and evaluate its impact on treatment duration and symptom changes in the youth. Given the potential of project EMPOWER for rapid scalability (as a free, self-guided, web-based intervention), future studies should also evaluate its possible use across multiple settings and among diverse populations. This initial trial recruited the parents of young children; however, project EMPOWER teaches skills of potential relevance to any adult who interacts with children, including teachers, mentors, and health care workers. Therefore, project EMPOWER may be integrated into numerous existing environments of the youth through direct distribution to adults who care for them, who may utilize the program however and wherever they choose.

Conclusions

In conclusion, project EMPOWER shows promise as a scalable, brief, self-guided approach to reducing accommodation behaviors and strengthening distress tolerance among parents of school-aged children, who have high levels of anxiety—at least over the short term.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Control (ORR) Condition - Online Resources and Referrals, Project EMPOWER. [PDF File (Adobe PDF File), 316 KB - mental v8i7e29538 app1.pdf]

Multimedia Appendix 2 CONSORT-eHEALTH checklist (V.1.6.1). [PDF File (Adobe PDF File), 1201 KB - mental_v8i7e29538_app2.pdf]

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Abbreviations

DTS: Distress Tolerance Scale FASA: Family Accommodation Scale—Anxiety ORR: Online Resources and Referrals PFS: Program Feedback Scale PSWQ: Penn State Worry Questionnaire RCADS-25-P: Revised Children's Anxiety and Depression Scale-Parent Report SSI: single-session interventions

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Original Paper

A Digital Toolkit (M-Healer) to Improve Care and Reduce Human Rights Abuses Against People With Mental Illness in West Africa: User-Centered Design, Development, and Usability Study

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Abstract

Background: The resources of West African mental health care systems are severely constrained, which contributes to significant unmet mental health needs. Consequently, people with psychiatric conditions often receive care from traditional and faith healers. Healers may use practices that constitute human rights violations, such as flogging, caging, forced fasting, and chaining.

Objective: The aim of this study is to partner with healers in Ghana to develop a smartphone toolkit designed to support the dissemination of evidence-based psychosocial interventions and the strengthening of human rights awareness in the healer community.

Methods: We conducted on-site observations and qualitative interviews with healers, a group co-design session, content development and prototype system build-out, and usability testing.

Results: A total of 18 healers completed individual interviews. Participants reported on their understanding of the causes and treatments of mental illnesses. They identified situations in which they elect to use mechanical restraints and other coercive practices. Participants described an openness to using a smartphone-based app to help introduce them to alternative practices. A total of 12 healers participated in the co-design session. Of the 12 participants, 8 (67%) reported having a smartphone. Participants reported that they preferred spiritual guidance but that it was acceptable that M-Healer would provide mostly nonspiritual content. They provided suggestions for who should be depicted as the toolkit protagonist and ranked their preferred content delivery modality in the following order: live-action video, animated video, comic strip, and still images with text. Participants viewed mood board prototypes and rated their preferred visual design in the following order: religious theme, nature motif, community or medical, and Ghanaian culture. The content was organized into modules, including an introduction to the system, brief mental health interventions, verbal de-escalation strategies, guided relaxation techniques, and human rights training. Each module contained several scripted digital animation videos, with audio narration in English or Twi. The module menu was represented by touchscreen icons and a single word or phrase to maximize accessibility to users with limited literacy. In total, 12 participants completed the M-Healer usability testing. Participants commented that they liked the look and functionality of the app and understood the content. The participants reported that the information and displays were clear. They successfully navigated the app but identified several areas where usability could be enhanced. Posttesting usability measures indicated that participants found M-Healer to be feasible, acceptable, and usable.

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Conclusions: This study is the first to develop a digital mental health toolkit for healers in West Africa. Engaging healers in user-centered development produced an accessible and acceptable resource. Future field testing will determine whether M-Healer can improve healer practices and reduce human rights abuses.

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KEYWORDS

mobile phone; low- and middle-income country; schizophrenia; bipolar disorder

Introduction

Background

At any given time, up to 6.8% of the world's population has a serious mental illness (SMI), such as schizophrenia or bipolar disorder [1]. These psychiatric conditions are major causes of impairment and disability that produce particularly devastating long-term outcomes for individuals and communities with extreme resource constraints [2]. Individuals with SMI are at a heightened risk of homelessness, medical comorbidity, incarceration, victimization, and suicide [3]. In West Africa, the hardships of SMI are compounded by pervasive societal stigma, scarce treatment options, systematic exclusion, neglect, and abuse [4-7].

West African mental health care systems have severely constrained resources that contribute to significant unmet mental health needs [8-11]. Consequently, people with SMI who require mental health services often receive care from traditional and faith healers rather than from medically trained mental health professionals [12-14]. Ghana is a prime example of the disproportionate gap between the population's mental health needs and access to mental health care providers trained in evidence-based practices: in 2017, the country had an estimated 27 million residents and approximately 6 psychiatrists and 7 psychologists for every 10 million residents, 3 psychiatric hospitals in total, and 4 community residential care facilities throughout the country [15]. Conversely, there are more than 44,000 traditional and faith healers in Ghana [9].

Ghana is one of the most religious countries on the planet [16]. The majority of the population in Ghana is Christian (ie, Pentecostal, Charismatic, and Evangelical), with the exception of the Northern region, which is predominantly Muslim [17]. Less than 6% of the population still follows the traditional religion, which expresses belief in both a supreme being and spiritual entities that reside in nature, but traditional shrines and remedies are still common and interwoven with other religious practices. Beyond economic and access barriers, many people seek out traditional and faith healers because they believe they will provide the type of care they or their family members are looking for [14]. Depending on the region's dominant religion, an individual with mental illness may receive services from fetish priests, Christian pastors, or Muslim mallams [5]. Healers typically have no formal training in the etiology, diagnosis, or evidence-based treatment of mental illness. Traditional and faith-based care is not uniform and may vary dramatically across healers [12-14]. Healers often share the belief that psychopathology is spiritual in nature, and therefore, they may provide spiritual consultation, prescribe prayer, engage in sacrifices, or administer various ceremonial or herbal remedies

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[12-14,18,19]. In addition to these strategies that may have psychosocial benefits (eg, preaching helps address feelings of fear and offers patients a sense of hope and optimism [13]), healers may also use practices that constitute human rights abuses (eg, flogging, keeping patients in overcrowded enclosures or cages, forced fasting, shackling, exposure to the elements, and chaining patients to trees or concrete slabs for weeks or months) [7,18,19]. Chaining or similar forced mechanical restraining of people with SMI occurs in Africa, Asia, Europe, the Middle East, and the Americas [20]. These practices are psychologically damaging and physically dangerous [7,18-20].

Despite their oftentimes controversial practices, healers are the de facto providers and gatekeepers of care for people with SMI in West Africa [21,22]. Recent findings suggest that healers are open to engaging with mental health professionals, researchers, and technologists to learn about new and alternative approaches to managing the care of people with mental illness [23,24]. Our multinational, multidisciplinary research team has partnered with healers to develop and assess *M*-Healer, a digital toolkit designed to support the dissemination of evidence-based psychosocial interventions and the strengthening of human rights awareness and knowledge among healers in West Africa. The first stages of our development process focused on a *feasibility assessment*.

Objectives

The primary objectives of this phase of the development process were to identify design requirements for a prototype M-Healer toolkit through off-site and on-site research activities, create the M-Healer prototype, and gather user feedback about the prototype from primary stakeholders in Ghana. On the basis of this foundational work, we concluded that (1) M-Healer would be most accessible if it was developed to be deployed via smart mobile devices with multimedia players that can deliver content in modalities other than written text for users with limited literacy; (2) content that undermines or negates the spiritual beliefs of the intended healer users or attempts to bypass them altogether (eg, directed at patients at the prayer camps while they are under the care of healers) would be counterproductive and may impede M-Healer adoption; and (3) in addition to the more typical illness-focused mental health intervention material that is typically used in mobile health (mHealth) treatment apps, there is also a crucial need to integrate content that focuses on the preservation of human rights, human dignity, and safety in practice [25]. Guided by these principles, we progressed to the next stages in the M-Healer user-centered design (UCD) and development process: individual interviews with healers, group co-design session, intervention content development and programming, and preliminary usability testing of a beta version

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of the M-Healer system with traditional and faith healers in West Africa.

Methods

Overview

The research reported here was approved by the institutional review boards of the University of Washington and the University of Ghana. Typical of digital health development work [26-29], the UCD, development, and testing procedures that produced M-Healer were segmented into distinct steps. Although the overall sequencing of the development process was predetermined, the outcomes of each step informed the specific content and rollout of activities in subsequent steps.

We conducted on-site interviews and observations at prayer camps in Ghana, a collaborative co-design session with healers to gather rapid feedback regarding possible design approaches, content development and prototype system build-out, and usability assessment with target end users. Interview protocols and elicitation materials drew on our previous work in Ghana [25], existing scientific literature on digital health and psychiatric services in West Africa, and user-centered technology design best practices from the field of information and communications technology for developing communities [30]. Study preparatory activities included conducting a comprehensive stakeholder analysis, researching digital infrastructure requirements, and developing participant interview materials. Our stakeholder analysis included identifying potential primary, secondary, and tertiary user groups; listing challenges of involving each of these stakeholders in on-site activities; and weighing anticipated costs and benefits of engaging with each stakeholder group. Digital infrastructure requirements focused on the likelihood of certain technologies being readily used, data and storage limitations, and other factors that would constrain future app development. We prepared visually enhanced data collection guides to help mitigate possible low literacy rates of the primary stakeholder population as well as potential language barriers between members of the research team and the faith healers. A reference library of descriptive photographs featuring African people and depicting a range of relevant situations, circumstances, relationships, and emotional states was created to use as needed when conducting interviews.

Study Sites and Participants

Data collection activities were conducted with individuals who provided care to people with psychiatric illnesses in prayer camps in Ghana (ie, *healers*). Healers in the study varied in their position and rank within each camp and ranged from the most senior representative (ie, prayer camp leader or *prophet*) to more junior-level staff. All participants had regular direct interactions with patients in the camps. Individual interviews and usability testing activities were conducted with individuals at the camps where they worked. The co-design session involved a group discussion with participants from several different prayer camps and was therefore conducted in a neutral meeting center at a hotel in the region where all camps were located. Prayer camps varied in the number of patients with SMI they served at any given time, the number of staff members employed, and their specific service characteristics. All camps provided residential or inpatient care to people with psychiatric conditions. They range from well-appointed lodging with individual rooms to much more rustic communal settings. In one camp, patient stays were completely voluntary, and they could elect to leave at any time. At least two camps used observable forms of forced restraint and confinement. Shackles were observed in at least one camp, and locked enclosures were observed in another. Per participant reports, at least two camps used forced fasting as an intervention modality. All camps had centralized areas where communal prayer services were conducted daily and separate communal living areas where patients slept. Several camps had mattresses located in the main prayer area to accommodate *overflow* patients.

Qualitative Interviews

Healer interviews were conducted by research team members who visited 3 prayer camps. Participants were compensated 50 Ghanaian cedi (approximately US \$8.50) for their time. Camp representatives verbally indicated their willingness to participate in our research before the site visits and anticipated the team's arrival. At the beginning of each site visit, the prayer camp leaders and staff were briefed about the nature of the project and the overall objectives of the research program. At all 3 prayer camps, healers offered a tour of the facilities to the research team either before or after the interviews. All healers present that day were invited to participate. Following informed consent, a research team member trained in qualitative interviewing strategies together with a team member fluent in Twi co-conducted the interview with a single participant in a private setting. Interview questions focused on healers' current practices, needs, assessment of situations that lead to human rights abuses (eg, chaining, fasting, and forced seclusion), readiness to change practices, and interest in integrating technology to support their practices at the prayer camps. Interviews were audio recorded with permission and subsequently transcribed.

Co-design Session

Healers were invited to participate in an upcoming co-design session. Interested individuals provided their contact information, and within a few days, a member of the research team followed up via telephone with an invitation and details. We convened a co-design session, including members of the research team and faith healers. The session was audio recorded and later transcribed. The objective of this session was to collectively ideate and assess the feasibility of the design directions for the M-Healer system. Before the session began, lunch was provided to the participants. Participants were compensated 100 Ghanaian cedi (approximately US \$17) for their time. The session was cofacilitated by 1 Ghana-based (SMA) and 1 US-based researcher (DBZ), with materials developed by team members with expertise in participatory design (JS) and mHealth app content development (SM). Participants sat around a large table and were explicitly invited to share their experiences, opinions, and ideas. Following informed consent, participants were assigned a number (1-12) via an index card to facilitate rapid data collection. Facilitators referred to participants by this number, aiding in the proper attribution of speakers in transcripts. Participants were first

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introduced to mHealth and provided background information on the proposed mHealth technology. Participants were asked to evaluate and rate the aspects of the mHealth intervention model, intervention content, intervention modalities, and design preferences and rate them from 1 to 10 (0=strongly dislike and 10=like a lot). Participant numerical ratings directly informed the rapid synthesis of emergent design requirements and specifications.

Content Development and System Design

M-Healer content was conceptually guided by the stress-vulnerability model [31] and social rank theory [32,33], as they apply to the emergence and maintenance of psychopathology. The stress-vulnerability model posits that the course and outcomes of SMI are determined by the interplay of biological vulnerability, stress, and coping. To improve illness outcomes, illness management strategies based on this model aim to interrupt the cycle of stress and vulnerability that often lead to exacerbation of one's condition [34,35]. Social rank theory suggests that pathological responses may emerge when vulnerable individuals find themselves in unwanted low status or rank positions with little ability to affect change or alter others' perceptions of them. Feelings of shame and powerlessness are associated with the emergence, maintenance, and exacerbation of psychiatric conditions [36-39]. Furthermore, the use of restraints has been shown to worsen mood symptoms, hallucinations, and psychological distress and lengthen psychiatric inpatient stays [40-42]. M-Healer was created to guide healers on reducing their use of interventions that increase the stress placed on their patients (eg, mechanical restraints, fasting, isolation, and humiliation) and to train them on the use of simple psychosocial strategies to help patients better cope with their psychiatric symptoms in a manner that does not increase their feelings of shame and powerlessness.

M-Healer intervention content was initially developed by members of our team who are clinicians with expertise in providing care to people with SMI. Intervention module scripts were then circulated among all team members in the United States and Ghana to provide clinical input, lexical modification suggestions (ie, adopting terminology used in West Africa), and guidance on religious contextual anchoring to ensure that M-Healer content does not contradict or undermine prevailing beliefs in the region. Following appropriate modifications, we created a brief digital animation video depiction for each M-Healer intervention script in collaboration with a graphic artist. In parallel, we recorded spoken descriptions of each intervention in English and Twi (the most common languages in Ghana) by native Ghanaians. Audio recordings were then added to the digital animation videos so that users could select their preferred narration language for each intervention.

The M-Healer prototype development included building out a stable and self-contained Android platform, key path information architecture, integration of preliminary M-Healer branding, and examples of animated video and text content; the M-Healer user interface was developed in accordance with UCD principles and programmed to maximize accessibility and usability. We anticipate that M-Healer will be used in settings with low broadband support; therefore, the app was built to be

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self-contained with content delivered via optimized animated videos. Power-saving features, such as the dark mode, were integrated whenever possible.

Usability Testing

User testing was conducted in Ghana in 2020, administered by the members of the research team based in Accra. The primary objective of prototype testing was to assess the perceived usefulness (value of the format and organization of content) and usability (ease of use of the interface and information architecture) of the M-Healer prototype. Faith healers who participated in the previous stages of the study were invited to provide feedback on the prototype. In addition, representatives of 2 additional camps participated in the testing. Participants were compensated 100 Ghanaian cedi (approximately US \$17) for their time. Prayer camp leaders indicated their willingness to participate in our research before site visits and anticipated the team's arrival. The research team members followed COVID-19 sanitation and social distancing practices as part of the research procedure. M-Healer was downloaded on team members' Android smartphones and was used to introduce the tool to participants during testing. Following informed consent, a trained team member conducted a semistructured interview with a healer participant in their preferred language. Interviews were audio recorded in the participants' preferred language and recorded in writing in English.

Participants were asked to interact with M-Healer for 2 minutes before initiating the interview. Participants were asked a series of open-ended questions about their experience navigating the tool, design preferences, and assessing content in 4 different domains: human rights content, relaxation content, verbal de-escalation content, and cognitive behavioral therapy skills training content. The research team focused on evaluating app content, interactivity, information design, and navigation.

Participants completed a 27-item measure comprising items drawn from a feasibility and acceptability questionnaire used in previous mHealth research [43] and items drawn from the user burden scale [44]. Participants also completed the 10-item system usability scale [45]. Participants were asked to rate their agreement with the measure statements using a 5-point bipolar rating scale (range 1=strongly disagree to 5=strongly agree).

Results

Qualitative Interviews

A total of 18 healers (16 males and 2 females) from 3 prayer camps completed individual interviews with our study team. The sample had an average age of 43 years (SD 11.2; range 26-66 years). All participants were Ghanaian. Self-identified titles ranged from *prophet* to *attendant* depending on roles, responsibilities, and position within the prayer camp organizational structure.

Participants reported their understanding of the causes and treatments of mental illnesses. Participants varied in their understanding of the etiology and treatment of mental illnesses. Most participants made clear distinctions between the conditions they believed were caused by spiritual problems that require spiritual or religious intervention and what they designated as

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mental illnesses with physical or biological origin that required medical intervention. They expressed confidence that they or the highest-ranking member of their prayer camp could accurately distinguish between these types of conditions. For example, one faith healer explained:

There are some that are caused by spirits. There are some that are physical and some problems that are spiritual. So those problems that are physical, when they come in and they pray for them, they refer them to the hospital.

Participants described situations in which patients with SMI become aggressive or violent. Participants reported a variety of strategies to manage these behaviors, including prayer, fasting, mechanical restraints, and seclusion. These treatments are often prescribed by a high-ranking member of the prayer camp, such as a prophet or other spiritual leader, and implemented by attendants. Most participants interviewed indicated that using mechanical restraints (ie, chaining) was a controversial practice. Recent exposure to government-sponsored campaigns to disincentivize such practices may have influenced their viewpoints; however, many participants stated that there were very few viable alternatives and that there was often no choice when a patient was aggressive or violent.

To better understand the factors that influenced whether patient behaviors were seen as resulting from spiritual or medical illness, we asked participants about the criteria they used when prescribing interventions such as forced fasting or restraints and how they assessed when to discontinue such interventions. Participants described how this was seldom a systematic process:

...A general reduction in the symptoms for which they were brought in, determines when they get out of chains. If somebody comes in shouting, suddenly he'll quiet down and gain a certain level of consciousness that says-- why am I in chains? Because in the beginning they wouldn't even know they were in chains and then when they get them out of the chains finally, they're not acting out and they seem to follow instructions. There's no specific criteria or specific things to look out for to get someone out of chains, but a general drop in the symptoms.

During the site visits, the team did not directly observe the chained patients. However, we did see a locked enclosure with patients at one of the sites and evidence of mechanical restraints in another, where unused shackles were connected to a wooden post in the main prayer or congregation area. When we inquired about the use of mechanical restraints, it became apparent that many healers were influenced by recent government campaigns, media reports, and advocacy efforts to reduce chaining practices. One participant described recent trends in reducing shackling:

...We stopped [using chains]...some people can be overzealous or overly aggressive that you can't do much about...But now this has changed from the times where, from years ago the frequency would have been more compared to now.

In contrast, forced fasting was acknowledged to still be widely used. One healer explained that most patients entering the camp were expected to abstain from food according to a schedule determined by a healer:

Or sometimes if the person is a new person, a fresh person, when we see that the person is too aggressive we give them fasting. During the fasting the person will calm down. After 21 days, the person becomes sober.

Participants reported on their use of smartphones and their interest in a smartphone-based app in their daily work. When the research team showed an example of an mHealth app to participants, they were interested in the idea and at times endorsed the content displayed. One participant was now a pastor at a camp but previously was a patient who experienced auditory hallucinations. He described excitement hearing about an intervention to help people who hear voices and wanted to learn more about it.

Co-design Session

A total of 12 participants (10 males and 2 females) from 3 prayer camps participated in the group co-design session. The sample had an average age of 45 years (SD 8.8; range 35-66 years). All participants were Ghanaian. All but one participant had participated in the previous qualitative interviews. In total, 67% (8/12) participants reported owning and using a smartphone.

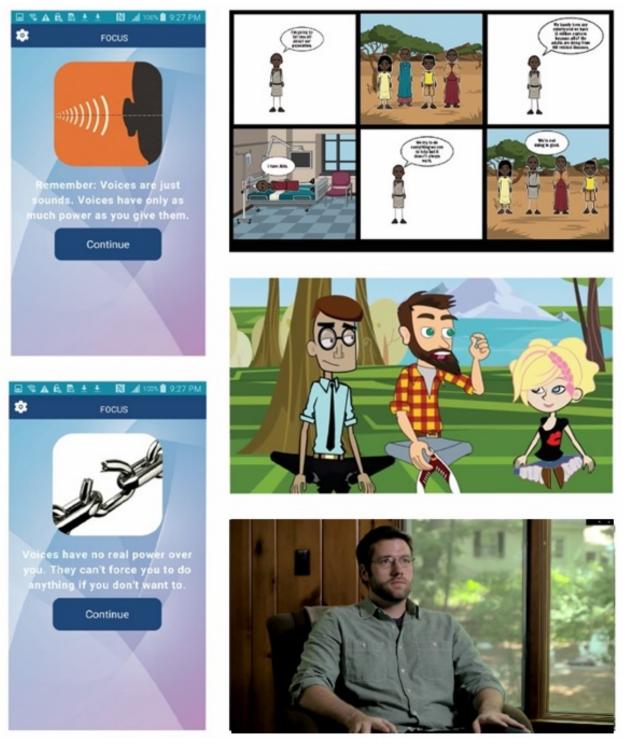
Participants reported that they prefer spiritual guidance to medical guidance for working with patients. The research team indicated that they do not have the spiritual or religious expertise to assist in guiding those elements of their work and inquired whether it would be acceptable if M-Healer would provide mostly nonspiritual guidance, and all participants responded affirmatively. When asked who should deliver the M-Healer content or be depicted as a protagonist in the app, participants identified *pastors* (a term used for the higher ranking workers at the prayer camps) and doctors as the most trusted and credible source of information.

Participants were then shown a series of projected slides detailing different content delivery modalities: educational text with images, comic strips with text, animated digital videos with narration overlaid, and a live-action video discussing educational information (Figure 1). The live-action video was rated the highest (average score 9.5, SD 0.5), animated digital video was rated second (average score 6.7, SD 1.9), comic strip was rated third (average score 4.2, SD 2.6), and still images with text received the lowest rating (average score 2.8, SD 1.9). Although live-action videos were preferred overall, on further inquiry, participants reported no concern that animated content was too juvenile or made light of the topic.



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Figure 1. Presentation modes presented to participants during the co-design session. From upper left: 1, static text; 2, graphic novel style; 3, animated video; and 4, live-action video.

