JMIR Mental Health

Journal Impact Factor (JIF) (2023): 4.8
Volume 7 (2020), Issue 10 ISSN 2368-7959 Editor in Chief: John Torous, MD, MBI

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Examining an App-Based Mental Health Self-Care Program, IntelliCare for College Students: Single-Arm Pilot Study

Emily Lattie[1,2], PhD; Katherine A Cohen[3], MA; Nathan Winquist[2], MS; David C Mohr[2], PhD

[1]Department of Medical Social Sciences, Northwestern University, Chicago, IL, United States

[2]Department of Preventive Medicine, Northwestern University, Chicago, IL, United States

[3]Department of Psychiatry and Behavioral Sciences, Northwestern University, Chicago, IL, United States

Corresponding Author:
Emily Lattie, PhD
Department of Medical Social Sciences
Northwestern University
750 N Lake Shore Drive
10th Floor
Chicago, IL, 60611
United States
Phone: 1 3125033741
Email: emily.lattie@northwestern.edu

Abstract

Background: In recent years, there has been an increase in symptoms of depression, anxiety, and other mental illnesses in college student populations alongside a steady rise in the demand for counseling services. Digital mental health programs, such as those delivered through mobile apps, can add to the array of available services but must be tested for usability and acceptability before implementation.

Objective: This study aims to examine how students used IntelliCare for College Students over an 8-week period to examine the preliminary associations between app use and psychosocial targets and to gather user feedback about usability issues that need to be remedied before a larger implementation study.

Methods: IntelliCare for College Students is an app-based platform that provides symptom assessments with personalized feedback, information about campus resources, lessons on mental health and wellness topics, and access to the suite of interactive skill–focused IntelliCare apps. A total of 20 students were recruited to participate in an 8-week study. To test for a broad range of potential users, we recruited a mixed sample of students with elevated symptoms of depression or anxiety and students without elevated symptoms. Participants completed psychosocial questionnaires at baseline, week 4, and week 8. Participants also completed user feedback interviews at weeks 4 and 8 in which they provided feedback on their experience using the app and suggestions for changes they would like to be made to the app.

Results: Of the 20 students who downloaded the app, 19 completed the study, indicating a high rate of retention. Over the study period, participants completed an average of 5.85 (SD 2.1; range 1-8) symptom assessments. Significant improvements were observed in the Anxiety Literacy Questionnaire scores (Z=−2.006; *P*=.045) and in the frequency with which participants used both cognitive (Z=−2.091; *P*=.04) and behavioral (Z=−2.249; *P*=.03) coping skills. In the feedback interviews, we identified a high degree of usability with minor bugs in the app software, which were quickly fixed. Furthermore, in feedback interviews, we identified that users found the app to be convenient and appreciated the ability to use the program in short bursts of time.

Conclusions: The findings indicate that the IntelliCare for College Students program was perceived as largely usable and engaging. Although the program demonstrated usability and preliminary benefits to students, further testing is needed to determine its clinical utility among college students.

Trial Registration: ClinicalTrials.gov NCT04035577; https://clinicaltrials.gov/ct2/show/NCT04035577

(JMIR Ment Health 2020;7(10):e21075) doi:10.2196/21075

KEYWORDS

mHealth; college students; depression; anxiety; mobile phone

Introduction

Over the last decade, the number of college students experiencing symptoms of depression and anxiety has increased [1]. Students with these and other mental health concerns are typically directed toward campus counseling centers as the first, and many times only, option for treatment. Consistent with the rising rates of depression and anxiety, the number of students seeking mental health services in campus counseling centers has increased. A national survey of college students showed that 6.6% of students received treatment at a college counseling center in 2007, whereas 11.8% of students received treatment in a college counseling center in 2017 [2]. As a result, campus counseling centers often report that they were over capacity and unable to immediately meet the needs of the large number of students requesting services. Limited available sessions, long wait lists, and small staff numbers are among a number of concerns that counseling centers across the United States encounter. To address these concerns and ensure that students receive care, innovative and scalable solutions are needed.