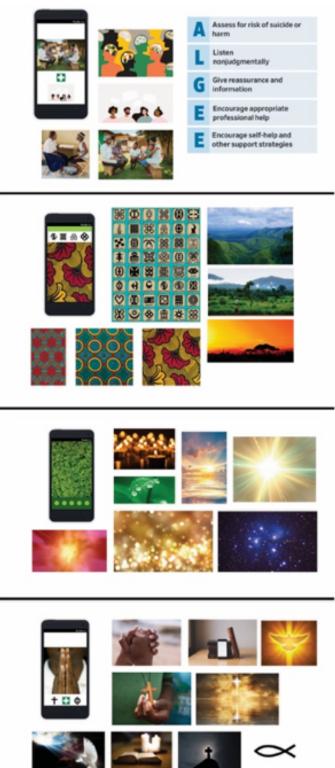


Finally, participants viewed a series of 4 *mood board* visual prototypes to assess their preferences for the look and feel of app content and design (refer to Figure 2 for visual prototypes). The explicitly religious theme was rated highest (average score

9.3, SD 0.8), nature motif was rated second (average score 9.0, SD 0.9), community or medical was rated third (average score 6.9, SD 1.3), and Ghanaian culture was rated last (average score 5.0, SD 1.6).



Figure 2. Four variations on visual motifs presented to participants during the co-design session. From top: community or medical, Ghanaian culture, nature motif, and explicitly religious.



Content Development and System Design

M-Healer content is organized into modules, including an introduction to the system, brief mental health interventions, verbal de-escalation strategies, guided relaxation techniques, and human rights training. Each module contains several individually scripted digital animation videos that are approximately 1 minute long, with narration in English or Twi.

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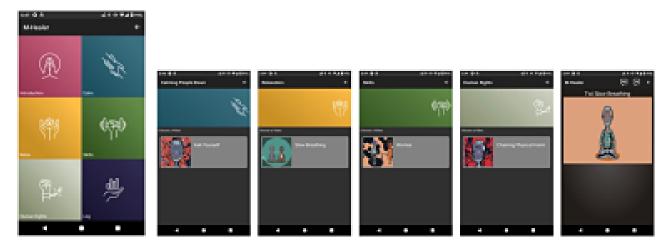
XSL•FO RenderX The visual style of the app integrates spiritual motifs and metaphors without explicitly referencing any one particular religious iconography. M-Healer's digital animations address healers as users and depict a healer or pastor figure as the main protagonist. Digital animations provide information on the physical harm; spiritual harm; and psychological effects of chaining, forced seclusion, and forced fasting. Combined with animations for training on psychosocial strategies, these tools

are meant to increase healer awareness of their own decisions to use coercive practices and help reframe their own interpretations (ie, a loud or distressed patient is not necessarily going to act violently; if someone is hearing voices, they may be feeling afraid; and there is a high long-term cost to patients who experience chaining) and to offer viable alternative solutions.

The M-Healer touchscreen user interface was designed and programmed to maximize accessibility and usability. The module menu is represented by touchscreen icons and a single

Figure 3. User interface of the prototype M-Healer app.

word or phrase so that users with limited literacy would be able to navigate the system successfully based on visual depictions of the content of each module. The app is compatible with smartphones running Android operating system version 4.1 or higher (the majority of smartphones in West Africa) and can be made available for download from the Google Play store. M-Healer is navigated entirely by clicking on icons on the device touchscreen. The software enables flexible user-initiated demand access to all modules and digital animations via the home screen (Figure 3).



Usability Testing

A total of 12 participants (11 male and 1 female) from 5 prayer camps participated in the M-Healer usability testing. The participants had an average age of 50 years (range 34-63 years). All participants were Ghanaian. Participants reported an average of 18 years of experience working with patients with mental illness in camps. Of this sample, 7 individuals participated in at least one of the previous study steps.

Overall, the open-ended feedback on the M-Healer app was positive. Participants commented that they liked the look and functionality of the app and understood the content. Participants reported that the information and display of the app were clear:

I am okay with the app. I feel the app contains information that could be useful. I am satisfied with animation and audio.

In total, 2 participants reported issues with the home screen icons representing different content areas; for example, one reported that the icons were confusing.

Participants were able to view, understand, and summarize clinical content from the animated videos shown during the usability testing: (1) calming down before working with aggressive patients (de-escalation), (2) deep breathing skills (relaxation), (3) skill for managing worried thoughts (cognitive

intervention), and (4) harm of chaining practices on patient health (human rights). Animated video narrations were available in Twi or English, and all participants preferred the Twi language version:

I don't know the breathing technique but think it might work. But I would need to practice to be able to do it effectively.

In addition, participants reflected on learning new concepts and skills that could be used in work with patients with SMI: "I did not know I could use this to help people get less aggressive." Some participants indicated that the content was acceptable because some features incorporated spiritual values and practices: "I am happy about the use of prayer in the skills video." Participants generally did not like the written text below the home screen module icons and preferred audio Twi content. The research team learned that although the local dialect is commonly spoken, it is not often read or written. Therefore, having an audio indicator associated with each module icon would enable greater usability and ease of content selection: "A voice to say what each tab is would be helpful." Participant ratings of app feasibility and acceptability were promising, with the majority of participants rating the M-Healer app as intuitive, functional, and understandable (Table 1). Their system usability scale ratings (mean score 75, SD 12) indicate above-average usability [46].



Table 1. Participant ratings of M-Healer feasibility and acceptability.

Statement Response	Participants, n (%)
"I am satisfied with M-Healer."	
Neutral	2 (17)
Agree	5 (42)
Strongly agree	5 (42)
"I think that I would like to use M-Healer often."	
Agree	7 (58)
Strongly agree	5 (42)
"It was easy to learn to use M-Healer."	
Neutral	3 (25)
Agree	7 (58)
Strongly agree	2 (17)
"I found M-Healer very awkward to use."	
Strongly disagree	3 (25)
Disagree	8 (67)
Agree	1 (8)
"I felt comfortable using M-Healer."	
Agree	9 (75)
Strongly agree	3 (25)
"I found M-Healer to be very complicated."	
Strongly disagree	2 (17)
Disagree	7 (58)
Neutral	3 (25)
"I get frustrated when using M-Healer."	
Strongly disagree	5 (42)
Disagree	6 (50)
Neutral	1 (8)
"M-Healer is fun to use."	
Neutral	1 (8)
Agree	7 (58)
Strongly agree	4 (33)
"M-Healer works the way I want it to work."	
Neutral	3 (25)
Agree	6 (50)
Strongly agree	3 (25)
"It was easy to find the information I needed."	
Disagree	2 (17)
Neutral	1 (8)
Agree	5 (42)
Strongly agree	3 (25)
No answer	1 (8)
"I would imagine that most people would learn to use M-Healer very quickly."	
Neutral	1 (8)

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Statement	Response	Participants, n (%)
	Agree	9 (75)
	Strongly agree	2 (17)
"M-Healer	forces me to make changes to how I normally use smartphone apps."	
	Disagree	1 (8)
	Neutral	1 (8)
	Agree	8 (67)
	Strongly agree	1 (8)
	No answer	1 (8)
"M-Healer	demands too much mental effort."	
	Strongly disagree	5 (42)
	Disagree	6 (50)
	Agree	1 (8)
"I need assi	stance from another person to use M-Healer."	
	Strongly disagree	3 (25)
	Disagree	3 (25)
	Neutral	2 (17)
	Agree	3 (25)
	Strongly agree	1 (8)
"I found tha	at the different parts of M-Healer work well together."	
	Neutral	2 (17)
	Agree	7 (58)
	Strongly agree	3 (25)
"How thing	s appeared on the screen was clear."	
	Agree	6 (50)
	Strongly agree	6 (50)
"If I have a	ccess to M-Healer, I will use it."	
	Agree	4 (33)
	Strongly agree	8 (67)
"I would re	commend M-Healer to a friend."	
	Agree	6 (50)
	Strongly agree	6 (50)
"I feel I nee	d to have M-Healer."	
	Agree	6 (50)
	Strongly agree	6 (50)
"Using M-H	lealer makes me feel like a bad person."	
	Strongly disagree	4 (33)
	Disagree	8 (67)
"Overall, I	am satisfied with how easy it is to use M-Healer."	
	Neutral	1 (8)
	Agree	9 (75)
	Strongly agree	2 (17)
"The inform	nation provided for M-Healer was easy to understand."	
	Agree	8 (67)

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Statement	Response	Participants, n (%)
	Strongly agree	4 (33)
"Informatio	on, such as images and sounds, from M-Healer is hard to understand."	
	Strongly disagree	2 (25)
	Disagree	5 (42)
	Neutral	1 (8)
	Agree	3 (25)
	Strongly agree	1 (8)
"M-Healer	is not appropriate for my cultural background."	
	Strongly disagree	2 (17)
	Disagree	8 (67)
	Neutral	1 (8)
	Strongly agree	1 (8)
"M-Healer	requires me to remember too much information."	
	Strongly disagree	3 (25)
	Disagree	6 (50)
	Neutral	1 (8)
	Agree	2 (17)
"M-Healer	presents too much information at once."	
	Strongly disagree	3 (25)
	Disagree	8 (67)
	Agree	1 (8)
"I am worr	ed about what information gets shared by M-Healer (privacy)."	
	Strongly disagree	4 (33)
	Disagree	7 (58)
	Neutral	1 (8)

Discussion

Principal Findings

Digital technology can play an important role in the management of psychiatric illnesses in low- and middle-income countries [47]. Our multinational team successfully developed and completed the preliminary testing of M-Healer, a novel mHealth intervention designed to be used by healers who provide care to people with psychiatric illnesses in West Africa. Healers and staff from several prayer camps in the region were engaged throughout our development process and provided valuable input and guidance on M-Healer design, functionality, and content. Our study findings suggest that healers found the M-Healer prototype to be feasible, acceptable, and usable. These promising findings set the stage for further development and deployment of M-Healer in the context of real-world services at prayer camps in West Africa.

This project makes several valuable contributions to the field. The technology we developed was specifically designed to be used by healers serving people with mental illnesses. To our knowledge, this constitutes the first attempt to develop a digital mental health intervention to be used by this population.

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M-Healer content depicts a healer character as the main protagonist in the app's digital animations and incorporates generalized spiritual visual motifs that were rated as favorable by healers in our user-centered development process.

Globally, there is a growing awareness of the need to protect the human rights of people with mental illness [18]. The World Health Organization has developed a toolkit designed to educate leaders, health care professionals, administrators, and policy makers on the assessment and advancement of more humane mental health care [48]. The M-Healer technology developed in this study complements these efforts by addressing human rights issues in a manner that may be more suitable for community-based paraprofessionals and laypeople. M-Healer content is directed toward healers and prayer camp staff who make day-to-day decisions and is designed to discourage the use of chaining, forced fasting, and other coercive practices. The technology provides recommendations for alternative psychosocial intervention strategies, including verbal de-escalation, guided relaxation, and active listening. As a downloadable smartphone app, M-Healer could be disseminated efficiently in prayer camps and other informal practice settings,

which often fall beyond the reach of formal educational campaigns or governmental oversight and regulation.

The iterative M-Healer development and usability testing process demonstrated that by leveraging simple design and digital animations rather than written content, mHealth technology can be made to be accessible to people with limited education, literacy, or familiarity with digital health tools. Our user testing demonstrated that M-Healer was navigable and understandable by the intended target audience. Our intention to use digital animations with overlaid narration (English or Twi) rather than videos depicting actors speaking local dialects was to facilitate greater flexibility and future opportunities for leveraging the same digital animations in other regions in Africa where healers operate by adding more narration options in different languages (eg, Yoruba and French).

The project adds to the growing literature showing that despite their differing conceptualizations of the causes of mental illness and appropriate treatments, when treated with respect and mutual appreciation, healers and paraprofessionals who subscribe to more spiritual models of psychopathology are open to collaboration with academic researchers and clinicians promoting Western notions of evidence-based care [22]. This study extends previous findings in West Africa involving the integration of spiritual practices with pharmacological approaches [21,23,24] and demonstrates that healers are also open to exploring the use of digital mental health tools that guide them on psychosocial approaches.

Limitations and Future Work

This study had several limitations. First, although English is Ghana's official language, some participants did not speak English or felt more comfortable communicating with our group in Twi. In such situations, members of the research team who are fluent in Twi assisted the English-speaking investigators conducting interviews and group discussions by translating the information bidirectionally, in real time. In the context of these dynamic interactions, some content might have been lost in translation or misinterpreted. Second, many of the healers involved in the study participated in more than one stage of data collection (eg, interviews, co-design sessions, and usability testing). Continuity in their participation was useful in our iterative-staged technology development. However, the disadvantage of such an approach is that most of the individuals who completed usability testing were not naïve to M-Healer concepts or content, and responses may have been affected by previous exposure. Similarly, the continuity in the relationship between our group and participants may have instilled in healers a sense of heightened commitment to the study and loyalty to the research team. We took active steps to overtly emphasize to participants that all forms of feedback are welcome and useful, and there were several instances when participants voiced their criticisms of proposed M-Healer ideas or concepts and suggested alternatives. Nevertheless, participant bias or social desirability effects may have influenced some of their responses. Future testing with novel participants will help determine whether fully naïve healers are similarly enthusiastic about the technology. Third, healers were notified ahead of time when the project team will be visiting their prayer camps. It is possible that prayer camp staff modified their practices (eg, unchained, clothed, or bathed patients) in preparation for these site visits. Finally, the study examined system use and collected subjective user evaluations but did not evaluate M-Healer's effectiveness. Systematic clinical deployment of M-Healer and rigorous evaluation of its effects on healer behavior and patient outcomes will determine whether the technology is useful in enhancing healers' knowledge of psychosocial interventions and alters their use of more controversial practices. Addressing healer beliefs and practices is one piece of a multifaceted puzzle that influences why, how, and from whom people with mental illness receive care in Ghana. Additional work with a wide range of stakeholders, from people with lived experience and their family members to policy makers, will help inform the development and implementation of multicompetent mental health reform strategies to improve care and reduce human rights violations in the region.

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Conflicts of Interest

DBZ has an intervention content licensing agreement with Pear Therapeutics; financial interests in FOCUS technology and Merlin LLC; and has consulted for eQuility, Trusst Health, and Otsuka Pharmaceuticals Ltd.

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Abbreviations

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mHealth: mobile health **SMI:** serious mental illness **UCD:** user-centered design

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Original Paper

Understanding the Role of Social Media–Based Mental Health Support Among College Students: Survey and Semistructured Interviews

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Abstract

Background: Mental illness is a growing concern within many college campuses. Limited access to therapy resources, along with the fear of stigma, often prevents students from seeking help. Introducing supportive interventions, coping strategies, and mitigation programs might decrease the negative effects of mental illness among college students.

Objective: Many college students find social support for a variety of needs through social media platforms. With the pervasive adoption of social media sites in college populations, in this study, we examine whether and how these platforms may help meet college students' mental health needs.

Methods: We first conducted a survey among 101 students, followed by semistructured interviews (n=11), of a large public university in the southeast region of the United States to understand whether, to what extent, and how students appropriate social media platforms to suit their struggle with mental health concerns. The interviews were intended to provide comprehensive information on students' attitudes and their perceived benefits and limitations of social media as platforms for mental health support.

Results: Our survey revealed that a large number of participating students (71/101, 70.3%) had recently experienced some form of stress, anxiety, or other mental health challenges related to college life. Half of them (52/101, 51.5%) also reported having appropriated some social media platforms for self-disclosure or help, indicating the pervasiveness of this practice. Through our interviews, we obtained deeper insights into these initial observations. We identified specific academic, personal, and social life stressors; motivations behind social media use for mental health needs; and specific platform affordances that helped or hindered this use.

Conclusions: Students recognized the benefits of social media in helping connect with peers on campus and promoting informal and candid disclosures. However, they argued against complete anonymity in platforms for mental health help and advocated the need for privacy and boundary regulation mechanisms in social media platforms supporting this use. Our findings bear implications for informing campus counseling efforts and in designing social media–based mental health support tools for college students.

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KEYWORDS

college mental health; social media; social support; mobile phone



Vornholt & De Choudhury

Introduction

Background

Students' mental health problems are pervasive and serious. In a survey conducted a few years ago, 32.9% of college students answered that they were diagnosed with or treated by a professional for a number of mental health–related issues, such as anorexia, depression, and panic attacks. [1,2]. In the same survey, 60% reported feeling overwhelming anxiety in the last 12 months, and 57% of students answered that the overall level of stress they experienced was higher than the stress experienced by their nonstudent peers. Such mental health concerns can negatively impact students' academic success and their career development [3].

However, many college students with mental health conditions are not seeking help because of stigma they would face from family, friends, faculty, or other students [4]. The National Alliance on Mental Health surveyed college students and found that 50% of students who left school because of mental health reasons did not access mental health services and support offered on campus [5]. The National Survey of Counseling Center Directors similarly revealed that 87% of students who died by suicide in 2010 never sought assistance from counseling or mental health services provided at their campuses [6].

Therefore, it has been posited that the introduction of supportive interventions, coping strategies, and mitigation programs might decrease the negative effects of mental illness in college students, especially among those who might be hesitant to utilize formal psychological services on campus [7-9]. These approaches can also counteract and compensate for limited access to psychiatric facilities and systems for treating and managing mental health conditions in college students, such as those centered around education and therapy [10]. In particular, social support is recognized as a key ingredient in managing mental health [11] and preventing anxiety and depression from becoming a serious concern [12]. Support is particularly critical to overcoming the burden of stigma among college students who find themselves in a new and unfamiliar environment. They may fear that self-disclosing their mental health challenges with counseling services can lead to biased or negative judgments about them or compromise their privacy [13]. Avoidance factors, such as fear of treatment, desire to conceal distress or personal information, and the desire to avoid experiencing increased painful feelings during therapy, may additionally impact college students' decisions to not make use of formal psychological services [14]. Talking to a peer coach or student counselor can help students find social support through alternative and informal means; research has found that peer support specialists can go beyond treatment as usual and use different training and skills to support recovery in conjunction with professionals like therapists, social workers, and psychiatrists [15]. However, not every student feels comfortable seeking support in person within their campus communities. Moreover, college students move across towns, states, and even countries to come to colleges where they often know no one. Although they may still have some support from family and friends back home, finding new

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in-person support at school can be challenging and time-consuming for students dealing with mental illness [16].

The web is increasingly used to seek and share health information on the web [17]. In particular, social media platforms have begun to offer new opportunities to meet the mental health needs of college students and serve as a means of support [18]. In an early work, Eysenbach et al [19] reported that web-based communities could be seen as platforms to deliver mental health and social support interventions-they often have the function and character of self-support offline groups. A key aspect of these communities is providing members with access to other people with similar challenging conditions [20]. Adopting Cutrona and Suhr schema called Social Support Behavioral Code for understanding and assessing support along the dimensions of emotional support and informational support [21], prior research has found that members of web-based communities receive emotional support either directly, through empathetic messages, or indirectly, by being exposed to others having similar experiences [22]. They also gain informational support by receiving helpful information and advice related to treatment and medication, identifying possible explanations for their problems, and building social capital [23].

Currently, more than 90% of young adults or individuals of college-going age use social media [24]. A study of a student-centered social media site, SpartanConnect (a website specific to Michigan State University), showed that the website increased students' perception of a diverse social support system [25]. With a variety of social media platforms available to them, students have many options for finding social support as they transition into college. However, are students making use of these social media platforms to address their mental health needs? What benefits and challenges do they experience in using these platforms to find mental health support?

Objectives

This paper presents a formative study to *explore and understand the role of social media technologies as a complementary source of social support to college students experiencing mental health concerns.* Adopting a two-prong approach, we accomplish 2 goals: (1) we first surveyed a large public university located in the southeast of the United States to identify the extent to which students are appropriating social media platforms to suit their mental health needs. (2) Next, we conducted semistructured interviews with students who identified themselves as struggling with mental health concerns. The interviews sought to describe and provide insights into college students' attitudes and their perceived benefits and limitations of social media as platforms for mental health support.

Methods

Survey

We began by conducting a web-based survey aimed at students currently enrolled full-time at a large public university in the southeast of the United States. Our goal was to assess how attributes of mental well-being are related to students' social media use and to what extent they were appropriating these

platforms to cater to their mental health needs. The survey was approved by the authors' institutional review board.

To gauge student well-being, we used 4 well-validated measures, selection for which was guided by prior research on college student mental health [12]. These measures assessed both objective manifestations of different mental health challenges (eg, anxiety and stress) common in the college student demographic [16] (stress and anxiety are among the most common mental health concerns among college students [9]) as well as identify factors that affect (eg, college environment) or are affected by mental health challenges (eg, self-esteem). A variety of prior research has explored how social-ecological factors affect students' mental health [8,25]. Accordingly, we included the following: (1) the College Adjustment Test (CAT) [26] (Cronbach α =.79), (2) Generalized Anxiety Disorder-7 scale [27] (Cronbach α =.83), (3) Perceived Stress Scale [28] (Cronbach α =.87), and (4) the Rosenberg Self-Esteem Scale [29] (Cronbach α =.86). To evaluate levels of social support, we included the medical outcomes study (MOS) social support survey [30] (Cronbach α =.97). We also included a final measure, borrowing questions from the Facebook Intensity Scale [31] (Cronbach a=.83) and the Zammit Social Media Questionnaire [32] (Cronbach α =.96), which gauged participants' social media usage and behavior-this was because of our focus on examining the role played by social technologies in providing support around mental illnesses. Along with these measures, we included a single question on the extent to which participants used social media to seek help, advice, and support for their mental health; this included a 5-point Likert scale where 1-2 indicated little or no use, 3 indicated moderate use, and 4-5 indicated high use. Finally, our survey contained open-ended questions that aimed to identify how students may or may not use social media to gain social support around mental health needs, such as questions on their intent and motivation, what methods they use to manage their mental health (eg, stress or anxiety) on social media, how they appropriate social media to cope with stress or anxiety, and any perceived barriers to mental health support seeking on social media. The survey also collected basic academic and demographic information, including academic year, major, sex, and ethnicity.

Our selection criteria included any undergraduate or graduate students aged 18 to 24 years enrolled full-time at the university at the time of the survey; part-time students were excluded as they likely experienced a significantly different set of mental health stressors. That said, even among those included, although the 2 student groups (undergraduate and graduate) may experience slightly different sets of mental health stressors, we recruited from both populations as a way of demonstrating the feasibility and role of web-based social support in mental health as well as reaching a large and diverse population. We used both online and offline recruitment strategies. We posted the survey on the university's Reddit community, the campus YikYak (a now deprecated hyperlocal social media platform), Twitter (with the university hashtag), various public and private Facebook student groups, personal Twitter and Facebook profiles, in-person word-of-mouth advertisements, and flyers in different buildings around the campus, including the counseling center on the university campus. Each participant was compensated for their time using a US \$10 gift card. Multimedia Appendix 1 includes our survey recruitment ad.

Interviews

The survey provided a way to examine the patterns of social media use for individuals who choose or do not choose to seek mental health help in social media. As surveys cannot provide nuanced, subjective perceptions and opinions on why and how these platforms are being appropriated for mental health needs, we conducted the following interview study. We adopted a top-down and bottom-up approach to develop a semistructured in-person interview protocol. The top-down approach involved referring social science literature on how support is appropriated by college students to manage and overcome mental health challenges [8], particularly around identifying specific personal and ecologically grounded environmental stressors [5,6], and social media literature that explained how design (or affordances), underlying norms and conventions, identity choices, self-disclosure behaviors, and community interactions shape people's help and information-seeking attitudes on the web [33]. With these theorizations and conceptualizations, we framed interview questions focusing on the web-based aspect of social support. In the bottom-up approach, we revisited the open-ended responses in our survey to identify issues and topics that could use more elaborate discussion. On merging the outcomes of the two approaches, the final protocol focused on the following aspects: (1) stressors or sources of anxiety and mental health concerns students face; (2) the role that social media plays in satisfying students' mental health needs; and (3) the affordances of social media sites that they identify to be most critical to their success as a platform for mental health disclosure and support. Our interview guide is included in Multimedia Appendix 2.

Our selection criteria included full-time undergraduate students who used social media sites for mental health needs. We exclusively focused on undergraduates as the target group as our survey identified them to be most challenged with mental health concerns. Recruitment for interviews occurred in a manner similar to the survey. In addition, we met with 2 licensed psychologists at the counseling center: the assessment services coordinator and the outreach and professional development coordinator as well as the mental health student coalition group toward our recruitment efforts.

Our research team conducted semistructured interviews with 11 undergraduate students. This N was determined based on the number of interviews at which some level of theoretical saturation for the interview questions was achieved; that is, we found interviewees after the first 10 generally reiterated themes and patterns observed in the already collected data, and those interviews did not lead to drastic revisions of the themes or categories in the analysis. This practice is common in qualitative research [34]. Interviews lasted 23 to 71 minutes (median 40 minutes). Participants were told that they could stop the interview at any time and provided with a counseling information resource handout before the interview began, in case they experienced unexpected emotions as a consequence of the ensuing conversation. Each participant was compensated for their time with another US \$10 Amazon gift card for the

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interviews. This study was approved by the authors' institutional review board, as with the survey.

Following the interviews, the authors transcribed the interviews and used an inductive and iterative semiopen coding approach; 2 researchers separately read the transcripts and noted codes manually, relying on our survey findings and literature on self-disclosure and social support [35,36]. This step was followed by a mutual discussion in which more codes were incorporated, and the inconsistencies resolved. Our final list consisted of 32 codes, on which we had 100% agreement; interrater reliability before the mutual discussion was 0.69 (Cohen κ). Finally, the researchers used this codebook to code all transcripts and identify interpretive broader themes that captured commonalities and patterns across different codes, using grounded theory and inductive qualitative thematic analysis. Multimedia Appendix 3 includes the codes developed.

Positionality

The research team includes researchers with backgrounds in psychology and computer science, particularly familiar with both the mental health and social support domains as well as social media systems. The team has extensive experience in qualitative and quantitative methods, spanning the past 15 years of experience in social media research and the past 8 years of research at the intersection of social media and mental health. Finally, the team had adopted participatory approaches to engage with domain stakeholders in this type of research, spanning mental health clinicians, advocacy groups, and public health organizations. This experience has been valuable in shaping the analytical approach of this qualitative study.

Results

Observations From the Survey

Overview

A total of 147 participants responded to our survey, which was active for 2 months. After removing incomplete responses, we were left with 101 responses that we used in our ensuing analysis. The removed data included survey responses completed extremely quickly (less than 5 min) and those that failed *trap* questions to complete (σ =16.2). Our final set of 101 participants

included 56.4% (57) males and 40.6% (41) females, and 3% (3) others included in the survey to eliminate people who were not paying attention. On average, the survey took 37 minutes for those who preferred not to disclose their gender. In total, 60.4% (61/101) of participants indicated that they were White, 18.8% (19/101) were Asian, 7.9% (8/101) were African American, 7.9% (8/101) were Hispanic or Latino, 2% (2/101) were Native American, and 3% (3/101) were of other ethnicities. Our respondents were evenly distributed across different academic years. Across academic years, sophomores (25/101, 24.8%) were the largest group, followed by graduate students (Masters, PhD: 22/101, 21.8%; juniors: 21/101, 20.8%; freshmen: 14/101, 13.9%; and seniors: 14/101, 13.9%), and academic year not disclosed: 5% (5/101). Computing (30/101, 29.7%) and Engineering (21/101, 20.8%) were the 2 most common academic majors, with Sciences at 19.8% (20/101) and Liberal Arts at 14.9% (15/101). We ascribe this bias toward science, technology, engineering, and mathematics disciplines to the nature of the general student body at this university.

An overwhelmingly large number of participants (71/101, 70.3%) indicated feeling stressed and/or anxious from college life. Analyzing responses to the single survey question that assessed the extent to which students used social media for support seeking around their mental health, we assigned participants with responses 1-2 to the do not use cohort and those corresponding to responses 3-5 to the use social media cohort. In total, 51.5% (52/101) of participants indicated that they had used social media to find support from friends, peers, anonymous users, or others to cope with stress and/or anxiety (Table 1 for additional details on social media use). Comparing different online and offline recruitment strategies (university social media, public social media, word-of-mouth, and physical flyers and ads), we did not observe any statistically significant differences in these variables based on a one-way analysis of variance (P>.05).

In the remainder of this subsection, we focus on contrasting these participants with those who did not use social media for their mental health needs (49/101, 48.5%) and a number of dimensions, including their mental wellness (extent and characteristics) and how they use social media.



Table 1. Social media usage among survey respondents (N=101).

Usage factor	Respondents, n (%)
Social networking sites and app use	
Facebook	69 (69)
Snapchat	45 (44)
Twitter	42 (42)
Instagram	37 (32)
YikYak	24 (24)
Reddit	21 (21)
LinkedIn	17 (17)
Google+	14 (14)
Tumblr	10 (10)
Pinterest	6 (6)
Other	2 (2)
Hours per day spent using social media	
<1	19 (19)
1-3	33 (33)
4-6	26 (26)
7-9	4 (4)
≥10	18 (18)
Primary source for using social media	
iPhone	57 (57)
Android phone	54 (27)
iPad	26 (26)
Public computer	12 (12)
Tablet (other than iPad)	11 (11)
Other	9 (9)
Purpose for using social media	
To become updated on events	54 (53)
To communicate with family or friends	54 (53)
To become updated on friends' activities	47 (47)
To meet new people	29 (29)
To find people (old friends, classmates)	28 (28)
For playing web-based games	11 (11)
For using apps for smartphones	10 (10)
To promote business or organization	4 (4)
Other	2 (2)

Mental Health

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From Table 2 and based on Mann-Whitney U tests, we observe that the cohort of participants who scored consistently higher on mental health issues, such as in the Perceived Stress Scale (51% more; P=.005) and Generalized Anxiety Disorder-7 scales (62% more; P<.001), also used social media more extensively to disclose and obtain support. This cohort that used social

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media for mental health needs also had lower access to social support as measured by the MOS scale (11% less; P=.02) and across all MOS factors. Among the various forms of support, we observed that emotional or informational support the average social media mental health help seekers expressed lower self-esteem (38% less; P=.009). In addition, overall college adjustment, as measured by the CAT scale, was lower in this cohort (5% less; P=.03). Thus, we conjecture that this cohort

may not receive as much empathy, advice, or help from their existing support systems, and therefore might be appropriating web-based resources. Next, this cohort also felt higher homesickness (31% more; P=.006); this measure reflects the extent to which a student misses their home or friends or feels lonely at college [26]. They also expressed higher negative affect (27% more; P=.009) and lower positive affect (28% less;

P=.009), as given by the same scale. Here, the CAT scale assesses positive affect using responses to questions such as whether the responder liked their classes or roommates or whether they liked their social life. Negative affect, however, is assessed using responses to questions such as feeling angry, feeling worried about academic performance or intimate relationships, or feeling lonely.



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Table 2. Mental well-being attributes and social media platform usage of participants who do and do not use these tools for their mental health needs (N=101).

Social media for mental health disclosure and support ^a	Used	Did not use
Academic background, n (%)		
Undergraduate ^b	82 (82)	82 (72)
Graduate ^b	17 (17)	27 (27)
Engineering or computing major	59 (59)	42 (42)
Mental well-being scores, mean (SD)		
Positive affect ^c (CAT ^d)	16.6 (3.9)	23.1 (2.6)
Negative affect ^c (CAT)	31.8 (7.4)	24.9 (3.5)
Homesickness ^c (CAT)	24.5 (5.3)	18.7 (3.8)
Overall adjustment ^b (CAT)	79.4 (10.7)	83.5 (9.1)
Self-esteem ^c	18.6 (5.5)	29.8 (3.4)
Perceived Stress Scale ^c	25.5 (5.4)	16.8 (6.5)
General Anxiety Disorder-7 ^e	9.3 (4.6)	5.1 (4.3)
Emotional or informational support ^b	2.2 (0.5)	3.4 (0.9)
Tangible support ^b	3.1(0.7)	3.7 (0.4)
Affectionate support ^b	2.9 (0.8)	3.5 (0.7)
Positive social interactions	3.6 (0.5)	4.1 (0.3)
Medical outcomes study ^b	2.9 (0.6)	3.6 (0.7)
Platform use, n (%)		
Facebook	66 (66)	69 (69)
Twitter	40 (40)	42 (42)
Snapchat ^b	44 (44)	33 (33)
Instagram ^b	41 (41)	32 (32)
Yik Yak ^d	41 (41)	24 (24)
Reddit ^c	36 (36)	21 (21)
Tumblr ^d	37 (37)	18 (18)
Characteristics of social media use, n (%)		
Time spent on social media (hours/day)		
4-6 ^d	55 (55)	37 (37)
1-3 ^c	26 (26)	43 (43)
Purpose of social media use, n (%)		
Communicating with friends, family ^b	68 (68)	56 (56)
Staying updated on friends' activities ^d	41 (41)	76 (75)
Finding people (old friends, classmates) ^c	33 (33)	58 (57)
Instant access to information on social media ^c	21 (21)	48 (48)
Connection strategy (FBI ^f), mean (SD)		
Initiation ^b	1.9 (0.9)	3.2 (0.6)

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Social media for mental health disclosure and support ^a	Used	Did not use
Social information-seeking ^c	3.8 (0.5)	2.2 (0.7)
Maintaining ^b	2.3 (0.8)	4.1 (0.7)

^aDifferences are statistically significant based on Mann-Whitney U tests followed by false discovery rate correction for multiple pairwise comparisons. ^bP<.05.

^cP<.01.

^dCAT: College Adjustment Test. ^eP<.001.

^fFBI: Facebook Intensity Scale.

Social Media Use

Next, among the participants who used and did not use social media for mental health disclosure and support, there were differences in social media use levels and the various purposes behind its use. As shown in Table 2 and based on Mann-Whitney U tests and false discovery rate correction for multiple pairwise comparisons, Facebook was the most popular platform for both cohorts. However, semianonymous, ephemeral, and anonymous platforms (such as YikYak, Tumblr, and Reddit) were more actively used by those using social media for mental health help. Tumblr, for instance, was found to be used 105% more frequently in this group than in the other groups (P<.001), whereas Reddit was used 71% more frequently (P<.01).

Participants who derived value in using social media for mental health help also reported using social media more frequently (56/101, 55.4% reported using them 4-6 h a day) and for communicating with friends and family (21% more; P<.05). However, the other cohort used these platforms more often to stay updated about friends and find people (42-45% more; P<.01) and for accessing instant information (56% more; P<.01). Perhaps because of more frequent participation in social media and use of the platforms for social exchange, students in the former cohort felt encouraged to seek mental health help in an environment they already frequent. The individuals in this cohort also seem to identify with social media use for its social affordances, in contrast to the other cohort who used them for more informational purposes.

Finally, the 2 cohorts used distinct connection strategies or relational communication activities on Facebook, as included in the Facebook Intensity Scale. Social media mental health help seekers used Facebook more for information seeking (73% more; P<.01) than those who did not. However, they initiated fewer new connections (41% less; P<.05) and engaged less in the maintenance of social capital (44% less; P<.05). This aligns with the findings above regarding their desire to utilize these platforms to obtain information from, and communicate with their existing network, compared with nonhelp seekers who may have more proclivity to seek new friendships.

Observations From the Interviews

Follow-up interviews were conducted following the survey. Our interview sample was heavily biased toward engineering or computing female freshmen students (8/11, 73% female; 8/11, 73% engineering or computing major; 8/11, 73% freshmen). In the remainder of this subsection, we describe the

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major themes that emerged from the qualitative analysis of the interviews with the students.

Why and How Social Media is Used for Mental Health Help

Engaging in Candid Self-Disclosure

Interviewed students found social media platforms to be places they visited to seek a break from stressful experiences. They also noted the value of social media as a platform to vent and commit to mental health concerns. Students reported *talking out* their frustrations with friends, posting rants on Facebook, or leaving venting voicemails on others' WhatsApp accounts. For some, just the release of their frustrations to a friend or family member made them feel better:

I can vent and share concerns with people, like classmates, where we can both get their frustrations out. [Freshmen, female, mechanical engineering major]

Friends on social media also help by reminding me of bigger picture things; I just feel like it makes me feel better. [Freshmen, female, mechanical engineering major or computer science minor]

Some other students identified the value of self-disclosing to someone who dealt with the same type of stressor. Occasionally, students liked pep talks and thought they encouraged them and helped built their self-esteem:

I love the random moments of connection with people. Good to see what and how everyone else is doing. [Sophomore, male, psychology major]

Mitigating the Feelings of Isolation

Interviewed students also identified companionship as a way social media satisfied their mental health needs. For most, this is just the feeling of not being alone. Having someone *out there*, or having someone there to listen to them, often helped the students relieve some of the stress and anxiety they experienced from college life. For instance, on social media, this type of companionship support can come from people simply *liking* or commenting on a post they wrote:

Often I find just the ability to connect to another person to be grounding, um if like I know them. You know, kind of assuage feelings of isolation that can spiral out and escalate the level of stress because you like you are in your own bubble and if you inside and

this amplifies your feelings internally [...] you do not have external stimulus to bring you back and level you out. Just having a person on social media listen to you is really helpful. [Senior, male, economics major]

Receiving Informal Help

Interviewed students also found social media helpful for mitigating mental health challenges because of the casual nature of support, advice, and help they provide. They viewed phone calls and texts as more pressing than a Facebook or WhatsApp message, and they preferred the more informal *respond whenever you get the chance* approach offered by most social media sites. They noted that this informality helps reduce stress and improve their mood in that they do not feel they are pestering or pressuring their friends or family to respond. In addition, they felt that they themselves were not obligated to respond to a social media message from a peer unless they wanted to:

Whenever I wasn't feeling well, I could go onto *Facebook and talk to my friends. I found [Facebook]* really beneficial because it would kind of be sporadic and not really something I could articulate in a phone call because it wasn't a very pressing matter or wasn't as intense as the feelings of being upset. But then I could talk to people over Facebook and it might take a couple hours for them to respond, but when I did get the messages they were really helpful [...] I could reach out to a couple people and talk to three close friends from back home just to see how they were doing, get that off my mind, and then some responded and some didn't. I think people feel more obligated to respond to a text immediately, but on Facebook they can say, 'Sorry I had three tests. But are you ok now?' and it was completely fine. [Freshmen, female, biomedical engineering major]

Students also recognized the informational and tangible support and help social media platforms provide, specifically, advice, guidance, and suggestions as well as assistance with any problems they may face. They reported that although talking to their family and friends may help get advice on a relationship problem, they may ask peers on social media to help with homework assignments. Through such informational and tangible support, they recognized the casual help necessary to solve whatever problem they are facing:

I asked some friends on Facebook to help me with a project that I needed, like, people to act for and, like, they came through and they were so amazing, and I was like 'Yes, thank you. You guys were here for me to pull me out of this anxiety. [Sophomore, female, psychology major]

Platform Affordances and Mental Health Help

Next, our in-person interviews sought information on what affordances and features of existing social media platforms were found to be invaluable or detrimental to meeting mental health needs. Interviewed students also included their thoughts and opinions on the affordances they felt could make these sensitive disclosures and support seeking better.

Anonymity

The social media feature that consistently emerged in our interviews was anonymity. Students expressed both enthusiasm and concern regarding the utility of this feature. Support for the feature ranged from its ability to allow disclosure around stigmatized topics to promote quality and honest exchange: they felt that anonymous accounts eliminate components that could make a person easily identifiable (eg, name, email, and photos) or those that could trigger feelings of inadequacy in users:

I think anonymity is really important to a lot of people because like you said of the stigma behind it [...] If you have the option to be anonymous, you could even just pick a username. So if you were talking to one person, you could continue to talk to them, be able to identify them, but not know who they are on campus. [Freshmen, female, biomedical engineering major]

At the same time, some of the other interviewed students felt anonymity would lower accountability on an issue that is sensitive in nature and can lead to counterproductive outcomes for mental wellness. They also brought up issues with not being able to *connect* with other users on anonymous social media websites, saying that they did not know enough about the anonymous users to feel any kind of emotional connection. They also consistently felt that a unique identifier for users would be a desired feature that could balance the pros of anonymity and the pros of having an identified account. Such user profiles, including information about academic year, area of study, or hobbies, can not only provide some context for each user but also create a means for other users to feel connected to them and want to engage with them within the tool:

I feel anonymity tends to lead to problems of lack of accountability and some people will use that to be funny in sort of a mean way. [Freshmen, women, business major]

Trust

Trust was recognized by the students as an important construct for social media platforms, enabling mental health disclosure and support. They advocated for mechanisms that can enhance trust, such as the ability to learn more about the help seekers and providers and to curb the dissemination of illegitimate or inadvertent disclosure of personal information to web-based audiences:

I think it is nice for people to be able to voice their problems on an anonymous social support site, you know, to feel like they won't be judged. But can you trust them? Nothing stopping people from using other people's names in posts. [Freshmen, female, biomedical engineering major]

Interpersonal and Collective Interactions

Interviewed students discussed a variety of different provisions for social interaction that could be beneficial for social media–based mental health disclosure and support. Generally, they felt that conversations could be more genuine and candid



in a discussion board format instead of private direct messages. Private messages could increase the risk of getting bullied around disclosures as sensitive to mental health. In a discussion board setting, these risks are reduced because of the collective attention of several individuals. Students also recognized the value of smaller-sized support groups, where individuals might be more involved and committed to helping others:

I think one of the things that helps is smaller groups. I think if there is an amount of group separation, while you get access to less people as a support network, I think you get people who are more tailored to be a support network. This is mostly from my experience with Reddit [...]. People will talk about their problems and there are certain communities on Reddit, especially a lot of times, smaller communities that are super helpful and super receptive to that sort of thing. But there are other communities where, because of the size that they are because of the nature of the community, they are super unreceptive and super hostile. [Freshmen, women, business major]

Mental Health Interventions

Finally, the interviewed students talked about explicit interventions and provisions that could better support mental health disclosures on social media platforms. These interventions could include dedicated content catering to different needs around mental health concerns (personal, academic, etc) as well as specific communities where individuals could go to seek help and advice:

A little "help me" button will be great, like, if you're feeling particularly stressed or want help (like can't quite get this problem). I'd also like different levels of help "what should I do?." [...] There could be a specific area [for mental health], so if you don't want to be looking at it, it won't bog you down. [Freshmen, female, mechanical engineering major or computer science minor]

Students also recognized the need for mechanisms to ensure rigorous security and privacy of the participants and balance the urgency for help seeking and receiving. Some students also brought up the challenges of building communities of people living with mental illness, indicating that they can amplify negative feelings that are detrimental to well-being:

Probably something also to control if you have a lot of people that are under a bunch of stress. If you have a bunch of people with the same kinds of problems in a closed space, there's going to be an issue eventually. Like, it could be two people really, really upset, and it could bring them both down instead of up.

Discussion

Principal Findings

Our survey revealed that mental challenges such as stress and anxiety are fairly pervasive in the university students we studied—70.3% (71/101) of the participants indicated that they felt stressed or anxious recently. Half of them (52/101, 51.5%)

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also reported having appropriated some social media platforms for self-disclosure or help seeking, indicating the pervasiveness of this practice. Taken together, the survey results indicate that individuals who tend to use social media for mental health disclosure or social support were already challenged by heightened mental health concerns. They also seemed to be less adjusted to college life, with lower access to social support in offline settings. This might explain their tendency to utilize web-based tools for this purpose: previous literature has indicated that social media can provide a great deal of social and emotional support [33,37,38]. A lowered sense of self-esteem may also explain why these participants appropriated social media for their mental health needs. Previous work has revealed that using platforms like Facebook can boost self-esteem and self-worth [31]. Through our interviews, we obtained deeper insights into the initial observations. We identified specific academic, personal, and social life stressors, motivations behind social media use for mental health needs, and specific platform affordances that helped or hindered this use. Students argued against complete anonymity in platforms for mental health help, recognized the benefits of connecting informally with peers with similar challenges, and advocated the need for privacy and boundary regulation mechanisms in social media platforms supporting this use.

Study Implications

In light of the ongoing crisis of mental health in college campuses [39], this study, combining the insights from the survey as well as the follow-up interviews, provides important insights regarding the role of social media in supporting mental health needs of students.

Mental Health Help via Social Media

Our study reveals that social platforms gave students the ability to find support while still maintaining some level of informality, anonymity, and privacy. Essentially, this benefit of social media disclosures of mental health concerns aligns with what has been noted in the offline context by Jourard [40]: "self-disclosure is a basic element in the attainment of mental health" and sharing narratives, stories, and experiences in written form can promote candid self-disclosure of difficult, stigmatized conditions [41]. In many ways, this student population's mental health help-seeking behaviors, as reflected in the survey as well as the interviews, align with the observations derived from studies of the general population, such as depressed individuals seeking others out on Reddit [42,43], Instagram [37], or Twitter [44,45]; sexual abuse survivors self-disclosing about their experiences on Reddit [46]; individuals recovering from substance use appropriating online health forums [47,48]; or eating disorder patients engaging in recovery-related self-disclosure on Tumblr **[49]**.

Informing Counseling Efforts and Campus Administration

Our interviews also provided insights into the practices and motivations behind students' use of social media for mental health. It also helped us identify specific affordances provided by these platforms that were particularly facilitative of this practice. Interviewed students further identified many benefits

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of social media platforms for mental health disclosure and support seeking. This included provisions for both casual and emotional help, informal and private mechanisms to vent difficulties in sharing feelings, helping seek feedback on dealing with specific academic and personal life-related stressors, and the ability to connect with a large on-campus commiserating student community. Together, these pieces of information can be highly beneficial to campus counseling centers in understanding attributes of the mental health of students and the pervasiveness of these challenges, especially given the limited counseling workforce and resources available in many college campuses relative to student needs. Observing what student users are discussing in a web-based social support platform could offer these professionals insights into the types of problems students are currently facing. In addition, observing how students use the platforms and how they interact with others could provide a better understanding of how students manage their problems and handle social interactions. This information could potentially help counseling centers with their services and strategies to better reach students and better fit their needs.

Recommendations for Social Media–Based Support Technology Design

Our findings also have implications for the design of next-generation and improved social media support tools that can address mental well-being issues in college students. These interventions can also take advantage of the affordances of both current social media and their social support mechanisms to better help students tackle mental health challenges.

Anonymity and Identifiability

Our survey reported high usage of anonymous and ephemeral social media sites among students seeking mental health help on the internet; it was 70% more than that among the students who did not use social media for mental health needs. However, somewhat surprisingly, the interviewed students did not recognize the unanimous utility of having anonymity as a helpful feature. Although they also mentioned the potential risks of using a fully identified platform for the purpose, semianonymity seemed to be an agreed-upon compromise. This was because semianonymity allowed moderate accountability and the ability for students to connect with like-minded peers on campus, thus helping establish credibility and trustworthiness, but could prevent disclosing information that may be personally identifiable. We note that this type of trade-off or dichotomy between anonymity and identifiability is well-documented in the literature, although not in the context of mental health help seeking. As Cutrona [50] notes, "how to disclose enough of one's misery to gain the benefits such revelations can provide, without disclosing in such a way or to such an extent that it will drive others away." This dichotomy also reflects interviewed students' concern that anonymity can encourage offensive behaviors, bullying, or harassment toward those who might be in crisis and in need of help around a stigmatized condition. College student-oriented or campus-restricted Reddit-like forums may thus be designed to better cater to student-specific needs around mental health issues identified in our study, such as schoolwork, relationships, college life, or career paths.

Trustworthiness and Credibility

On a related note, interviewed students also recognized trust as an important element driving their desire to obtain mental health help on social media. As Altman described in his work on interpersonal exchange [51], sensitive self-disclosures modify a self-boundary (the boundary around the individual) and a dyadic boundary that ensures the discloser's safety from leakage of information to uninvited third parties. Both boundaries are influenced by interpersonal factors such as the level of trust in the disclosure target. In other words, trust in sensitive disclosure is of utmost importance. This is because mental health help seeking can impose certain risks to disclosers. This may include becoming defenseless and unguarded, receiving negative feedback, or what Wenburg and Wilmot termed the reverse halo effect [52] (the possibility of revealing a weakness can lead the disclosed-to person to generalize about other weaknesses of the discloser). Therefore, it is understandable that surveyed students, who used social media for mental health help, used connection strategies that were more informational and were less likely to initiate new ties.

Thus, to make trust a built-in feature, social and reputation markers may be included in campus-specific web-based communities of support. For example, user responses can be appropriately weighed in terms of trustworthiness. Such markers could also include point systems for the number of helpful comments or advice provided, badges of community service toward mental health help, or dynamic up- and down-voting mechanisms to evaluate the quality of responses in real time. Interpersonal trust information can also be incorporated by assessing the strength of historical social interactions between 2 individuals.

Peer Support

Our survey identified that students who used social media for mental health help had lower offline social support than those who did not (11% less). It is not surprising that many students, in the interviews, reported social connectedness facilitated by small web-based groups to be one of the most prominent motivations behind their desire to use social media platforms for mental health. Why students seek social connectedness can spring from specific needs related to mental health challenges? The social comparison theory [53] states that one turns to those that are similar to themselves in terms of the experience because they are presumed to provide the most relevant information for making an accurate judgment of how to respond. Furthermore, participation in smaller groups can enhance the perceived benefits of social connectedness that can allow people to vent or open up more comfortably. As a design feature, social media platforms could, therefore, incorporate the ability to start on-demand interpersonal or smaller group chats, aside from allowing content sharing in a larger community. These informal but more focused disclosure mechanisms could promote a secure way of social bonding, mitigating feelings of isolation and engaging in mutual commiseration.

Boundary Regulation

Students' desire for small group disclosures of mental health concerns can also stem from the challenges of context collapse



and difficulties in boundary regulation and managing privacy [54]. Therefore, many web-based platforms allow people to better regulate the boundaries of their self-disclosures, primarily via privacy access control mechanisms. However, as Ellison et al [55] noted, "privacy behaviors on SNSs are not limited to privacy settings." Naturally, individuals adopt a variety of other techniques for information regulation, such as the creation of multiple identities [56] or adjusting profile visibility [57]. Our interviewed student cohort identified value in small group disclosures on the web as a way to circumvent the issues of context collapse and regulate information disclosure boundaries. Along these lines, social media platforms could create private and topic-oriented spaces to discuss stigmatized topics, wherein individuals could seek and provide mental health help from time to time without disrupting their activities elsewhere on the platform or compromising their privacy in other discourses.

Web-Based Interventions

Finally, interviewees shared many elaborate thoughts about mental health support mechanisms and interventions that could be built on future social media platforms. These ranged from help me buttons to elaborate information on how to cope with stress and mental health crises and structured provisions not only for help seekers but also providers. Accordingly, we described 2 such support-based interventional strategies: (1) platforms could issue public service announcements, emotionally uplifting content, and informational pointers to support seeking individuals, such as an appropriate hotline on or off campus. This would increase students' likelihood of being exposed to coping strategies or supporting resources, and (2) social media platforms can pair up students experiencing particular college and academic life stressors with others who have been successful in addressing these challenges. This would encourage informal ways of seeking and providing peer support.

Limitations

Our work has some limitations that we acknowledge. The first relates to the generalizability of the findings. Although our survey can be applied to any college campus, the specific findings apply only to students at the university we study. From the survey data, we found a large fraction of students who self-report and score to be challenged by mental health concerns, such as stress and anxiety. We note that these findings may not apply to the broader student community in the United States or elsewhere in the world. In particular, we also note the limitations of some of the survey scales used, such as the MOS social support survey. This scale captures offline social support, and we used this scale in this study to understand the extent of availability of offline social support to students and how students with less or more offline social support appropriate social media to supplement and complement it. Future work can develop and adapt a scale that would serve as a web-based counterpart to the MOS survey to corroborate the extent to which web-based help-seeking behaviors of college students mirror their offline needs and support.

In addition, there are possible limitations of social media as a solution to help cope with mental health challenges-a dimension that was not explored through our survey or interviews. Although social media websites offer students a low-pressure, informal way to seek support, as our study revealed, presumably, they do not provide the same type of direct social support as an in-person interaction would. Therefore, we suggest caution in the interpretation of this study's findings. That is, we recognize that social media tools cannot be used as standalone counseling or treatment mechanisms, which is particularly true for the interventions outlined above. Essentially, given the potential of social media to support students' mental health needs, as revealed in this paper, it could act as a catalyst for in-person support, providing a way for students to meet other students on the web in an informal, real-time setting without feeling stigmatized.

Conclusions

As suicide is the second leading cause of death on college campuses, addressing the mental health of college students is extremely important. Motivated by this observation, in this paper, we present a comprehensive study to investigate the role of social media in meeting students' mental health needs. Our survey of students at a large public university in the southeast of the United States revealed extensive use of social media platforms for seeking mental health help; 51.5% (52/101) of the surveyed students reported this use. We followed up with in-person semistructured interviews with students to identify the intent and motivation behind these practices and the benefits and challenges they perceived to exist on social media platforms toward mental health help seeking. We found that students turned to social media to seek help because they could vent and engage in candid self-disclosure and mitigate feelings of isolation, all in an informal, semianonymous setting. We believe our findings provide fresh insights into how social media-based interventions and provisions for support can be built to improve college students' mental well-being as well as to help inform campus mental health counseling and mitigation efforts.

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Conflicts of Interest

MDC received unrelated funding from the National Institutes of Health, National Science Foundation, Intelligence Advanced Research Projects Activity, The Centers for Disease Control and Prevention, Microsoft, Facebook, Mozilla, Yahoo!, and Samsung.

Multimedia Appendix 1

Recruitment flyer used for online advertisements of the study.

https://mental.jmir.org/2021/7/e24512

[PDF File (Adobe PDF File), 65 KB - mental_v8i7e24512_app1.pdf]

Multimedia Appendix 2

Interview guide outlining semistructured questions for participants. [PDF File (Adobe PDF File), 213 KB - mental_v8i7e24512_app2.pdf]

Multimedia Appendix 3

Codebook used for qualitative coding of the interview transcripts. [PDF File (Adobe PDF File), 509 KB - mental_v8i7e24512_app3.pdf]

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Abbreviations

CAT: College Adjustment Test **MOS:** medical outcomes study

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Original Paper

Examining the Pro-Eating Disorders Community on Twitter Via the Hashtag #proana: Statistical Modeling Approach

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Abstract

Background: There is increasing concern around communities that promote eating disorders (Pro-ED) on social media sites through messages and images that encourage dangerous weight control behaviors. These communities share group identity formed through interactions between members and can involve the exchange of "tips," restrictive dieting plans, extreme exercise plans, and motivating imagery of thin bodies. Unlike Instagram, Facebook, or Tumblr, the absence of adequate policy to moderate Pro-ED content on Twitter presents a unique space for the Pro-ED community to freely communicate. While recent research has identified terms, themes, and common lexicon used within the Pro-ED online community, very few have been longitudinal. It is important to focus upon the engagement of Pro-ED online communities over time to further understand how members interact and stay connected, which is currently lacking.

Objective: The purpose of this study was to explore beyond the common messages of Pro-ED on Twitter to understand how Pro-ED communities get traction over time by using the hashtag considered to symbolize the Pro-ED movement, #proana. Our focus was to collect longitudinal data to gain a further understanding of the engagement of Pro-ED communities on Twitter.

Methods: Descriptive statistics were used to identify the preferred tweeting style of Twitter users (either as mentioning another user in a tweet or without) as well as their most frequently used hashtag, in addition to #proana. A series of Mann Whitney U tests were then conducted to compare preferred posting style across number of followed, followers, tweets, and favorites. This was followed by linear models using a forward step-wise approach that were applied for Pro-ED Twitter users to examine the factors associated with their number of followers.

Results: This study reviewed 11,620 Pro-ED Twitter accounts that posted using the hashtag #proana between September 2015 and July 2018. These profiles then underwent a 2-step screening of inclusion and exclusion criteria to reach the final sample of 967 profiles. Over 90% (10,484/11,620) of the profiles were found to have less than 6 tweets within the 34-month period. Most of the users were identified as preferring a mentioning style of tweeting (718/967, 74.3%) over not mentioning (248/967, 25.7%). Further, #proana and #thinspo were used interchangeably to propagate shared themes, and there was a reciprocal effect between followers and the followed.

Conclusions: Our analysis showed that the number of accounts followed and number of Pro-ED tweets posted were significant predictors for the number of followers a user has, compared to likes. Our results could potentially be useful to social media platforms to understand which features could help or otherwise curtail the spread of ED messages and activity. Our findings also show that Pro-ED communities are transient in nature, engaging in superficial discussion threads but resilient, emulating cybersectarian behavior.

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KEYWORDS

Twitter; infodemiology; eating disorders; proana; thinspo; hashtags; transient; cybersectarianism

Introduction

The prevalence of eating disorders (EDs) has been on the rise ever since the condition was listed in the Global Burden of Disease Study [1]. Recent estimates show EDs claim the lives of 3.3 million people globally every year [2], a number that has doubled over the last 10 years [3]. Of all the ED types, anorexia nervosa (AN) in particular poses severe life-threatening health risks, with the highest mortality rate of all mental illnesses [4]. In addition, nonfatal presentations are listed as the fifth cause of chronic disease among adolescents aged 15-19 years old in the Australian female population [5].

Traditional media platforms and their representation of the "thin ideal" have long been associated with body dissatisfaction, a known risk and maintenance factor of EDs [6,7]. However, the media landscape has changed dramatically in recent years, and the last decade has seen a surge in social media use globally, where recent figures show more than half of the world's population, or 3.8 billion people, are active on social media [8]. The use of the internet to communicate using common online platforms has become more popular due to the increasing focus on usability, the decreasing cost in access, and the ability of communications to cross large geographical distances [9]. This transition has seen the emergence of social and interpersonal support networks for users and in particular, the emergence of pro-eating disorder (Pro-ED) communities online [10-12].

Pro-ED communities are a controversial subculture that promotes positive attitudes toward EDs, namely AN (pro-anorexia/proana) and bulimia nervosa (pro-bulimia/promia). These communities share content to promote thinness, provide advice to other members, and glorify low body weight as ideal [13]. A shared group identity is formed through interactions between community members and can involve the exchange of "tips," restrictive dieting plans, extreme exercise plans, and motivating imagery of thin bodies, also known as "thinspiration" or "thinspo" [11,14]. Boero and Pascoe [15] described these communities as being able to "bring people together who rarely talk about their disorder face to face in non-therapeutic settings" and noted that these groups are present online at their own will with no formal offline equivalent.

There is now a significant body of literature highlighting the way in which Pro-ED communities exist on the internet and in particular on social networking platforms such as Twitter [10,16,17]. The Twitter platform is a social networking service known for its microblogging capability and is used by 339.6 million people, mostly between the ages 18 years and 34 years [8]. Twitter users can create a profile known as a "handle" and post microblogs or "tweets," typically text comprising 140 characters or less (although this was increased to 280 characters in 2017) from which other users can then share, known as a "retweet," or follow other users to create their own personal, interconnected social network. The platform has become a center for online social activity and the quick exchange of information, with the option now to post content other than text such as

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images, videos, or web links, and users can contribute to larger conversations by adding keywords or hashtags within the tweet [10,16,17].

Hashtags can connect users and be used to form communities around common interest topics [18]. In the online Pro-ED community, #proana signifies a post supporting pro-ED attitudes and behaviors and is considered to be the established term to describe the Pro-ED movement's consistent referencing of EDs (eg, explicit mentions of bulimia and AN) within these accounts. Most of these accounts have acquired followers who themselves posted about EDs [10]. Other research has focused on #thinspiration ("motivating" imagery of thin bodies) and #fitspiration ("motivating" imagery of "fit" bodies) and their use within a variety of social media formats. Across social media platforms, typically #thinspiration encourages more weight loss behaviors with a stronger connected community than that of #fitspiration [17]. However, both have been found to essentially share the same themes of encouraging guilt, dieting, and restraint [19-21]. Nevertheless, longitudinal hashtag research within the Pro-ED communities is still limited. Since Twitter does not currently have a policy for blocking such hashtags, unlike other social media sites such as Instagram, Facebook [22], and Tumblr [23], it presents a unique space to use these freely and has played host to a shift to a space in which the Pro-ED community now communicates [10,16].

Furthermore, research to date has typically focused on the characteristics of the specific social networking sites for interaction and overlooked the exploration of the broader implications of online communities. Indeed, a meta-analysis of pro-anorexia and pro-bulimia website studies reported that the main body of research has neglected the investigation of individual members that comprise the communities, including their behaviors, motivations, and state of health, instead examining the role and content of the websites in community building. However, research suggests that the effects of personal social groups and peer behavior are prominent features in this space. Allison et al [24] proposed that the forces of social imitation and competition drive group behavior and put forward the idea that the "authoritative voice" of AN partly results from the expectations of the social group. This finding was further supported by Ferguson et al [7], who suggested peer competition as more prominent than traditional media effects when looking at body dissatisfaction in teenage girls.

With this in mind, we suggest that focus needs to be placed upon the engagement of Pro-ED online communities to further understand how members interact, as Girvan and Newman [25] demonstrated through the creation of social graphs in which communication is visualized as relationships between entities. In addition, recent research suggests identifying terms, themes, and a common lexicon used within the Pro-ED online community as beneficial in understanding a Pro-ED identity [10,16]. Choudhury [26] looked at Tumblr to understand how both pro-anorexia and pro-recovery communities interact through tags and a common lexicon, with findings suggesting

that AN content can be detected with a high level of accuracy due to distinctive "affective, social, cognitive, and linguistic style markers." Chancellor et al [14] further explored the lexicon of Pro-ED community members, this time on Instagram, both before and after attempts of moderation by the social networking site to create a codebook of variations used to circumvent restrictions. A similar codebook of keywords was developed by Arseniev-Koehler et al [10] and Zhou et al [16] for Twitter, in an attempt to summarize and describe ED content. However, both of the studies did not track user profiles over time, and in particular, their study did not consider the tweeting styles of community members that could provide insights into how Pro-ED communities communicate and interact.

Our study sought to extend upon previous examinations of Pro-ED tweets and in particular examine profiles and engagement of Pro-ED communities together with preferred tweeting styles among Pro-ED users.

A secondary objective was to identify the most frequently used hashtag among Twitter profiles that include "proana" as a primary hashtag. A greater understanding of the Pro-ED communication networks on Twitter could have implications for the identification, prevention, and treatment of young people with EDs who may be receptive to online therapeutic interventions.

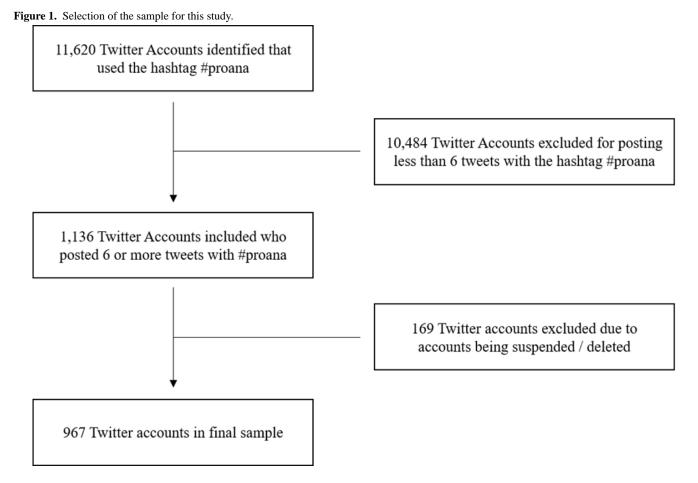
Methods

Ethics Approval

The current study was approved by the Swinburne University Human Research Ethics Committee (SUHREC) Project ID: 20190402-1922. In line with SUHREC advice, it was not possible to directly quote individual twitter usernames or their posts; thus, data are presented in aggregated form only.

Sample

This study utilized publicly available Twitter data from Pro-ED profiles collected between September 15, 2015 and July 1, 2018, adhering to university ethics requirements. To identify Pro-ED profiles, we used an online scraping tool to gather posts (tweets) and reposts (retweets) using Twitter's public Application Program Interface (API). Twitter offers a systematic collection of sampled tweets as they are posted through a public API filtered by specific criteria. For this research, the hashtag #proana was the qualifying criteria, which resulted in 54,506 tweets and retweets (tweets that are recirculated by other users) across 11,620 Twitter profiles from various time zones and geographic locations. These profiles then underwent a double pseudonymization process to preserve anonymity before a 2-step screening process using inclusion and exclusion criteria was imposed to reach the final sample of 967 profiles (see Figure 1).





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Data Analysis

The 967 profiles were further classified into 1 of 2 categories (with-mention or without-mention) based upon the user's preferred posting style. A without-mention message pertained to the user sending a tweet not to a particular individual, whereas a mention relates to the user including another Twitter account in the message. In the initial phase, descriptive statistics were ascertained to compare the proportion of tweets or retweets in relation to the user's most frequently used hashtag. A series of Mann Whitney U tests were then conducted to compare preferred posting style across number of followed, followers, tweets, and favorites. Finally, a multiple linear regression model, using ordinary least squares [27], was then used to estimate the number of followers based upon the number of followed users, tweets, and favorites. The criteria for stepwise selection were based upon changes in the adjusted R^2 values at each new step.

Skewed predictor variables were trimmed by excluding extreme cases, as identified with a Cook distance >3 SDs from the mean. Analyses were conducted in SPSS Version 26.0 (IBM Corp, Armonk, NY).

Results

The individual tweets or retweets across all 967 profiles were explored to ascertain the most frequently used hashtag associated with each account, as shown in Table 1. The "Top Hashtag" variable represents the most frequently used hashtag among users; for example, for this sample, 611 users (63.2%) had #thinspo as their most frequently used hashtag (excluding #proana). In contrast, the "Hashtag usage" variable relates to how many individual tweets across all accounts included the said hashtag.

Table 1.	Comparing the top 10 r	nost used hashtags (excludin	g proana) in this sample (9	67 users and 54,506 tweets or retweets).
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Hashtag	Top hashtag, n (%)	Hashtag usage, n (%)
Thinspo	611 (63.2)	10,854 (20.53)
41DaysofStarvation	46 (4.8)	172 (0.33)
Ana	39 (4.0)	2615 (4.95)
Thinspiration	38 (4.9)	4499 (8.51)
Promia	31 (3.2)	2549 (4.82)
Anorexia	30 (3.1)	2537 (4.80)
Redbraceletpro	29 (3.0)	845 (1.60)
Skinny	21 (2.2)	2930 (5.54)
Bonespo	18 (1.9)	2429 (4.59)
ED book review	13 (1.3)	394 (0.75)
Total	876 (90.6) ^a	29,824 (56.42) ^a

^aOnly the top 10 hashtags are shown; thus, the % values do not equal 100.

The hashtag #41DaysOfStarvation was the most used hashtag for 46 users (46/967, 4.8%); this was the second highest category after #proana and #thinspo (Table 1). Conversely, #41DaysofStarvation was only mentioned in 172 (172/54,506, 0.33%) of the total tweets and retweets in this sample.

The 967 profiles were further classified into either "without-mention" or "with-mention" groups based upon their

tweeting style. Overall, most profiles were classified as preferring "with-mention" tweeting styles (718/967, 74.3%) over "without-mention" tweeting styles (248/967, 25.7%). Table 2 displays the descriptive statistics for the 2 groups across the number of (1) profiles followed, (2) followers, (3) tweets, and (4) favorites. There were no significant differences between the 2 groups for all of the categories (followed, followers, tweets, and favorites).

Table 2. Online behaviors grouped by tweeting behavior.

Behaviors	Without mention (n=248) With mention (n=7		With mention (n=718	i)	Mann-Whitney U test Z score	Р
	Mean (SD)	Median	Mean (SD)	Median		
Followed	778.55 (2269.93)	168.5	758.23 (1938.82)	187.5	-0.88	.381
Followers	1001.16 (3605.59)	235.0	887.11 (2192.43)	210.0	-0.42	.675
Tweets	10390.46 (46922.71)	876.0	9886.84 (26378.60)	1281.0	-1.36	.173
Favorites	3476.15 (8781.05)	483.5	4228.01 (11702.89)	570.5	-0.74	.462

The relationships between the aforementioned factors (see Table 2) were also examined via a Pearson correlation test (see Table 3). The results indicated that all the factors were significantly

correlated with each other, with the largest correlation being between number of followers and accounts followed.

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Table 3. Intercorrelations of online behaviors (N=966).

Variable	Followed	Followers	Tweets	
Followers			· · · · · ·	
r	0.85	1	a	
P value	<.001	_	_	
Tweets				
r	0.36	0.60	1	
P value	<.001	<.001	—	
Favorites				
r	0.30	0.30	0.42	
P value	<.001	<.001	<.001	

^aNot applicable.

The study further investigated if numbers of accounts followed, tweets, and favorites were significant predictors of number of followers. A forward stepwise model based upon the adjusted R^2 was utilized to determine the best-fitting model:

Followers = -215.74 + 1.58(Followed) + 0.05(Tweets) (1)

In the final model (Table 4), favorites was no longer a significant predictor, with the remaining 2 predictors (followed and tweets) together explaining 35.5% of the variation in the number of followers.

Table 4.	Regression coe	efficients for pred	dictors of num	ber of followers.
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Predictor	Model 1 ^a			Model 2 ^b			
	В	SE	Р	В	SE	Р	
Followed ^c	1.58	.10	<.001	1.58	.10	<.001	
Tweets ^c	0.05	.01	<.001	0.05	<.01	<.001	
Favorites ^c	<-0.01	.02	.558	N/A ^d	N/A	N/A	

^aAdjusted R²=0.354.

^bAdjusted R²=0.355.

^cTransformed.

^dN/A: not applicable.

Discussion

Principal Findings

Our study explored the common lexicon of the Pro-ED Twitter community by identifying popular key words and phrases tagged in tweets. Results of this analysis indicate #thinspo as the most prominent hashtag within the Pro-ED Twitter community, other than #proana, suggesting considerable overlap between the topics and their intent. This indicates that wider conversation involving #thinspo across other social media platforms needs to be further scrutinized and treated as ED-related discussion. Previous research [17,19,28] has found that thinspiration tweeters, that is individuals using #thinspo or #thinspiration to accompany appearance- or weight-related posts on Twitter, form part of a closely connected genuine virtual community and differ to those propagating fitspiration content. Indeed, #fitspo or #fitspiration did not feature as one of our top 10 most used hashtags, suggesting that this hashtag is potentially identifying a different community focused more on the promotion of fitness and muscle building [28]. Taken together, these findings suggest #thinspo as a salient aspect of a Pro-ED

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lifestyle, with #proana and #thinspo used interchangeably in online spaces to communicate a supposedly motivating weight loss message to other community members.

Observing communication within online communities provides insight into their structure, member roles, and tribal behavior [29-31]. Typically, the communication patterns and network structures of online ED communities are differentiated by their intentional online behavior. Members of pro-recovery communities who view EDs as an illness and are actively working towards recovery generate more original content and actively seek out new profiles to follow when compared to Pro-ED communities [31]. Our findings suggest the communication patterns within Pro-ED Twitter communities to be more community driven. The type of tweet (with-mention vs without-mention) did not differ significantly across followed, followers, tweets, and favorites. This implies that whether a member is the source of the content or merely sharing it, they are equally likely to contribute to the growing Pro-ED community and its formation. As previously suggested by Wang et al [31], members within the Pro-ED Twitter community use the platform as a tool for community engagement and not

typically as a means of communication per se as indicated by the number of retweets within our findings. This is a crucial finding as there is a greater role that social media platforms can play in addressing the communication. In essence, social media platforms could fill this void with tools that can facilitate communication and extend ED-related discussions with the ED community users. One approach would be to channel them to external sites, such as the National Butterfly Foundation (official organization for ED-related matters in Australia), mediated by a chatbot for cost efficiency.

The Pro-ED community chatter was dominated by retweets, by 75%, rather than genuine threads of communication. For example, the exchanges featuring "41DaysofStarvation" were a passing superficial topic in a particular subgroup of users that garnered quick interest and then discontinued. This could be due to the members' transient [32-34] nature, which prohibits them from building longer-lasting discussion threads, with over 10,484 profiles only engaging in no more than 6 tweets. It is possible that this "41 days" of extreme weight control led to a deterioration in their physical health and subsequent inpatient admission. However, this pattern of communication could also be indicative of the network structure. Previous findings indicate that Pro-ED communities have a far-reaching online community [15] but low reciprocity rates of communication with other users through replies and mentions [31]. This alludes to the allegiance the members have towards the topic and care shown among members but rarely are there extended discussion threads [35]. Additionally, the possibility of users being barred for violating the rules of engagement, especially if their postings included suicidal and self-harm messages, may account for hashtag attrition rates. This was evident within this study where 14.9% (169/1136) of the Twitter users had their account suspended or deleted between September 15, 2015 and July 1, 2018 as shown in Figure 1. A further analysis on the remaining 967 profiles revealed that only 632 profiles are currently still active, showing a 34% attrition from July 1, 2018 to September 15, 2020. For example, one Twitter user was barred for 2 months by Twitter for posting adverse Pro-ED content. This resulted in the removal of all previous postings and interactions. This account holder has since resumed being online with the same Twitter handle continuing posting Pro-ED content, however less active. This incident was documented by the authors due to the longitudinal data collected from Twitter, a strength of our study.

The data also showed retweets of the original postings being still "alive" on Twitter despite the corrective action by the platform. This leads us to question the amount of ED-related messages that could be retweeted and commented upon long after an account has been deleted. Impact of these unhealthy messages could be everlasting to the society. This warrants further investigation but also highlights the complexity in removing postings beyond the immediate network of an individual where postings are transversed fluidly and randomly. Social media platforms will need to take heed of the fact that user content lives beyond the immediate layer of where a posting has been initially lodged and could be shared across different platforms. This could impact policy development for content removal and moderation to avoid similar incidents to the live streaming of a mass shooting in Christchurch, New Zealand via

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Facebook [36]. To best address these and other contextual issues, social media platforms need to work closely with external support organizations to adopt a best practice approach. In the context of ED, Twitter will need to soon adopt national ED bodies as safety partners [37] to continuously engage and be advised on matters relating to ED.

From our analysis, there appears to be a reciprocal effect between followers and the followed. This implies that the Pro-ED community is resilient [38] and gains traction, as more and more people may be influenced to be part of it. This emulates cybersectarian society behaviors [39], whereby niche sentiments appeal to only a select community of people who propagate information and are virtually enduring. While opinion leaders and influencers have been found to exist within online ED communities [31], dominating members are not typically apparent. Dominating members can exert constant enforcement or exhibit power that could encourage members to change their allegiance behavior or even abandon the community [35]. As indicated through the type of tweets and number of retweets, the Pro-ED community engages with content and propagates it, and while externally, the community may appear just as an avenue for individuals seeking social support, the focus is potentially more about aligning with the collective identity of the community. Both issues with identity and social roles have been noted as risk and maintenance factors of EDs [31]. Adverse health outcomes of these groups have been observed over time on social media platforms in their desire to become "thin," hence the crucial need for an understanding of the community structure and development of innovative intervention methods. When faced with mediation, cybersectarian groups typically react impulsively to go incognito and reappear after a length of time or remain hidden forever. For the health and safety of the members of these groups, a more participatory treatment intervention would potentially generate better outcomes compared with an outright ban, as noted by Casilli et al [40].

Understanding the vitality of Pro-ED communities is relatively complex and is reliant on the emergence of health fads and the traction of passing themes. Here, social media platforms such as Twitter would need to play a proactive role in addressing these issues. For example, Twitter should directly communicate to the 632 active profiles reported in this study to reduce further ED-related discussion and minimize sharing of related content that has a negative impact, as reported by Tiggemann and Zaccardo [41]. While Twitter has already undertaken some action within the suicide and self-harm space [42], more would be expected to follow, as Boyd [43] noted that adolescent users frequently turn to social media platforms including Twitter as a coping mechanism to diffuse external pressures threatening their mental health. It would also be beneficial for this approach of analysis to be replicated on other social media platforms to observe whether Pro-ED communities behave in the same manner across platforms. Importantly, future research should address how hashtags and other message content can be utilized to identify and reach individuals who are struggling with EDs and provide them with much needed therapeutic interventions. However, a challenge for interventions is the rapidly changing lexicon of the community [44]. As our findings indicate, hashtags accompanying Pro-ED events such as

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#41DaysofStarvation were short lived; however, #proana persists as a consistent theme in an otherwise transient community, potentially providing an ideal starting point for intervention.

Our analysis showed that the number of accounts followed and number of Pro-ED tweets posted were significant predictors for the number of followers of a user compared to likes. Hence the "like" counter is an obsolete predictor for ED engagement and activity. This important finding could potentially be useful to social media platforms to understand which features could help or otherwise curtail the spread of ED messages. A recent report about Instagram's decision to turn off the "like" counter [45] might be futile to curtail ED, though the number of likes has been reported to give some indication of support [46,47].

Limitations

There are several limitations to the current study. First, some data may have been omitted in the data collection process owing to the free data access from the Twitter streaming API, which normally constitutes about 1% of the whole Twitter data stream [48]. However, as mentioned by Cavazos-Regh et al [28], the percentage of private Twitter accounts is very small, and Twitter accounts default to a public setting. Results might be more reflective if we had subscribed to Twitter premium API services [49] and targeted tweets from personal accounts, and a larger sample size would have made this study more generalizable across the board. Further, a suite of other ED-related hashtags described in [16] would have contributed to a larger data set. These factors will be considered in future to improve research outcomes.

Conclusions

Notwithstanding these limitations, our study contributes to the emerging literature examining Pro-ED content on social media platforms by providing an understanding of the Pro-ED communities and also the engagement of these groups. Continued research is needed to understand how we might use these messages and group dynamics to provide intervention and support to people with EDs in need.

Conflicts of Interest

None declared.

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Abbreviations

AN: anorexia nervosa
API: application program interface
ED: eating disorder
Pro-ED: promote eating disorders
SUHREC: Swinburne University Human Research Ethics Committee

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Review

New Evidence in the Booming Field of Online Mindfulness: An Updated Meta-analysis of Randomized Controlled Trials

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Abstract

Background: There is a need to regularly update the evidence base on the effectiveness of online mindfulness-based interventions (MBIs), especially considering how fast this field is growing and developing.

Objective: This study presents an updated meta-analysis of randomized controlled trials assessing the effects of online MBIs on mental health and the potential moderators of these effects.

Methods: We conducted a systematic literature search in PsycINFO, PubMed, and Web of Science up to December 4, 2020, and included 97 trials, totaling 125 comparisons. Pre-to-post and pre-to-follow-up between-group effect sizes (Hedges *g*) were calculated for depression, anxiety, stress, well-being, and mindfulness using a random effects model.

Results: The findings revealed statistically significant moderate pre-to-post effects on depression (g=0.34, 95% CI 0.18-0.50; P<.001), stress (g=0.44, 95% CI 0.32-0.55; P<.001), and mindfulness (g=0.40, 95% CI 0.30-0.50; P<.001) and small effects on anxiety (g=0.26, 95% CI 0.18-0.33; P<.001). For well-being, a significant small effect was found only when omitting outliers (g=0.22, 95% CI 0.15-0.29; P<.001) or low-quality studies (g=0.26, 95% CI 0.12-0.41; P<.001). Significant but small follow-up effects were found for depression (g=0.25, 95% CI 0.12-0.38) and anxiety (g=0.23, 95% CI 0.13-0.32). Subgroup analyses revealed that online MBIs resulted in higher effect sizes for stress when offered with guidance. In terms of stress and mindfulness, studies that used inactive control conditions yielded larger effects. For anxiety, populations with psychological symptoms had higher effect sizes. Adherence rates for the interventions ranged from 35% to 92%, but most studies lacked clear definitions or cut-offs.

Conclusions: Our findings not only demonstrate that online MBIs are booming but also corroborate previous findings that online MBIs are beneficial for improving mental health outcomes in a broad range of populations. To advance the field of online MBIs, future trials should pay specific attention to methodological quality, adherence, and long-term follow-up measurements.

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KEYWORDS

mindfulness; mental health; intervention; online; meta-analysis; mobile phone

Introduction

Background

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In the 1970s, mindfulness was introduced as an intervention to tackle various psychological symptoms, such as stress, depression, and anxiety [1]. Mindfulness has been defined as the ability to be aware of bodily sensations, feelings, and

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thoughts in the present moment with a curious and accepting attitude toward these experiences [2,3]. Since the 1970s, various mindfulness-based interventions (MBIs) have been developed. Mindfulness-Based Stress Reduction (MBSR) was originally developed for people with chronic pain to support them in coping with chronic stress [2,4]; Mindfulness-Based Cognitive Therapy (MBCT) was primarily developed for people with

recurrent depression [5]; Dialectical Behavior Therapy was developed for cultivating emotion-regulation skills in people with borderline personality disorder [6]; and Acceptance and Commitment Therapy (ACT) was developed to increase psychological flexibility and reduce distress in people with various mental health problems [7]. Although these interventions vary in the use and duration of specific meditation exercises and in their theoretical and psycho-educational frameworks, they share a core focus on promoting awareness of sensations, emotions, and cognitions and the ability to not react to and identify with these bodily and mental events. Over the past decades, a large number of systematic reviews and meta-analyses have been conducted on the effectiveness of MBIs in various target groups [8-24]. Following a general trend in mental health care, MBIs are increasingly being delivered through the internet [25-27]. In 2015, we conducted a meta-analysis to examine the effectiveness of online MBIs published in 2016 [28]. In this meta-analysis, 15 randomized controlled trials (RCTs) totaling 17 comparisons of an online MBI with a control group were included. At postintervention, online MBIs outperformed controls on all outcomes. Short-term effects were promising and included enhanced well-being (g=0.23), decreased depressive and anxiety symptomatology (g=0.29 and g=0.22, respectively), reduced levels of stress (g=0.51), and improved mindfulness (g=0.32). Although these findings indicate that online MBIs have the potential to contribute toward improving mental health, the observed effects had to be interpreted with caution considering the limited number of included studies and the fact that many of the included RCTs were limited in scope, comparability, and methodological quality.

One year later, another meta-analysis focused on the same topic [10]. This meta-analysis included data collected until October 23, 2015, and showed considerable overlap with our meta-analysis; 21 RCTs were included in this study. The findings indicated significant pre-post improvements in anxiety, depression, and quality of life compared with the control conditions. Online MBIs were not found to be more effective than the comparison interventions.

In 2018, Sevilla-Llewellyn-Jones et al [9] performed a systematic review and meta-analysis on the effectiveness of online MBIs, specifically focusing on populations with diagnosed mental health problems. On the basis of 12 studies, online MBIs were found to significantly improve mindfulness skills in people with mental disorders. Furthermore, the findings demonstrated that online MBIs are effective in reducing depression and anxiety and improving quality of life in people with anxiety disorder, but not in people with depressive disorder.

In 2020, two more meta-analyses of technology-enabled and online MBIs were performed, focusing on stress management in the general population (n=16) [29] and distress in clinical and nonclinical populations (n=43) [30]. The findings demonstrated small-to-medium effects on stress, anxiety, depression, and mindfulness compared with active and nonactive control conditions [29,30]. As these reviews address a narrower target population [29] and scope of interventions [30] than our original meta-analysis, a comprehensive review of online MBIs is still lacking.

Objectives

Indeed, reviewing the literature from the past few years indicates that developments in the area of online mindfulness emphasize the need to regularly update the current evidence base. First, as anticipated, the field of online mindfulness is booming, as evidenced by dozens of studies that have been published since our previous meta-analysis. Incorporating these studies in a new meta-analysis would provide a more thorough assessment of the clinical and nonclinical utility of online MBIs and improve the power of moderation analyses. Second, we noticed a transformation in the types of online MBIs that are being delivered to users. At the time that our 2016 meta-analysis was conducted, MBSR and MBCT and derivatives from these interventions dominated the field. Since then, there has been a rapid increase in online ACT interventions, allowing a more robust assessment of this specific MBI. Third, it appears that the components of MBIs are increasingly mixed or hybrid, resulting in numerous MBIs that show considerable overlap and all seem to have a beneficial impact on mental health. It remains unclear whether mixtures of MBIs are equally effective in improving mental health. Fourth, not only is the content of today's online MBIs different from 5 years ago but also the delivery method is different. MBIs are increasingly delivered through smartphone apps instead of websites, increasing access modality and ease of usage. These developments spurred the desire to update and extend our 2016 meta-analysis to provide more robust evidence of the short-term and long-term effects of online MBIs, as well as the potential moderators of these effects.

Methods

This study was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [31]. The data collection and analysis procedures were similar to those used in our previous meta-analysis [28].

Literature Search and Eligibility Criteria

We searched the PsycINFO, PubMed, and Web of Science databases three times for RCTs published since 2015—that is, September 6, 2018; July 19, 2019 (by MSS and WP); and December 4, 2020 (by JA). The search strategy was identical to that used in our previous meta-analysis [28]. Search terms included synonyms, both in text words and Medical Subject Headings or thesaurus terms, for (1) mindfulness (eg, *mindful** and *meditation*), (2) intervention (eg, *intervention** and *treatment**), (3) online (eg, *e-health* and *Internet**), and (4) RCTs (eg, *random** and *trial*). The search results were filtered for English-language journal articles. For complete search strings, we refer to our previous meta-analysis [28].

Trials were included when they met the following criteria:

 Examines the effectiveness of an MBI, that is, an intervention consisting of at least one guided or unguided session and a combination of psycho-education and more than one experiential exercise with a primary focus on enhancing mindfulness skills. Both mindfulness-only interventions (eg, MBSR and MBCT) and mindfulness-integrative interventions such as Dialectical

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Behavior Therapy, ACT, or Mindfulness-Based Compassionate Living were included. Derivatives and mixtures of programs were also eligible, provided that teaching mindfulness was at the core of the intervention.

- The MBI is delivered via the internet and can be followed on a computer or a mobile device such as a smartphone or tablet. Interventions that used a combination of face-to-face and online sessions were eligible when face-to-face sessions were limited to the introduction of the study.
- Use of a randomized controlled design with at least one experimental condition and one active or inactive control condition (ie, no treatment, usual care, or any active treatment other than the experimental intervention).
- Depressive symptoms, anxiety symptoms, stress, well-being, or mindfulness was measured pre- and postintervention, using a validated measure.
- Studies simultaneously using MBIs and non-MBIs were eligible for inclusion, provided that the design allowed us to distinguish the independent effects of the MBIs.
- The study population consisted of adults aged ≥18 years. Both clinical (mental and physical disorders) and nonclinical samples (eg, students and community samples) were eligible.
- The reported findings allow the calculation of effect sizes, or the necessary data were made available by the authors. In addition, RCT protocols were screened for eligibility and included when the authors provided the necessary data.

The selection of studies took place in three phases: first, the review of titles; second, abstracts; and third, full texts. The selection was conducted independently by MSS, JA, and WP. Disagreements were resolved through discussion.

Data Extraction

Population, intervention, and methodological characteristics (Multimedia Appendix 1; Gao et al, unpublished data, 2021; [32-125]) as well as effect size data were extracted from the full-text papers by 3 raters (ie, MSS, JA, and WP) independently. When discrepancies occurred, these were resolved in the discussion. When the article provided insufficient information regarding the study characteristics, the authors were contacted.

Quality Assessment

Three raters (alternatingly, MSS, JA, and WP) independently assessed the methodological quality of each study using the same criteria as outlined in [28]. In brief, the criteria included (1) adequate sequence generation and allocation concealment; (2) blinding of main outcome assessments; (3) drop-out analysis; (4) adequate handling of missing data; (5) adequate sample size calculation; (6) comparability of experimental and control participants at baseline; and (7) diagnostic assessment of participants (only applicable for clinical samples). Raters coded each criterion as 1 (criterion is met) or 0 (criterion is not met). Disagreements between raters were resolved through discussion. Studies were scored between 0 and 7 points, with higher scores reflecting greater methodological quality. The methodological quality of each study was assessed as high (7 points), moderate (5-6 points), or low (\leq 4 points).

Data Analysis

Meta-analytic procedures were performed using the Comprehensive Meta-Analysis software, version 2.2.064. Hedges g effect sizes were calculated for (1) depressive symptoms, (2) anxiety symptoms, (3) stress, (4) well-being, and (5) mindfulness, using the same steps as reported in [28]. We calculated pre-to-post between-group effect sizes for all studies and pre-to-follow-up between-group effect sizes, thereby including only studies with a follow-up period of 1-3 months. Effect sizes reflect the number of SDs with which the online MBI group had more changed than the control condition between pre- and postmeasurement and pre- and follow-up measurement. Where available, intention-to-treat data were used to calculate effect sizes. If a study used more than one measure for the same outcome, we used the most valid instrument. However, in the case of well-being, we observed different dimensions of well-being (eg, a measure of emotional well-being and a measure of psychological well-being). In these cases, we extracted all relevant outcomes and computed the combined (average) effect sizes. When studies used more than one comparison condition, we used the strongest comparison to calculate the effect size. Following the study by Lipsey and Wilson [126], effect sizes from 0 to 0.32 were considered a small effect, 0.33 to 0.55 were considered a moderate effect, and 0.56 to 1.20 were considered a large effect.

Per outcome, forest plots of the pre-to-post effect sizes and pre-to-follow-up effect sizes were generated. A random effects model was used [127]. Meta-analyses were conducted, both including and excluding outliers. Outliers were identified through visual inspection of forest plots. In line with our previous meta-analysis [28], a study was deemed an outlier when its 95% CI fell outside the 95% CI of the overall mean effect size (on both sides). As a sensitivity analysis, meta-analyses were repeated, thereby omitting low-quality studies (including outliers).

The statistical procedures used to assess heterogeneity, publication bias, and moderators were identical to those used in our previous meta-analysis [28]. A priori, specified subgroup analyses were conducted to assess the differential effects of online MBIs based on (1) intervention type: MBSR, MBCT, ACT, or MBI (ie, mixture); (2) therapist guidance, with or without; (3) delivery mode: app or website; (4) population type: clinical or nonclinical; (5) type of symptoms: psychological, physical, or no symptoms; and (6) type of control: active (ie, treatment as usual, psycho-education, or other intervention) or inactive (ie, waitlist or no intervention). We conducted mixed effects analyses, thereby using a random effects model to pool studies within each subgroup and a fixed effect model to test whether effect sizes between subgroups significantly differed from one another. Only subgroups with five or more comparisons were reported. In addition to study quality and number of intervention sessions, mean age and proportion of females were included in the meta-regression analyses (mixed effects model and unrestricted maximum likelihood). Subgroup and meta-regression analyses were conducted, including outliers and only with pre-to-post data.



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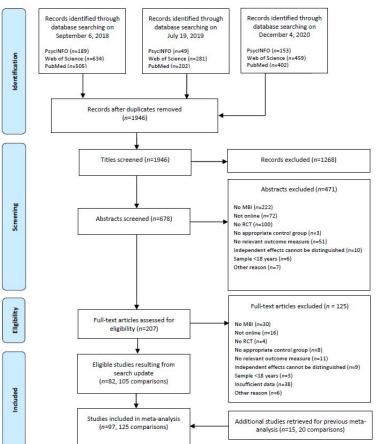
Results

Selection of Studies

The first search yielded 1328 hits, the second yielded 532 hits, and the last yielded 1014 hits. A total of 928 duplicates were removed. After reviewing 1946 titles, 678 abstracts, and 207

full articles, we identified 82 new studies, totaling 105 comparisons, which were not included in our previous meta-analysis (Figure 1). In addition, 15 eligible studies, including 20 comparisons identified in our previous meta-analysis [28], were included. Accordingly, 97 RCTs, totaling 125 comparisons, were included in this meta-analysis.

Figure 1. Flowchart of the study selection process. MBI: mindfulness-based intervention; RCT: randomized controlled trial.



Study Characteristics

Although research on the effectiveness of online MBIs has been undertaken in 21 countries across the globe, nearly one-third of all studies were conducted in the United States (n=31). Other countries in the top 5 included the United Kingdom, Sweden, the Netherlands, and China with 12, 10, 8, and 5 RCTs, respectively. Multimedia Appendix 1 shows the population, intervention, comparison, and outcome characteristics of all studies included in the meta-analysis.

The total study population consisted of 17,464 participants, with a mean age of 40 years. A total of 9066 participants were in the experimental condition and 7832 were in the control condition. There were large differences in sample sizes, ranging from 16 in a small-scale pilot RCT [32] to 2161 in a large-scale trial [33]. The proportion of women ranged from 41% to 100%. Most studies were conducted among the general population, employees, or student samples (45/97, 46% of studies). In 24 studies, online MBIs were targeted at populations with somatic illnesses, such as cancer (n=11) and chronic pain (n=7); 11 studies were targeted at health care professionals (n=4) and spousal or family caregivers (n=7). The remaining 17 studies

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included samples with psychological symptomatology, with depressive and anxiety symptoms being the most prevalent (n=12).

In 70.4% (88/125) of comparisons, a mindfulness-only intervention was used, with the most commonly studied intervention being MBSR (n=21), followed by MBCT (n=14), and a mixture or derivative of MBSR and MBCT and related exercises (n=53). Mindfulness-integrative interventions were used in the remaining 29.6% (37/125) of comparisons, specifically ACT (n=29), acceptance-based intervention (n=3), compassion-based intervention (n=4), and Mindfulness-Based Compassionate Living (n=1).

MBIs were mostly delivered through a website (n=84), followed by an app (n=27), virtual online classroom or videoconferencing software (n=4), or a combination (n=3). The number of online MBI sessions varied between 2 and 45. Sessions were used over a period of 10 days to 14 weeks. In 28.8% (36/125) of comparisons, online MBIs were provided with therapist guidance.

In 52% (65/125) of comparisons, the effectiveness of online MBIs was examined relative to a waitlist control (n=61) or no

intervention (n=4) condition. An active control condition was used in 48% (60/125) of comparisons, including psycho-education (n=13), an online discussion forum (n=7), treatment as usual (n=14), and an alternative intervention (n=26; eg, expressive writing, cognitive behavioral therapy, and behavioral activation).

Outcome measures for depressive symptoms, anxiety, stress, well-being, and mindfulness were administered in 82, 70, 54, 48, and 67 comparisons, respectively; 44.3% (43/97) of studies reported not only pre- and postmeasurement but also follow-up measurements, with follow-up times ranging from 1 to 12 months.

Adherence

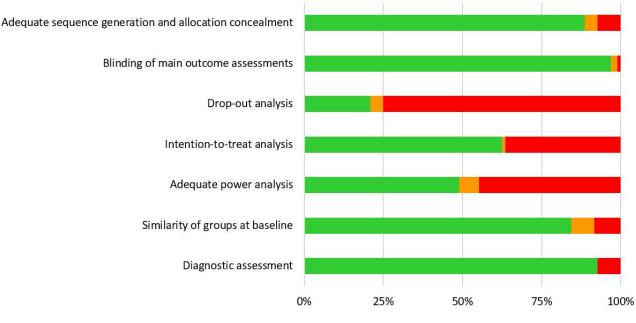
Although 70% (68/97) of studies reported important information regarding adherence to the intervention (eg, time spent on the

intervention, number of modules started, number of completed sessions, and daily meditation practice), only 23% (22/97) studies provided a definition or cut-off to determine adherence versus nonadherence. Using various definitions of adherence, these studies reported adherence rates ranging from 35% to 92%.

Quality of Included Studies

Scores for methodological quality varied between 1 and 7 points (Multimedia Appendix 2; Gao, M, unpublished data, 2021; [32-125]). Of the 97 included studies, 33 (34%) were considered low-quality studies; 66% (64/97) of the studies were rated as moderate (n=53) or high (n=11) quality. The results per quality criterion are shown in Figure 2.

Figure 2. Results of methodological quality assessment per criterion presented as percentages across all included studies.



Pre-to-Post Between-Group Effects

Main Findings

Table 1 provides an overview of the pre-to-post between-group effects. For depression (89 comparisons) and anxiety (74 comparisons), significant moderate and small effects were observed (depression: g=0.34, 95% CI 0.18 to 0.50, P<.001; anxiety: g=0.26, 95% CI 0.18-0.33, P<.001). Significant, moderate effects were found for stress (56 comparisons; g=0.44, 95% CI 0.32-0.55, P<.001) and mindfulness (72 comparisons; g=0.40, 95% CI 0.30-0.50, P<.001). No significant effect was observed for well-being (52 comparisons; g=0.21, 95% CI -0.03 to 0.45, P=.08). The level of heterogeneity was moderate to

high (I^2 =64.92-96.64). When outliers were removed, similar effect sizes were observed (depression: g=0.30; anxiety: g=0.22; stress: g=0.38; well-being: g=0.22; and mindfulness: g=0.39), with no changes in significance of the effect except for well-being (P<.001), and the level of heterogeneity remained moderate to high (I^2 =41.26-93.23). After omitting low-quality studies from the analysis, the effect size for well-being was significant (g=0.26, 95% CI 0.12-0.41; P<.001). For the remaining outcomes, no significant changes were observed for any of the outcomes, and all effect sizes remained virtually the same. Heterogeneity remained moderate to high $(I^2 = 65.72 - 83.06).$



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Table 1. Pre-to-post effects of online mindfulness-based interventions compared with controls^a.

Outcomes	$N_{\rm comp}^{\rm b}$	Hedges g (95% CI)	Ζ	Heterogeneity		Fail-safe N
				Q value	I ²	
All studies (including o	utliers)			,		
Depression	89	0.34 (0.18 to 0.50)	4.10 ^c	1326.41 ^c	93.37	5507
Anxiety	74	0.26 (0.18 to 0.33)	6.70 ^c	208.10 ^c	64.92	2763
Stress	56	0.44 (0.32 to 0.55)	7.48 ^c	262.80 ^c	79.07	1355
Well-being	52	0.21 (-0.03 to 0.45)	1.75	1516.62 ^c	96.64	121
Mindfulness	72	0.40 (0.30 to 0.50)	7.72 ^c	407.80 ^c	82.59	2624
All studies (excluding o	utliers)					
Depression ^d	86	0.30 (0.14 to 0.46)	3.69 ^c	1254.96 ^c	93.23	2903
Anxiety ^e	67	0.22 (0.15 to 0.28)	6.62 ^c	112.35 ^c	41.26	1217
Stress ^f	47	0.38 (0.29 to 0.48)	7.72 ^c	130.94 ^c	64.87	1947
Well-being ^g	46	0.22 (0.15 to 0.29)	6.02 ^c	89.18 ^c	49.54	727
Mindfulness ^h	65	0.39 (0.29 to 0.49)	7.65 ^c	180.91 ^c	74.37	3719
Moderate- and high-qu	ality studies					
Depression	61	0.37 (0.27 to 0.47)	7.43 ^c	237.26 ^c	74.71	2196
Anxiety	55	0.28 (0.20 to 0.37)	6.35 ^c	157.54 ^c	65.72	1563
Stress	38	0.39 (0.27 to 0.51)	6.26 ^c	159.77 ^c	76.84	1433
Well-being	31	0.26 (0.12 to 0.41)	3.50 ^c	154.25 ^c	80.55	398
Mindfulness	45	0.43 (0.29 to 0.56)	6.20 ^c	259.72 ^c	83.06	2486

^aAnalyses were conducted using a random effects model.

 ${}^{b}N_{\text{comp}}$: number of comparisons.

^cP<.001.

^dThree outliers were removed: Kladnitski et al [34] (study 4); Querstret et al [35,36]; Yang et al [37].

^eSeven outliers were removed: Forbes et al [38] (study 1); Gao, M (unpublished data, 2021); Levin et al [48]; Mak et al [39]; Querstret et al [35,36]; Segal et al [40]; Yang et al [37].

^fNine outliers were removed: Allexandre et al [41] (study 1); Beshai et al [42]; Champion et al [43]; El Morr et al [44]; Huberty et al [45]; Kladnitski et al [34] (study 4); Levin et al [46]; Nadler et al [128]; Walsh et al [47].

^gSix outliers were removed: Allexandre et al [41] (study 1); Hoffmann et al [129]; Levin et al [130] (study 1); Levin et al [48]; Ly et al [49]; Mak et al [39].

^hSeven outliers were removed: Forbes et al [38]; Henriksson et al [131]; Huberty et al [45]; Krusche et al [132]; Mak et al [33] (study 1 and study 2); Nadler et al [128].

Publication Bias

Whereas visual inspection of funnel plots indicated no remarkable evidence of publication bias, trim-and-fill analyses and fail-safe numbers suggest that publication bias has occurred in the reporting of effects on depressive and anxiety symptoms, well-being, and mindfulness. The Duval and Tweedie [133] trim-and-fill procedure indicated publication bias for depression, anxiety, and well-being. After adjustment for missing studies (n=19), the effect size for well-being dropped from g=0.21 to g=-0.04 (95% CI -0.23 to 0.15). For anxiety and depression, effect sizes were found to be higher, with three imputed studies on anxiety (g=0.31, 95% CI 0.23-0.38) and 19 on depression (g=0.48, 95% CI 0.39-0.57).

Subgroup Analyses

Subgroup analyses can be found in Multimedia Appendix 3. For stress, two subgroup analyses resulted in significantly higher effect sizes: (1) guided online MBIs compared with unguided online MBIs (guided: g=0.61, 95% CI 0.43-0.82; unguided: g=0.34, 95% CI 0.21-0.47; P=.02) and (2) studies that used an inactive control condition compared with studies with an active control group (inactive: g=0.56, 95% CI 0.43-0.69; active: g=0.15, 95% CI -0.04 to 0.35; P=.001). For mindfulness, inactive control groups also resulted in higher effect sizes than active control groups (inactive: g=0.52, 95% CI 0.41-0.63; active: g=0.19, 95% CI 0.03-0.34; P<.001). For anxiety, higher effect sizes were found in samples with psychological symptoms

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than in those with physical or no symptoms (psychological symptoms: g=0.47, 95% CI 0.33-0.61; physical symptoms: g=0.16, 95% CI 0.03-0.30; no symptoms: g=0.21, 95% CI 0.11-0.030; P=.008). For depression and well-being, no significant differences were found between subgroups.

Meta-Regression Analysis

The meta-regression analysis (Table 2) revealed that study quality had a significant positive influence on the observed

	Table 2.	Meta-regression	analyses ^a .
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effects of anxiety but not on the remaining outcomes. Furthermore, a significant moderating impact of age on stress was observed, whereby online MBIs were found to be more effective in reducing stress in older samples. For mindfulness, the number of sessions had a significant negative influence on the effect size, with more sessions resulting in lower effect sizes.

Dutcome and predictor	$N_{\rm comp}^{\rm b}$	Slope	Ζ	P value
Depression				
Study quality	88	0.05	1.09	.28
N sessions	84	0	0	.99
Mean age	80	0	0.47	.64
% female	87	0.01	1.37	.18
nxiety				
Study quality	73	0.07	2.04	.04 ^c
N sessions	69	0	-1.25	.21
Mean age	66	0	-0.03	.98
% female	73	0	0.83	.40
Stress				
Study quality	55	-0.04	-0.74	.46
N sessions	49	0.03	2.45	.05
Mean age	43	0.01	2.88	.004 ^d
% female	55	0	0.25	.80
Vell-being				
Study quality	51	0.07	0.90	.37
N sessions	49	0	-0.33	.74
Mean age	51	0	-0.28	.78
% female	51	0	0.17	.86
Aindfulness				
Study quality	71	0.01	0.26	.80
N sessions	66	-0.01	-2.80	.005 ^d
Mean age	65	0	0.06	.95
% female	71	0.01	1.83	.07

^aMeta-regression analyses were conducted using a mixed effects model with unrestricted maximum likelihood.

 ${}^{b}N_{comp}$: number of comparisons.

^cP<.05.

^dP<.01.

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Pre-to-Follow-up Between-Group Effects

Main Findings

The pre-to-follow-up effects are shown in Table 3. At follow-up, significant small effects were found for depression (26 comparisons: g=0.25, 95% CI 0.12-0.38, P<.001), and anxiety

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(21 comparisons: g=0.23, 95% CI 0.13-0.32; P<.001). The effects of stress were in favor of control conditions (15 comparisons: g=-0.24, 95% CI -0.40 to -0.09, P=.003). Effect sizes for well-being (18 comparisons: g=-0.02, 95% CI -0.53 to 0.49, P=.08) and mindfulness (27 comparisons: g=0.06, 95% CI -0.05 to 0.16, P=.28) were not significant. Heterogeneity

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varied considerably, from I^2 =36.49 for stress to I^2 =98.73 for well-being. After the removal of outliers, effect sizes for depression and mindfulness remained fairly the same (depression: g=0.27, 95% CI 0.14-0.40, P<.001; mindfulness: g=0.05, 95% CI -0.03 to 0.14, P=.21), with no changes in the significance of the effect and the level of heterogeneity remaining moderate (I^2 =40.36-53.930). For stress, the effect size was higher after removing outliers (stress: g=-0.11, 95% CI -0.21 to -0.02, P=.02). The fixed effects models showed similar results. For anxiety and well-being, no outliers were detected. When only medium- and high-quality studies were included, similar effect sizes were found for all outcomes, except for well-being which showed a substantial increase in effect size from g=-0.02 to g=0.17 (nonsignificant, 95% CI -0.03 to -0.37, P=.09). Effect sizes for depression, anxiety, and stress remained significant (depression: g=0.24, 95% CI 0.09-0.38, P=.001; anxiety: g=0.21, 95% CI 0.07-0.34, P=.003; stress: g=-0.30, 95% CI -0.51 to 0.08, P=.008), with moderate heterogeneity (depression: I^2 =53.21; anxiety: I^2 =43.56; stress: I^2 =71.02). The effect size for mindfulness remained nonsignificant (g=0.08, 95% CI -0.08 to 0.23; P=.34), with moderate heterogeneity (I^2 =70.06).

Table 3. Pre-to-follow-up effects of online mindfulness-based interventions compared with controls^a.

Outcomes	$N_{\rm comp}^{\rm b}$	Hedges g (95% CI))	Ζ	Heterogene	Fail-safe N	
				Q value	I^2	
All studies (including outliers)	· · · · ·			· · · ·	· · ·	
Depression	26	0.25 (0.12 to 0.38)	3.80 ^c	74.12 ^c	66.27	201
Anxiety	21	0.23 (0.13 to 0.32)	4.62 ^c	31.49 ^d	36.49	189
Stress	15	-0.24 (-0.40 to -0.08)	-2.97 ^e	37.09 ^e	62.25	71
Well-being	18	-0.02 (-0.53 to 0.49)	-0.09	1254.86 ^c	98.73	171
Mindfulness	27	0.06 (-0.05 to 0.16)	1.09	75.05 ^c	65.36	0
All studies (excluding outliers)						
Depression ^f	25	0.27 (0.14 to 0.40)	4.18 ^c	53.93 ^c	55.50	220
Anxiety	N/A ^g	N/A	N/A	N/A	N/A	N/A
Stress ^h	13	-0.11 (-0.21 to -0.02)	-2.31 ^d	9.35	0	12
Well-being	N/A	N/A	N/A	N/A	N/A	N/A
Mindfulness ⁱ	25	0.05 (-0.03 to 0.14)	1.23	40.36 ^d	40.53	0
Aedium- and high-quality studies						
Depression	16	0.24 (0.09 to 0.38)	3.23 ^e	32.06 ^e	53.21	75
Anxiety	13	0.21 (0.07 to 0.34)	2.99 ^e	21.26 ^d	43.56	45
Stress	11	-0.30 (-0.51 to -0.08)	-2.67 ^e	34.51 ^c	71.02	44
Well-being	13	0.17 (-0.03 to 0.37)	1.71	48.02 ^c	75.00	24
Mindfulness	18	0.08 (-0.08 to 0.23)	0.96	56.78 ^c	70.06	0

^aOnly studies with a follow-up period of 1-3 months were included. Analyses were conducted using a random effects model.

 ${}^{b}N_{\text{comp}}$: number of comparisons.

^cP<.001.

^dP<.05.

^eP<.01.

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^fOne outlier was removed: Mak et al [39].

^gN/A: not applicable.

^hTwo outliers were removed: Kladnitski et al [34] (studies 1 and 3).

ⁱTwo outliers were removed: Pots et al [50] and Huberty et al [45].

Publication Bias

For depression, anxiety, and well-being, funnel plots were somewhat skewed in favor of studies with a positive outcome

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at follow-up. The trim-and-fill procedure by Duval and Tweedie indicated publication bias for all outcomes except stress; 1, 3, 6, and 6 studies were trimmed for depression, anxiety, well-being, and mindfulness, respectively. The adjusted effect

sizes for depression (g=0.26, 95% CI 0.13-0.39), anxiety (g=0.18, 95% CI 0.07-0.29), and stress (g=-0.24, 95% CI -0.40 to -0.08) were similar to the unadjusted effect sizes, whereas effect sizes for mindfulness (g=-0.04, 95% CI -0.14 to 0.07) and well-being (g=-0.38, 95% CI -0.81 to 0.06) showed a considerable decline after adjusting for missing studies. Finally, the fail-safe N indicated that findings for depression, anxiety, and well-being may be considered robust, whereas this was not the case for stress and mindfulness. However, when only moderate-to-high quality studies were included in the analysis, for none of the remaining outcomes, the findings were deemed robust based on the fail-safe N.

Discussion

Principal Findings

An updated meta-analysis was conducted to assess the effects of the booming field of online MBIs on mental health across studies. In total, 97 RCTs were included in this meta-analysis, demonstrating the rapidly growing interest in implementing MBIs via eHealth platforms and apps. In comparison, only 15 RCTs were included in our meta-analysis conducted 5 years ago [28]. Overall, significant moderate pre-to-post effects were observed for depression (g=0.34), stress (g=0.44), and mindfulness (g=0.40), and a significant small effect was found for anxiety (g=0.26). After removing outliers and low-quality studies, similar results were found, except for well-being. Pre-to-follow-up analyses demonstrated significant small effects for depression and anxiety (g=0.25 and g=0.23, respectively). Our findings are largely in line with those reported in previous meta-analyses [9,10,28-30] and suggest that online MBIs have a significant low-to-moderate impact on mental health and that these effects are maintained at short-term follow-up.

Thus, when addressing depression and anxiety, the impact of online MBIs appears similar to MBIs in traditional face-to-face format [14,23], as well as to other common interventions such as cognitive behavioral therapy [134,135]. However, offering these interventions in an online format may have unique benefits of increased accessibility and scalability, thereby lowering the threshold for participation [136] and potential cost-effectiveness [137]. In addition, in the case of an app-based mode of delivery, the presence of a mobile device throughout most daily activities and experiences may facilitate the integration of newly learned skills into daily life [138,139]. Indeed, just-in-time information (eg, reminders) has been shown to contribute to the effectiveness of online MBIs [140]. Future research could further investigate the level of integration of skills learned in MBIs into daily life by using methods that allow for the assessment of daily fluctuations and situational contexts (eg, experience sampling methods) [141].

Our findings on well-being deserve special attention. In our updated meta-analysis, a significantly small effect on well-being was found, but only after omitting outliers (g=0.22) and low-quality studies (g=0.26). This is in contrast with our previous meta-analysis [28], where there was no difference in the effect on well-being when including or excluding low-quality trials. At first glance, one may consider the increase in the proportion of low-quality trials among those trials assessing

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well-being, from 13% (1/8 studies) to 36% (14/39 studies), as a possible explanation. As a result, studies of low quality may exert a larger influence on the effect size for well-being. However, this line of thought seems contradictory to our finding that study quality is not a moderator of the effect of online MBIs on well-being. Another potential explanation for this finding is that we used a different method to calculate the effect sizes for well-being. In our previous meta-analysis, we used the most valid outcome measure to compute the effect size. However, following the conceptualization of well-being by Keyes [142], in this meta-analysis, we computed combined effect sizes incorporating emotional, psychological, and social dimensions of well-being, where possible. Although we feel that this is the preferred method, this might have led to somewhat different results. In addition, we recognize a growing variability across studies as to how well-being is conceptualized and measured, which might have impacted the results. This is reflected in the increased levels of heterogeneity compared with our previous meta-analysis. Although heterogeneity was low to moderate $(I^2=32.86)$, when including all studies) in our meta-analysis published in 2016 [28], we found a heterogeneity level approaching 100% (I^2 =96.64) in this study. This calls for a more consistent assessment of well-being in future trials assessing the effectiveness of online MBIs. We support the recommendation by Chakhssi et al [143] that studies investigating the effects of interventions, in this case online MBIs, on well-being ideally include validated measures for emotional, psychological, and social dimensions of well-being.

The finding that studies of moderate-to-high quality indicate a positive impact of online MBIs on well-being is important because interventions such as MBSR, MBCT, and ACT emphasize well-being as an intervention outcome. Its relevance is further underlined by increasing evidence that mental well-being and mental illness are related yet discernible phenomena [144-146] and that higher levels of mental well-being reduce the incidence of mental health problems [147-149].

Remarkably, where online MBSR and online MBCT were the most prominent online MBIs 5 years ago, in this meta-analysis, online ACT dominates the field; 29 studies evaluated the impact of online ACT interventions compared with 5 studies in 2016 [28]. ACT is a distinct model of behavioral therapy, emphasizing the context and function of psychological phenomena as the target of psychological treatment [7]. Moderate-to-large effects on mental health have been found across studies evaluating the impact of ACT in clinical and nonclinical populations [21,150]. This meta-analysis thus shows that ACT is increasingly implemented as an online intervention in comparison with other types of MBIs. We found significant small effects of online ACT on depression (g=0.35), anxiety (g=0.23), and well-being (g=0.21), which is consistent with the findings of two other meta-analyses on the effectiveness of web-delivered ACT [151,152].

Whereas online ACT may have become an increasingly common type of intervention in this field of study, another development that is mirrored by our findings is that interventions are increasingly nonspecific. In 42.5% (53/125) of the comparisons,

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mixed or hybrid interventions, encompassing elements of both MBSR and MBCT as well as other mindfulness-based exercises, were used. We found that these programs prove to be effective in reducing symptoms of depression (g=0.37), anxiety (g=0.30), and stress (g=0.44), as well as in improving well-being (g=0.30) and mindfulness (g=0.40), an important finding considering that hybrid interventions are increasingly conquering the market of online MBIs. Interestingly, the type of intervention was not found to be a significant moderator of the effectiveness of online MBIs, suggesting that MBSR, MBCT, ACT, and hybrid MBIs are equally effective in improving mental health.

Subgroup analyses yielded significant differential effects of guidance, symptoms, and type of control group on stress, anxiety, and mindfulness. The effects of online MBIs on stress were significantly higher for interventions with therapist guidance (g=0.42) than for interventions without guidance (g=0.21). This is in line with our previous meta-analysis [28] and evidence demonstrating that guided interventions are more effective in reducing distress than unguided interventions [153]. Furthermore, the effects on anxiety were higher for samples with psychological symptoms than for those with physical or no symptoms. Populations without psychological symptoms may have less room to improve their psychological symptoms, due to lower baseline scores for anxiety (ie, a floor effect). In addition, the effects on stress and mindfulness were significantly larger when comparing online MBIs with inactive versus active control groups. In this regard, it should be noted that levels of heterogeneity were substantial, that is, it is questionable that indeed the types of subgroups are responsible for the differential outcomes. However, these results are in line with the common finding that effect sizes are related to the type of control group [154], with waiting list control groups typically yielding the largest effects [155].

Although the field of online mindfulness is booming, we noticed a number of undesirable phenomena that may undermine the accumulation of unbiased scientific knowledge in this specific domain, thereby hampering the development and optimization of novel online MBIs. The first phenomenon was related to adherence. Adherence is an important topic in the context of online interventions [156] and can be defined as the proportion of an intervention a person engages with or completes [157]. In this meta-analysis, it was found that although 70% (68/97) of studies reported relevant information regarding adherence to the intervention (eg, time spent on the intervention and number of modules started), only in 23% (22/97) of studies a definition or cut-off was provided for determining adherence versus nonadherence. This corroborates with an important systematic review demonstrating that a minority of studies evaluating eHealth interventions described a threshold for the intended use of the technology and that only 10% of the included studies reported a justification of the intended use [158]. The clinical relevance of online interventions is clear, as poor adherence may limit the effects of an intervention as a suboptimal dosage of the treatment may be received. For online MBIs, the relevance

may be even bigger as regular practice of mindfulness is assumed to be essential for the development of mindfulness skills [159]. Therefore, describing a justified threshold for intended use that is aligned with the aim of the technology seems not only relevant but also important for future studies, as this is the basis for a more precise evaluation of adherence and the impact of an intervention.

The indications for publication bias that were found for all outcomes except stress represent a second phenomenon. The pre-post effect size for well-being was substantially reduced after adjusting for missing studies, whereas pre-post findings for depression and anxiety indicated the opposite. We encourage researchers and publishers to publish not only studies with positive outcomes but also studies with nonsignificant or negative findings to overcome the accumulation of unbiased scientific knowledge and the unduly hampering optimization of novel online MBIs.

A third phenomenon that should be addressed is an increase in the proportion of studies with a high risk of bias from 20% (3/15 studies) in our previous meta-analysis [28] to 34% (33/97 studies) in this meta-analysis. In addition, in our meta-analysis, low trial quality resulted in biased effect sizes for well-being. This is an undesirable trend that potentially undermines the reliability of research in this specific domain. Most studies did not meet two of the seven criteria used for rating the quality of studies. Nearly 78% (76/97) of the studies did not perform an adequate drop-out analysis, and 51% (49/97) of the studies did not conduct adequate power analysis. Therefore, attention to these specific analyses in future studies is highly recommended.

Limitations

This meta-analysis included a large number of studies, which allowed moderator analyses and long-term follow-up measurements. However, some important limitations of this study must be considered. There was great variability in follow-up measurements, and the studies included in this meta-analysis only allowed for an overall assessment of effects until the 3-month follow-up. Owing to the limited number of studies using longer follow-up times (longer than 3 months), it remains unclear whether the effects of online MBIs remain at long-term follow-up. It should also be noted that heterogeneity was high for most moderator analyses. This suggests that other, yet unknown, factors may explain the effect differences rather than the observed factors.

Conclusions

This updated meta-analysis not only demonstrates that the field of online MBIs is booming, with a significant low-to-moderate impact on mental health, but also corroborates previous evidence that online MBIs are beneficial for a wide range of populations and symptoms. Future trials assessing the effectiveness of online MBIs should focus on methodological quality parameters, on a priori definition and monitoring of adherence, and on longer follow-up measurements.



Authors' Contributions

MSS and WP designed the study. MSS and JA conducted the literature search. MSS, JA, and WP performed data extraction and analyses. EB was an advisor for the project. MSS prepared the first draft of the manuscript, and all authors contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Study characteristics and outcome measures. [DOCX File, 82 KB - mental_v8i7e28168_app1.docx]

Multimedia Appendix 2 Methodological quality of studies included in the meta-analysis. [DOCX File , 34 KB - mental_v8i7e28168_app2.docx]

Multimedia Appendix 3 Subgroup analyses. [DOCX File, 37 KB - mental_v8i7e28168_app3.docx]

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Abbreviations

ACT: Acceptance and Commitment Therapy MBCT: Mindfulness-Based Cognitive Therapy MBI: mindfulness-based intervention MBSR: Mindfulness-Based Stress Reduction PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses RCT: randomized controlled trial

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Original Paper

Tele–Mental Health for Reaching Out to Patients in a Time of Pandemic: Provider Survey and Meta-analysis of Patient Satisfaction

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Abstract

Background: The COVID-19 pandemic threatened to impact mental health by disrupting access to care due to physical distance measures and the unexpected pressure on public health services. Tele–mental health was rapidly implemented to deliver health care services.

Objective: The aims of this study were (1) to present state-of-the-art tele-mental health research, (2) to survey mental health providers about care delivery during the pandemic, and (3) to assess patient satisfaction with tele-mental health.

Methods: Document clustering was applied to map research topics within tele–mental health research. A survey was circulated among mental health providers. Patient satisfaction was investigated through a meta-analysis of studies that compared satisfaction scores between tele–mental health and face-to-face interventions for mental health disorders, retrieved from Web of Knowledge and Scopus. Hedges g was used as the effect size measure, and effect sizes were pooled using a random-effect model. Sources of heterogeneity and bias were examined.

Results: Evidence on tele–mental health has been accumulating since 2000, especially regarding service implementation, depressive or anxiety disorders, posttraumatic stress disorder, and special populations. Research was concentrated in a few countries. The survey (n=174 respondents from Italy, n=120 international) confirmed that, after the onset of COVID-19 outbreak, there was a massive shift from face-to-face to tele–mental health delivery of care. However, respondents held skeptical views about tele–mental health and did not feel sufficiently trained and satisfied. Meta-analysis of 29 studies (n=2143) showed that patients would be equally satisfied with tele–mental health as they are with face-to-face interventions (Hedges *g*=–0.001, 95% CI –0.116 to 0.114, *P*=.98, *Q*=43.83, I^2 =36%, *P*=.03) if technology-related issues were minimized.

Conclusions: Mental health services equipped with tele–mental health will be better able to cope with public health crises. Both providers and patients need to be actively engaged in digitization, to reshape their reciprocal trust around technological innovations.

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KEYWORDS

telepsychiatry; telepsychology; e-mental health; document clustering; survey; COVID-19; access to care; patient satisfaction; mental health; tele–mental health; review; telemedicine; satisfaction; access



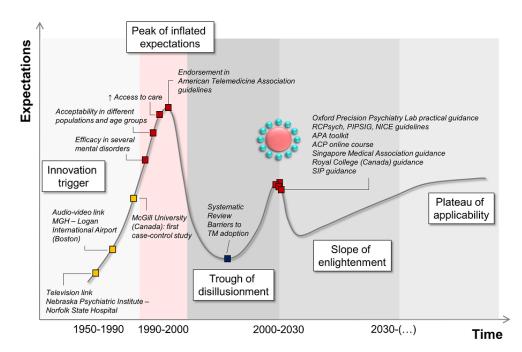
Introduction

In March 2020, a COVID-19 outbreak spread throughout the globe reaching the size of a pandemic. Most governments responded with physical distancing measures. In this science fiction–like context, mental health is expected to pay a heavy toll [1]. Paradoxically, in a time of increased mental health vulnerability, access to care had to be restricted by pausing nonurgent outpatient services, closing day centers, and reducing home visits [2-6]. There was one recourse to address reduced access to care—tele—mental health was used to reach out and support patients [7-9]. In most health care organizations, personnel had limited previous experience, and there were little or no regulations in place [10].

The term *tele-mental health* refers to the remote delivery of mental health care using telecommunications, such as telephone, email, interactive video, digital imaging, and health care monitoring devices [10-12]. The evolution of tele-mental health can be modeled with the double-peak effect Gartner Hype Cycle [13], which describes the course of new technological discoveries integrating special or unusual circumstances (ie, the COVID-19 pandemic) (Figure 1). The Gartner Hype Cycle has served as a useful descriptive model in other medical fields, such as the ultra-high risk for psychosis paradigm [14,15]. According to the Gartner Hype Cycle, new technologies trigger inflated expectations in the short term, and in the long term, expectations are largely underestimated. For tele-mental health, the innovation trigger (stage 1) was the set-up, in 1959, of the first television links between the Nebraska Psychiatric Institute and the Norfolk State Hospital for providing therapy, consultation-liaison psychiatry, and medical student training.

Over subsequent years, tele-mental health became increasingly common (stage 2, inflated expectations), expanding in scope to several diagnostic and therapeutic applications, and geographically, from the United States to other countries, in particular, to Australia and Canada. Much enthusiasm developed around tele-mental health's ability to reach remote rural areas, which suffer from systemic mental health care shortages. By the 2000s, evidence on the use of tele-mental health had accumulated, demonstrating its (1) validity and efficacy in several mental disorders, (2) applicability to different patient populations (eg, war veterans, comorbid medical conditions) and age groups, (3) versatility (diverse cultures), and (4) ability to increase access to care [16]. Despite encouraging evidence and endorsement in clinical guidelines, the adoption of tele-mental health has been slow and scattered, owing to several barriers from clinicians' perspectives, such as concerns regarding ability to establish a good doctor-patient rapport, confidentiality and data protection, safety, technology-related factors, and financial and legal aspects (stage 3, trough of disillusionment) [17]. The COVID-19 crisis has boosted the attention paid to tele-mental health. In an incredibly short time, a broad array of educational resources, toolkits, and guidelines have been made available. Mental health professionals from around the globe have joined forces and shared their experiences in an effort to provide the best care to patients during this terrible time. The digitization of the field of medicine has become a matter of public interest (stage 4, slope of enlightenment). We will find out, in the years to come, whether this unexpected massive public effort will crystallize into mental health service organization and resource allocation (stage 5, plateau of applicability).

Figure 1. The double-peak effect Gartner Hype Cycle describes the course of tele-mental health, integrating the COVID-19 pandemic as a special or unusual circumstance.



In this study, we provide an analysis of state-of-the-art scientific publications on tele–mental health by applying document clustering to map prominent research topics in the field. We surveyed mental health professionals about their experiences of care delivery during the pandemic, especially regarding their use of and attitudes toward tele–mental health. Patients' perspectives on tele–mental health were assessed through a systematic review and meta-analysis of satisfaction with tele–mental health compared to face-to-face interventions.

Methods

Analysis of Scientific Publications

Data Collection

The publication search was performed using Scopus advanced search [18], with the following search formula:

TITLE-ABS-KEY (telepsychiatry) OR TITLE-ABS-KEY (telepsychology) OR TITLE-ABS-KEY (telepsychotherapy) AND (LIMIT-TO (PUBSTAGE , "final")) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (SRCTYPE , "j")) AND (LIMIT-TO (LANGUAGE , "English"))".

We restricted the search to articles describing original research performed in the field of tele-mental health, while excluding review papers. Results (653 articles on June 4, 2020) were exported in .csv format, with as much information as possible.

Data Analysis

After excluding 212 articles for having no relation with tele-mental health (manual filtration) or no abstract, the remaining corpus of 441 articles was imported to Python (version 3; Pandas package, version 1.2.3). Abstracts and titles were concatenated and tokenized (NLTK package, version 3.5). After part-of-speech tagging (filtering only nouns, adjectives and verbs) and lemmatization, common stop words were removed, and stemming was performed. We calculated bigrams (gensim, version 3.8.1) and subsequently removed an array of stop words with broad meanings, such as "paper," "method," "analyze," and other terms that appear in almost every paper. Each tokenized abstract was transformed into a numerical multidimensional representation (TfidfVectorizer, version 0.22.1), which transforms the tokens into an array of term frequency-inverse document frequency values. The similarity between documents was computed with cosine distance between term frequency-inverse document frequency vectors and visualized with t-distributed stochastic neighbor embedding, which was used to perform hierarchical density-based spatial clustering of applications with noise [19]. The code is freely available [20].

Provider Survey

We developed an Italian-language web-based survey targeting mental health providers to map (an English-language version was circulated in an international network of mental health providers.): (1) COVID-19–related disruptions in care provision; (2) tele–mental health use during and prior to the COVID-19 pandemic; (3) tele–mental health intention-to-use; and (4)

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attitude toward tele–mental health. Sociodemographic (age and gender), employment role, setting, and geographic area information was collected. The survey, designed to be completed within 10 to 15 minutes, consisted of 6 sections, with 21 multiple- or forced-choice questions and 15 Likert-scale questions. The survey was shared through email invitations and social media. The survey remained open for 20 days (from May 30, 2020 to June 20, 2020). All respondents provided informed consent.

Meta-analysis of Patients' Satisfaction With Tele–Mental Health Interventions

Search Strategy and Selection Criteria

A systematic review and meta-analysis were conducted based on the Population, Intervention, Comparisons, Outcomes and Study Design (PICOS [21]) strategy. We used a 2-step search strategy. First, we searched the Web of Knowledge (Thomson Reuters) and Scopus databases, using the following terms:

(telepsychiatry OR telepsychiatric OR telepsychology OR teletherapy OR tele-mental health OR e-mental) AND (satisfaction).

The search was extended until June 10, 2020. Second, we implemented an electronic manual search of the reference lists of the retrieved articles. Duplicate references were manually removed. Articles were screened by title and abstract, and the full-texts of remaining articles were further inspected for eligibility against a priori defined inclusion and exclusion criteria.

We included original articles written in English that included patients with a diagnosis of any mental disorders and whose study design included both tele-mental health and face-to-face groups that reported satisfaction scores for both groups. Articles were excluded if they only reported data on service acceptability, credibility, and working alliance; failed to report enough data for meta-analysis (authors were contacted to obtain missing data); or presented data from overlapping data sets (in which case, we selected the largest one).

Literature search, study selection, and data extraction were performed by both authors independently. Disagreement was resolved by discussion. The study followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses [21]) guidelines (Table S1 in Multimedia Appendix 1). The protocol was registered in PROSPERO (CRD42020192299).

Data Extraction

We extracted author, publication year, setting (country, underserved area), mental disorder diagnosis, population type, study design, intervention type, intervention duration, intervention modality, satisfaction scale, number of participants in the tele–mental health and face-to-face group, age, and gender. As a measure of satisfaction, we extracted mean satisfaction score, standard deviation, or standard error of the mean, *t* test statistic, or *P* value of the *t* test, if the normality assumption was met in the original paper (Methods S1 in Multimedia Appendix 1).

Data Analysis

The meta-analysis was performed using R (version 4.0.0, The R Project; meta [22], metaphor [23], dmetar [24] packages). We calculated Hedges g and relative standard error. Since high heterogeneity was expected, we pooled effect sizes using a random-effect model [25]. We assessed between-study heterogeneity using the Q statistic and quantified total variability using the I^2 index [26]. To assess the robustness of results, we performed influence analyses with graphical display of heterogeneity plots [27], by sequentially fitting our meta-analysis model to all 2^{k-1} possible combinations of the studies. We applied 3 clustering algorithms—k-means, density-based spatial clustering of applications with noise, and the Gaussian mixture model-to detect studies with heavy influences on the overall effect size estimate. Sensitivity analyses were conducted by removing these heavy-influence studies and re-running the meta-analysis (Methods S2 in Multimedia Appendix 1). We performed subgroup analyses with mixed-effect models to determine the influence of predefined categorical moderators: mental disorder diagnosis, population type, underserved area, study design, intervention type, and satisfaction scale. Meta-regression models were fit to investigate the influence of predefined continuous predictors: publication year, mean age, proportion of females, intervention duration, and sample size. We assessed publication bias with the Egger test [28], and risk of bias was examined with the revised Cochrane tool for randomized trials [29].

Results

Analysis of State-of-the-Art Scientific Publications

The field was pioneered in 1973, by a paper published in the *American Journal of Psychiatry*, which described an interactive television system that connected Massachusetts General Hospital and a medical station in Boston (United States) [30]. In 1986, a group from McGill University (Canada) [31] published the first case-control study, which found no substantial difference between tele–mental health and face-to-face in terms of

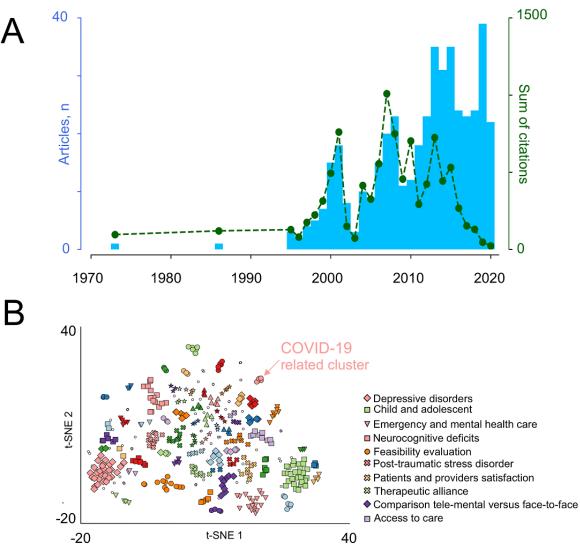
satisfaction among patients and providers. It was only in 1995 that a systematic interest developed, and the annual number of articles began to grow steadily, to reach 39 records in 2019. We expect a further surge in 2020, from a renewed interest for tele–mental health caused by the COVID-19 pandemic. Annual number of articles and sum of citations followed the same pattern until 2010. Then, the sum of citation declined, because more time is required for newly published articles to accumulate citations (Figure 2A).

Only 10 articles had more than 100 citations each (range 120-244; Table S2 in Multimedia Appendix 1). Of these, 1 was the above-mentioned study published in 1986 [31], 8 were published between 2000 and 2010 [32-39], and 1 was published in 2013 [40]. All top-cited articles, except one [37], were controlled trials. The 10 top articles came from only 4 countries-United States, Canada, Australia, and United Kingdom-which are the countries contributing the most to the whole article data set (N=363 articles, 82%; Figure S1A in Multimedia Appendix 1). In the remaining countries, including Italy, that delivered 5 articles or less, tele-mental health research might be at an early stage, corresponding to scarce, if not absent, applications. In terms of international cooperation, the main hub countries are United States, United Kingdom, Australia, and Canada. Other cooperation patterns are more scattered, possibly being more occasional (Figure S1B in Multimedia Appendix 1).

Document clustering identified 36 topics (Figure 2B). The top 10 topics (Table S3 in Multimedia Appendix 1) encompass 34% proportion of the data set. Of these, 6 are specific subjects concerning issues related to the implementation of tele–mental health services. Two topics regard tele–mental health interventions for depressive or anxiety disorders and posttraumatic stress disorder. Finally, 2 topics are focused on the use of tele–mental health in peculiar populations, such as children and adolescents, and patients with neurocognitive deficits (Figure 2B, Figure S1C, and Table S3 in Multimedia Appendix 1).



Figure 2. State-of-the-art of tele–mental health scientific publications: (A) Number of articles by year (blue bars) and the sum of citations for annual articles (green dotted line) and (B) Document clustering (total identified topics: 36) showing emerging COVID-19–related topics (pink dots, arrow) in relation to the top 10 topics (legend). PTSD: posttraumatic stress disorder; t-SNE: t-distributed stochastic neighbor embedding.



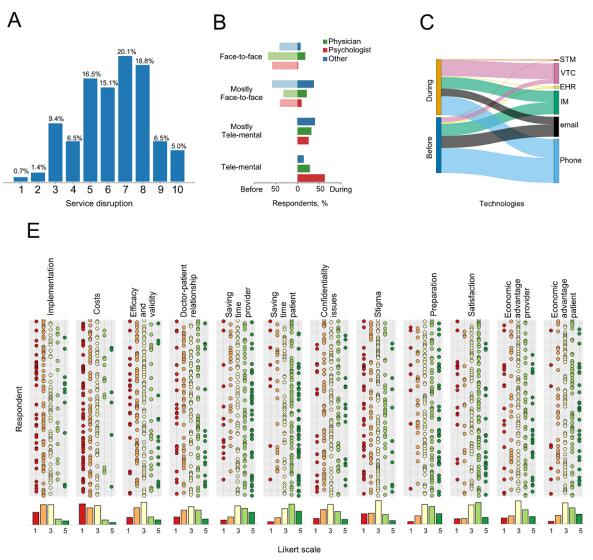
Providers' Responses to the Survey

The survey was completed by 174 Italian mental health care providers, 112 (64.4%) of whom were female. Most respondents (75/174, 43.1%) were between 30 and 40 years old. The most represented region was Tuscany (n=42), followed by Lombardy (n=37) and Apulia (n=28) (Figure S2A in Multimedia Appendix 1), and 67.8% of respondents (n=118) were employed in the public sector, including inpatient or outpatient clinics, hospitals, psychiatric residential facilities, residences for the implementation of safety measures, and addiction treatment services, while 56 (32%) worked in the private sector, either in solo or group (n=4) settings. Our sample consisted of 83 (47.7%)

physicians, 63 psychologists (36.2%), and 28 (16.1%) other mental health workers, that is, specialized nurses and professionals providing rehabilitative and educational interventions. The majority of the sample (134/174, 77.0%) reported that COVID-19 disrupted their normal service provision. The main reason (55%) was a reduction (or block) in nonurgent services, sometimes accompanied by conversion of structures to COVID clinics. Lockdown was the culprit in 44% of cases, while disruption was directly caused by the virus, that is, being infected or quarantined following contact with someone infected, in 2 cases. The median of COVID-19-related disruption was 7/10 (IQR 5-8) (Figure 3A).



Figure 3. Italian providers' responses to the survey on the use of tele–mental health during the COVID-19 pandemic: (A) COVID-19–related disruption in mental health service provision; (B) number of physicians, psychologists, and other mental health professionals offering services exclusively face-to-face, mostly face-to-face, mostly by tele–mental health, or exclusively by tele–mental health during and prior to the pandemic; (C) tele–mental health tools used during and prior to the pandemic; and (D) providers' attitude toward tele–mental health. EHR: electronic health record; IM: instant messaging; STM: supported telemedicine systems; VTC: video-based teleconferencing.



During the pandemic, the rate of respondents providing any services through tele-mental health doubled, passing from 47.7% (83/174) to 92.5% (161/174); 68% respondents reported using mostly or exclusively tele-mental health (vs 1/174, or 0.6%, prior to the pandemic) (Figure 3B). Psychologists reported the highest rate of tele-mental health almost exclusive use (56/63, 89%), compared with psychiatrists (45/83, 54%) and other mental health workers (17/28, 61%) (χ_6^2 =45.97, P<.001) (Figure 3B). Respondents provided a variable amount of care provisions through tele-mental health, in contrast to their previous practice, where tele-mental health was used for less than 25% of care provisions in 82% of cases (Figure S2B in Multimedia Appendix 1). The use of telephone, instant messaging tools, emails remained stable, while we observed a 3.7-fold increase in the use of video-based teleconferencing (Figure 3C). Even if most respondents (132/174, 75.8%) found tele-mental health much or very much useful during the COVID-19 crisis (Figure S2C in Multimedia Appendix 1), 82%

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XSL•FO RenderX (143/174) envisaged to reduce tele–mental health use after the pandemic was over. Half of respondents had to resort to personal telecommunications at their own initiative, as only a small fraction of work settings were adequately equipped (31/118, 26.2% and 19/56, 33.9% in the public and private sector, respectively); however, an effort was made by the Italian National Health System to strengthen tele–mental health during the crisis, as reported by 28% of those in public work settings.

Depression and anxiety disorders were deemed amenable to tele-mental health interventions by a large portion (70/174, 40.2%) of our sample. On the contrary, schizophrenia and other psychotic disorders, substance use disorders and major neurocognitive disorders ranked low (Figure S2D in Multimedia Appendix 1). One-third of respondents (50/174, 28.7%) considered tele-mental health particularly useful for underserved populations, but 25% (44/174) would offer tele-mental health

to any population group (Figure S2E in Multimedia Appendix 1).

Providers' global attitude was skeptical. Only 21.3% of respondents (37/174) thought that tele–mental health was as valid, accurate and effective as face-to-face; 66.1% (115/174) were not positive about the ability to establish a good doctor–patient relationship. Most (132/174, 75.9%) did not believe that tele–mental health could reduce the barrier of stigma. Less than half of respondents felt somewhat or very much trained and satisfied with tele–mental health (Figure 3D).

We received 120 responses from mental health providers from the 5 continents, which replicated Italian data, except for a more positive attitude toward tele–mental health interventions, in terms of: ability to reduce stigma (70/120, 58.3%); feeling prepared and satisfied with tele–mental health care (91/120, 75.8% and 80/120, 66.7%, respectively) (Results S1, Figures S3 and S4 in Multimedia Appendix 1).

Meta-analysis of Patient Satisfaction With Tele–Mental Health Interventions

Eligibility screening of 247 articles yielded 41 articles (Figure S5 in Multimedia Appendix 1). Of these, 12 could not be included in the meta-analysis because they did not report enough data for computation (Table S4 in Multimedia Appendix 1). The final sample included 29 studies (Table 1), contributing data from 2143 patients (tele–mental health: n=1039; face-to-face: n=1104; 34% female), with mean age of 39.4 years

(SD 14.3). The average sample size was 74 (range 12 to 254). The majority (n=19) of studies were conducted in the United States. Approximately half (n=13) of studies reported on tele-mental health in remote geographic areas, such as Thunder Bay in Canada [33,41], the Hawaiian Islands [42-44] and Pacific northwest of the United States [45], rural Australia [46], or targeted underserved communities, such as Native American communities [47], Hispanic communities [48], low-income patients with HIV [49], and inmates of correctional institutions [50-52]. The most represented diagnosis was depression or anxiety disorders (n=11), followed by posttraumatic stress disorder (n=6), alcohol or substance use disorders (n=3), and attention deficit hyperactivity disorder or disruptive disorders (n=2); 7 studies included individuals with any mental disorder. Thirteen studies recruited only adult individuals, while 3 recruited children or adolescents and their caregivers. Most studies offered services to special populations, such as military personnel or veterans (n=10) and individuals in correctional settings (n=3). Eleven studies used telepsychiatry (8 providing consultations and 3 assessment), 17 studies used telepsychology or counseling, and 1 study used both; most studies (n=24) were randomized controlled trials. Mean follow-up was 227 days (range 90 to 540 days) for telepsychiatry and 70 days for telepsychology. The preferred modality was video-based teleconferencing (n=24), the rest were telephone- or web-based interventions. Patient satisfaction was assessed with standardized validated scales in 21 studies: 8 studies used custom tools.



 Table 1. Studies included in the meta-analysis.

Diagnosis, study ype	Population	Age ^a	F (%) ^b	Intervention ^c	Measure	Tele-men- tal health, n/N (%)	Face-to-face, n/N (%)	Hedges g (95% CI)
ttention-deficit	hyperactivity dis	order						
RCT ^d [45]	Children and caregivers	9.3	30	Caregiver behavior training; 25 weeks	CSQ ^e -AD- HD	f/12 ()	—/25 (—)	-0.817 (-1.531 to -0.102
RCT [53]	Children and caregivers	10.4	32	Group parent training; 10 weeks	Custom	8/9 (88.9)	11/13 (84.6)	-0.005 (-0.916 to 0.906)
lcohol use disor	der							
Pilot [54]	Volunteers	36.6	43	2 motivational inter- views (phone also)	Custom	20	10	0.005 (-0.754 to 0.764)
ny mental disor	der							
RCT [55]	Patients (se- vere)	46.3	48	Telepsychiatry; 18- month follow-up	GGZ ^g	33/47 (70.2)	38/46 (82.6)	0.495 (0.022 to 0.969)
RCT, eq [33]	Outpatients	_	63	Telepsychiatry; 4- month follow-up	CSQ-8	125/241 (51.9)	129/254 (50.8)	-0.051 (-0.297 to 0.195)
Comp ^h , pilot [46]	Children and adolescents	12.3	28	Telepsychiatry	Survey	13	34	0.004 (-0.635 to 0.643)
Test-retest [47]	American Indi- an veterans	54	0	Telepsychiatry	Custom	53	53	-0.112 (-0.493 to 0.269)
Comp [50]	Forensic psychi- atric patient in- mates	34.2	_	Interview	Survey ⁱ	23	20	0.000 (-0.599 to 0.599)
Comp [52]	Correctional in- stitution in- mates	31.8	0	Telepsychiatry or telepsychology	CSQ-8	86	100	-0.081 (-0.369 to 0.207)
RCT [51]	Forensic psychi- atric patient in- mates ^j	42	43	Competency test ^k	Custom	11	10	-0.173 (-1.031; 0.685)
lajor depressive	disorder							
RCT [34]	Veterans	49.7	12	Telepsychiatry; 6- month follow-up	Custom	43/59 (72.9)	42/60 (70)	0.280 (-0.148 to 0.707)
RCT, pilot [41]	Outpatients	—	62	Telepsychiatry; 4- month follow-up	CSQ-8	8/12 (66.7)	9/12 (75)	-1.142 (-2.177 to -0.108
RCT [48]	Low-income Hispanic pa- tients	43	88	Telepsychiatry; 6- month follow-up	VSQ ¹ -9	69/80 (86.3)	78/87 (89.7)	0.166 (-0.159 to 0.490)
RCT, pilot [49]	Low-income patients with HIV	45.1	74	CBT ^m (phone only); 14 weeks	SIMH ⁿ	14/16 (87.5)	17/18 (94.4)	-0.354 (-1.067 to 0.359)
RCT, prag [<mark>56</mark>]	Outpatients	43.1	66	Psychotherapy and web-based; 12 weeks	CSQ-8	37/51 (72.5)	32/47 (68.1)	0.071 (-0.402 to 0.544)
RCT [57]	General	35.6	71	Telepsychiatry; 12- month follow-up	CSQ-8	45/53 (84.9)	40/54 (74.1)	-0.443 (-0.874 to -0.012
RCT, NI [58]	Older adult vet- erans	63.9	2.5	Behavior activation; 8 weeks	CPOSS- VA ^o	100/120 (83.3)	104/121 (86)	-0.256 (-0.531 to 0.020)
RCT, NI [59] ^p	Military and veterans	_	18	Behavior activation; 8 weeks	CSQ-8	45/62 (72.6)	42/59 (71.2)	-0.142 (-0.563 to 0.279)
lood or anxiety	disorders							
RCT [60]	Outpatients	30	58	CBT; 12 weeks	CSQ	13/14 (65)	11/12 (91.7)	0.115 (-0.689 to 0.919)

Obsessive compulsive disorder

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Diagnosis, study type	Population	Age ^a	F (%) ^b	Intervention ^c	Measure	Tele-men- tal health, n/N (%)	Face-to-face, n/N (%)	Hedges g (95% CI)
RCT, NI [61]	Outpatients	31.9	60	CBT (phone only); 10 weeks	CSQ	34/36 (94.4)	32/36 (88.9)	-0.331 (-0.818 to 0.155)
Opioid use disor	der							
RCT, pilot [62]	In treatment (methadone)	40.6	62	Web-based ^q counsel- ing; 6 weeks	Survey	20/33 (60.6)	17/17 (100)	0.004 (-0.642 to 0.651)
RCT [63]	In treatment (drug absti- nence)	41	56	Web-based ^q counsel- ing; 12 weeks	CSQ-8	22/50 (44)	35/35 (100)	0.437 (-0.103 to 0.976)
Posttraumatic st	ress disorder							
RCT, NI [38]	Veterans	55.5	0	Group ^r CBT; 14 weeks	CPOSS- VA	9/17 (52.9)	12/21 (57.1)	0.247 (-0.621 to 1.115)
RCT, NI [42]	Veterans	55.1	0	Anger management group; 12 weeks	CPOSS- VA	55/61 (90.2)	57/64 (89.1)	-0.015 (-0.386 to 0.355)
RCT, pilot [43]	Veterans	—	0	Coping skills group; 8 weeks	Custom	8/9 (88.9)	4/8 (50)	0.405 (-0.808 to 1.618)
RCT, NI [44]	Veterans	55.3	0	Cognitive processing therapy	CPOSS- VA	46/61 (75.4)	50/64 (78.1)	0.249 (-0.153 to 0.651)
RCT [64]	Veterans	50.0	0	Telepsychiatry ^s ; 3- month follow-up	Custom	30/37 (81.1)	30/34 (88.2)	0.888 (0.357 to 1.419)
RCT, NI [65]	Veterans	44	6	Prolonged exposure; 12 weeks	CPOSS- VA	27/75 (36)	40/75 (53.3)	-0.056 (-0.544 to 0.432)
Social phobia								
RCT [66]	Volunteers	24.4		Web-based ^t ; 2 months	Custom	—/30 (—)	—/22 (—)	0.104 (-0.446; 0.655)

^aMean, in years.

^bPercentage of female individuals included in each study.

^cThe intervention used video-based teleconferencing, unless otherwise indicated.

^dRCT: randomized controlled trial—eq indicates equivalence, NI indicates noninferiority, and prag indicates pragmatic.

^eCSQ: Client Satisfaction Questionnaire—8, 9, and ADHD indicate the 8-item, 9-item, and attention-deficit hyperactivity disorder versions, respectively. ^fData were not provided.

^gGGZ Thermometer.

^hComp: comparative study.

ⁱGroup Health Association of America Consumer Satisfaction Survey.

^JPatients with Schizophrenia spectrum disorders and mental retardation.

^kGeorgia Court Competency Test Mississippi State Hospital revision.

¹VSQ: Visit-specific Satisfaction Questionnaire.

^mCBT: cognitive behavioral therapy.

ⁿSIMH: Satisfaction Index Mental Health.

^oCPOSS-VA: Charleston psychiatric outpatient satisfaction scale: Veteran Affairs version.

^pMinor depressive disorder was also included.

^qGetgoing program.

^rSocial and emotional rehabilitation.

^sImo voice calls, text messaging, Telegram, and Skype.

^tTalk to me, a self-administered program.

Our meta-analysis revealed no difference in patient satisfaction between tele-mental health and face-to-face interventions (Hedges g=-0.001, 95% CI -0.116 to 0.114, P=.985; Figure S6 in Multimedia Appendix 1). There was moderate between-study heterogeneity (Q=43,83, $I^2=36\%$, P=.03).

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XSL•FO RenderX The graphical display of heterogeneity plot formed a symmetric distribution, around g=0, slightly deviating toward a pattern with positive effect sizes and moderate heterogeneity (peak around 50%) (Figure S7 in Multimedia Appendix 1). Clustering algorithms detected one study [64] that explained the shift toward higher heterogeneity estimates (Figures S7 and S8 in

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Multimedia Appendix 1). After removing this study, heterogeneity became nonsignificant (Q=32.51, $I^2=17\%$, P=.214); however, the overall effect size, though slightly more negative (ie, favoring face-to-face over tele-mental health), was not impacted (Hedges g=-0.032, 95% CI -0.132 to 0.068, P=.531; Figure S11 in Multimedia Appendix 1). These findings were corroborated by other influence diagnostics (Results S2, Figures S9 and S10 in Multimedia Appendix 1).

Subgroup analyses, performed after removing [64], did not show any significant differences between mental disorder diagnoses (P=.341), population types (P=.813), served vs underserved area (P=.683), study designs (P=.392), and satisfaction scales (P=.407) (Figures S12-16 in Multimedia Appendix 1). No significant difference emerged between telepsychiatry vs telepsychology studies, excluding studies providing assessment (total between group heterogeneity Q=0.176, df=1, P=.674). While there was virtually no heterogeneity among telepsychology studies (n=17, Q=15,66, $I^2=0\%$, P=.468), we found moderate to substantial heterogeneity among telepsychiatry studies (n=7, Q=15.78, $I^2=62\%$, P<.05) (Figure 4). None of the meta-regression models yielded significant results (publication year: P=.417; age: P=.207; gender: P=.433; intervention duration: P=.531; sample size: P=.588) (Figures S17-21 in Multimedia Appendix 1).

Figure 4. Forest plot of satisfaction scores for tele-mental health vs face-to-face interventions according by intervention type. Positive values favor tele-mental health, while negative values favor face-to-face.

Subgroup	Hedges g	95% CI
psychiatry Bishop, et al. 2002 Chong, et al. 2012 Dossetor, et al. 1999 Hulsbosch, et al. 2017 Hungerbuehler, et al. 2016 O'Reilly, et al. 2007 Ruskin, et al. 2004 Random effects model $l^2 = 62\%$ [13%; 83%], $\chi_6^2 = 15.66$ ($p = 0.016$)	0.166 [- 0.004 [- 0.495 [-0.443 [-0 -0.051 [- 0.280 [-	2.177; -0.108] 0.159; 0.490] 0.635; 0.643] 0.022; 0.969] 0.874; -0.012] 0.297; 0.195] 0.148; 0.707] 0.261; 0.272]
psychology/counseling Baca, et al. 2007 Berger, et al. 2018 Botella, et al. 2009 Christopher Frueh, et al. 2007 Egede, et al. 2016 Greene, et al. 2010 Gros, et al. 2018 Himelhoch, et al. 2013 King, et al. 2014 Lovell, et al. 2006 Luxton, et al. 2014 Stubbings, et al. 2014 Stubbings, et al. 2014 Stubbings, et al. 2015 Xie, et al. 2013 Random effects model l^2 = 0% [0%; 50%], χ_{16}^2 = 15.783 (p = 0.468)	0.071 [0.104 [0.247 [-0.256 [-0.015 [-0.056 [-0.354 [- 0.004 [0.437 [0.437 [-0.331 [0.405 [0.249 [0.115 [-0.817 [-1 -0.005 []	0.754; 0.764] 0.402; 0.544] 0.446; 0.655] 0.621; 1.115] 0.531; 0.020] 0.386; 0.355] 0.544; 0.432] 1.067; 0.359] 0.642; 0.651] 0.103; 0.976] 0.818; 0.155] 0.563; 0.279] 0.808; 1.618] 0.153; 0.651] 0.689; 0.919] .531; -0.102] 0.916; 0.906] 0.182; 0.067]
Fixed effects (plural) model Prediction interval $I^2 = 28\% [0\%; 57\%], \chi_1^2 = 0.176 (p = 0.674)$ -2 -1 0 1	-	0.159; 0.066] 0.362; 0.321]

No publication bias was detected (t=0.17, P=.867; Figure S22 in Multimedia Appendix 1). There was a high risk of bias for 9 studies, some concerns for 14 studies, and low risk for 6

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studies (Figure S24 in Multimedia Appendix 1). The main weakness was due to missing outcome data, as satisfaction scores were generally available for a fraction of randomized participants, which ranged from 36% [65] to 100% [62,63] and varied between intervention arms in the same study (eg, 44% vs 100% in the tele–mental health and face-to-face arms, respectively [63]) (Figures S23 and S24 in Multimedia Appendix 1).

Discussion

The field of tele-mental health has been continuously evolving since 2000. Such progress was limited to a few countries, namely United States, United Kingdom, Australia and Canada. This might be related to uneven incomes and scientific or technological levels among countries. In addition, tele-mental health may represent a valuable approach to overcome "the tyranny of distance" [46] in countries where substantial portions of the population live in remote rural areas and have unequal access to care. We found that a large amount of tele-mental health literature evaluates (1) service-centered parameters, such as feasibility, acceptability, and sustainability, and (2) care-centered parameters, such as therapeutic alliance, treatment outcome, and patient satisfaction. Depression and posttraumatic stress disorder stand out among the top 10 research topics. Evidence supporting the efficacy of tele-mental health interventions for depression, anxiety, and posttraumatic stress disorders is abundant and robust [67-69]. Another prominent research topic is children and adolescent, a population considered more suited to tele-mental health since they are perceived as digital natives. Two meta-reviews showed that tele-mental health is a valid option for youth with depression and anxiety, while its clinical benefits for autism spectrum disorder, attention deficit hyperactivity disorder, psychosis, and eating disorders remain questionable [70,71]. Tele-mental health has been proven to alleviate pressure on emergency departments (third research topic) [72,73].

Research in tele-mental health did not translate into policy changes and resource allocation. The World Psychiatric Association-Lancet Psychiatry Commission on the Future of Psychiatry has defined 6 core considerations to be met for technological innovations to transform health care: (1) patient and clinician engagement; (2) clinical evidence and standards; (3) clinical systems integration; (4) digital trust, ethics, and transparency; (5) interoperability and scalability; (6) data science and methods [74]. At present, tele-mental health has partially met these targets, due to factors related to both clinicians and patients. Clinicians are often reluctant to adopt tele-mental health because of concerns about the ability to establish a satisfying doctor-patient relationship and lack of knowledge of relevant privacy, transparency, and confidentiality issues [75,76]. A digital divide exists among patients, which excludes a large share of them from tele-mental health interventions [74,77].

When COVID-19 started its inexorable march over the planet, very few countries were sufficiently equipped with tele-mental health technologies, trained clinicians, and guidelines [10,78]. Italy was no exception. Less than one-third of respondents deemed their tele-mental health service to be adequate prior to COVID-19. Care provision was massively disrupted. Qualitative reports have been published, that mostly refer to the situation

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of the Italian National Health System in Lombardy, which was the most affected Italian region [2-6]. All reports agree that COVID-19 initiated an abrupt transition to tele-mental health delivery of care [2,4-6]. We observed that this change was more evident for psychologists, compared with physicians, probably because physicians carry out part of their clinical activity in in-patient units (COVID-positive patients with serious psychiatric conditions were still admitted to hospital wards) [5] and need to perform physical examinations, while psychotherapy may be more easily conducted remotely. We are aware that the relatively small number of respondents (n=174) hampers generalizability of our observations. Nevertheless, our findings were fully replicated by responses of international mental health professionals (Figure S3 in Multimedia Appendix 1). Also, similar trends have been reported by others in several countries. In China, when the novel human coronavirus (SARS-CoV-2) emerged in December 2019, there was rapid implementation of mental health hotlines and hospital tele-mental health services. In some cases, as the West China Hospital of Sichuan University, tele-mental health services collaborated with courier services to deliver medication to patients' homes [8]. In most European countries there was a boost in tele-mental health use and value, and regulatory barriers were substantially lifted [79,80]. An analysis of electronic health record data showed a substantial shift from face-to-face to tele-mental health contacts in London, United Kingdom after lockdown measures [81]. These findings are paralleled by those in Australia and Africa [82,83]. In May 2020, the American Psychiatric Association surveyed its members on the matter, and responses from 500 American psychiatrists grossly replicated our findings of a major transition to tele-mental health use-in a couple of months the percentage of respondents seeing more than 75% of their patient caseload via tele-mental health increased from 2.1% to 84.7% [84]. In addition, respondents reported that satisfaction was high or very high among patients first assessed via tele-mental health [84], and Sammons et al [85] reported a similar adaptation to COVID-19 among psychologists in the Trust and National Register (United States).

Half of respondents used personal tools on their own initiative. If, from one side, these spontaneous efforts are to be commended because they allow the system to rapidly adjust to unexpected stressors, then from the other, uncoordinated and uneducated use of such tools might increase the risk of breaches in consent processes, privacy, and data protection or may lack appropriate emergency management plans. We advocate that mental health departments be digitized in order to improve their resilience in face of public health emergencies [2]. Such technological leaps will only be successful if complemented with proper training and supported by policy changes. Conveniently, open-access resources have been flourishing during the last months; we recommend the practical guidance developed by the Oxford Precision Psychiatry Lab [12], and the American Psychiatric Association Toolkit [11]. A better understanding of best practices could modify skeptical views such as those we recorded in our survey. It has been reported that clinicians had a gatekeeper role against tele-mental health, and their concerns were mainly related to the ability to build a meaningful doctor-patient relationship [17]. The integration of tele-mental health in mental health care implies a transition from the current

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centralized model of care to a more distributed model, in order to re-define the equilibrium between clinicians and patients' responsibilities. Many issues regarding standard of care, access to data, clinicians' compensation remain open, thus it is no surprise that clinicians may feel uncomfortable. Research that explicitly addresses these issues will be needed. It will be fundamental to ensure that clinicians' needs and desires are heard effectively. Formal education about the role of technology in care provision will have to be implemented starting from medical school, without neglecting colleagues who may be less familiar with technology because they have practiced for years before the advent of smartphones and their application in health care. Furthermore, the field will need to meet some key requirements to support the transformation. Borrowing from the recommendations issued by the World Psychiatric Association-Lancet Psychiatry Commission [74] and the American Psychiatric Association [84], we maintain that (1) both psychiatrists and patients should be engaged in all phases of tele-mental health development and implementation and not only as final users; (2) patients' routine screening should include an assessment of digital access, literacy, and comfort, and specialized education, technical support, and internet (or device) access programs should be offered to improve treatment delivery (especially to vulnerable populations, eg, older people, homeless people, asylum seekers); (3) a tele-mental health ethical code will be needed, to reassure patients about confidentiality and safety issues and help them making informed decisions; (4) tele-mental health sustainability and scalability should be promoted, to avoid care fragmentation and abate costs; (5) current regulations should be reviewed regarding remote drug prescription, use of audio-only communications for patients' assessment and management, and service frequency in in-patient settings and nursing facilities; (6) careful considerations should be made about compensations and national health insurance programs. These considerations apply, not only to tele-mental health, but also, to digital psychiatry. The last decade has witnessed an expansion in smartphone apps, wearable sensors and other technologies for digital phenotyping of patients suffering from mental disorders, which has been accompanied by the growing use of artificial intelligence in health care. This expansion has mainly been driven by the opportunities offered by technological advancement, which often lack adequate scientific and clinical roots. Research, funded by government programs, will be needed [86]: for instance, digitization is one of the pillars of the €750-billion Next Generation European Union plan (equivalent to approximately US \$891 billion), which aims to support recovery from the COVID-19 crisis and also to invest in the future and resilience of our society.

To focus on service users, we investigated how tele-mental health compares to face-to-face interventions in terms of patient satisfaction, because this is a crucial influence on treatment outcome, particularly in mental health [87,88]. We performed a systematic review and meta-analysis, which did not detect a significant difference in satisfaction between tele-mental health and face-to-face (P=.985). Because studies were moderately heterogeneous, we applied 2 methods to explore heterogeneity. Both methods showed that one study—Haghnia et al 2019 [64], alone—explained much of the heterogeneity. This study was conducted in Iran, whose conditions might be different from

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high-income countries. The economic impact, difficulties of travelling, and accommodation requirements associated with face-to-face visits might be more burdensome for people living in the Middle East and justify the higher satisfaction scores found in patients treated by tele-mental health [89]. However, this study had marginal influence on the global effect size. Subgroup analyses showed homogeneity among studies focusing on psychotherapy, as opposed to those focusing on telepsychiatry interventions, which yielded substantially heterogeneous effect sizes. Psychiatric consultations are characterized by high variability, consisting of meetings of variable duration, separated by variable intervals, with variable content based on patients' incidental needs and medication management. On the contrary, psychotherapies are "healing relationships" [90] developing over a series of evenly distributed contacts of preestablished duration that use evidence-based (often manualized) methods [91]. A previous systematic review [88], which compared tele-mental health to face-to-face-delivered psychotherapeutic interventions, similarly found that patients were equally satisfied with both approaches but highlighted limitations (some of which are also relevant to our study). Most studies included in our review were affected by some risk of bias from high attrition rates, which led to small, underpowered sample sizes. Satisfaction scores were available just for the fraction of patients who remained in treatment. It is plausible that dissatisfaction with treatment was responsible for participants dropping out of the studies and becoming unavailable for satisfaction assessment. However, attrition rates in the 2 treatment arms (tele-mental health vs face-to-face) were similar, most likely causing satisfaction score inflation in both arms with negligible impact on the difference. A selection bias could have been introduced even before randomization, since 6 studies [49,56,57,62,63,87] excluded eligible participants who did not have access to computer and internet connection. In 16 studies [33,34,38,41-48,50-53,60] tele-mental health sessions were held in rooms fully equipped with high-definition video-based teleconferencing units and broadband internet access. In 2 studies, tele-mental health interventions were performed at home, but participants were provided with videophones [58] or computers [55] and a dedicated line. Therefore, in most cases, technology-based factors, which contribute to shape patient satisfaction [88], could have been minimized. This limits the generalizability of their results to ecological contexts: (1) many patients may be marginalized due to lack of access to technology and skills; and (2) problems with video definition, audio lag, or connection could dampen the perceived consultation quality. Another limitation is that we only considered overall patient satisfaction. This is a complex clinical outcome that includes several factors related to patient, disease, provider, therapy, environment, and technology [87]. Rohland et al [92] showed that patients rated tele-mental health higher than face-to-face for convenience, ease, technical skills, attention given, and time spent, while face-to-face was preferable to tele-mental health for self-reporting outcome, helpfulness, and eye contact. It has been suggested that tele-mental health patients develop lower levels of therapeutic alliance, resulting in worse continuity of care [38,93,94], but data are still inconclusive. Whether the relative preference for tele-mental health or face-to-face care has an impact on clinical

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outcomes in specific domains needs to be determined in future longitudinal studies.

In conclusion, evidence for the use of tele–mental health is robust, but it is concentrated in a few countries. The initial enthusiasm around tele–mental health did not translate to clinical application. During the COVID-19 pandemic, many mental health professionals resorted to tele–mental health, not without some aversion, feeling that "they had no other choice [6]." It is advisable that mental health services should become equipped with tele–mental health to increase the ability to efficiently cope with public health crises. We believe that this does not necessarily contradict the preferences of both clinicians and patients for in-person meaningful therapeutic rapports.

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Authors' Contributions

GR and RM designed the study. GR and RM designed the survey; performed the literature search, study selection, data extraction, and data analysis; and prepared the figures. GR wrote the first draft of the manuscript with input from RM.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary information. [DOCX File, 5994 KB - mental v8i7e26187 app1.docx]

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Abbreviations

COVID-19: coronavirus disease 2019 **HIV:** human immunodeficiency virus

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