Mobile apps and other digital mental health programs are increasingly being investigated as tools to supplement or enhance care on college campuses. Digital mental health programs offer the potential to provide self-management tools and help triage students to appropriate services on campus, thus lessening the burden that counseling centers may face from students with low-level concerns and increasing the number of students who can receive support. The efficacy of digital mental health programs in college populations has been established. A systematic review found that the majority of digital mental health interventions for college students were effective in producing changes in psychological outcomes, such as depression and anxiety, yet few of the tested programs were publicly available and fewer were delivered via apps [3]. In addition, the vast majority of college students own smartphones, making apps a potentially accessible option to deliver services [4]. In one study, although a small number of students had used a mental health app, more than one-fourth were open to using an app. At the same time, students were largely unsure of whether mental health apps were evidence based and voiced concerns about the efficacy and impersonal nature of apps [5]. This suggests that acceptability is a key factor to investigate when researching mental health apps for college students; students may find apps with clear research evidence or apps tailored to their specific needs more acceptable.

The IntelliCare app platform has demonstrated efficacy in reducing symptoms of depression and anxiety in general adult populations [6-8]. IntelliCare is a collection of quick and easy-to-use apps that each present a different evidence-based mood management strategy (eg, cognitive restructuring, behavioral activation). Although typically deployed in conjunction with coaching support delivered via text message, the results of a recent trial indicate that the effect of coaching was low and that users who did not receive coaching experienced similar benefits in reducing depression and anxiety symptoms. Although human support in the form of coaching has been shown to be effective for engaging users in mobile health interventions, it is also costly, and many colleges are working with very limited budgets for mental health care. Fully automated interventions are nonconsumable resources in that they can benefit a broad array of individuals without requiring additional therapeutic power. Thus, the cost is less dependent on the number of individuals accessing the intervention [9]. Thus, as we developed a version of IntelliCare specifically for college campuses, we opted to eliminate coaching so that the intervention could be used independently by students and be maximally scalable. The adaptation of IntelliCare to form the IntelliCare for College Students program was guided by a series of user-centered design activities with college students and counseling center staff members [10,11].

In this paper, we present an extended usability pilot study of the IntelliCare for College Students app that was conducted in preparation for the implementation of the app on 2 university campuses. The study was not powered nor intended to evaluate clinical outcomes, but rather, the purpose of this study is to examine how students used the app over an 8-week period, to examine the preliminary associations between app use and psychosocial targets, and to gather user feedback about usability issues to be remedied before the larger implementation study.

Methods

Recruitment

Students were recruited from 2 public 4-year universities in the same Midwestern state. Both universities involved in this study have large student bodies and serve more than 10,000 students per year. Print advertisements were posted in multiple buildings on the universities' campuses with information regarding *IntelliCare for College Students* and the research study. Digital recruitment materials were spread through social media and sent in mass emails to students. Research staff contacted student organizations and campus offices at each university to assist in disseminating recruitment materials to students. Interested students completed a screening questionnaire to determine eligibility for the study that included questions on demographics, student status, smartphone ownership, and symptoms of depression and anxiety. For screening purposes, symptoms of depression and anxiety were assessed using the nine-item Patient Health Questionnaire (PHQ-9) [12] and Generalized Anxiety Disorder seven-item scale (GAD-7) [13]. Scores on the PHQ-9 can range from 0 to 27, and scores on the GAD-7 can range from 0 to 21. To ensure a range of symptoms of depression and anxiety, we attempted to recruit a balanced sample of participants who had *higher symptoms* (defined as a baseline PHQ-9 or GAD-7 score ≥10, indicating at least moderate symptoms) and those who had *lower symptoms* (defined as baseline PHQ-9 and GAD-7 scores both <10) from each university. Eligible students were required to (1) be enrolled either part time or full time at one of the universities studied, (2) be at least 18 years old, (3) own an Android smartphone capable of running version 7.0 or higher or own an iPhone capable of running iOS 11 or higher, and (4) fill in a spot in either the higher symptom group or lower symptom group. Of the eligible participants who downloaded the app, 11 were in the higher symptom group and 9 were in the lower symptom group. A sample size of 20 was established a priori based on

previous data, suggesting that 20 users can find 95% of usability problems [14].

Intervention

Eligible participants (n=20) were instructed to download the *IntelliCare for College Students* app and encouraged to use it as they desired for 8 weeks. Several features were included in the *IntelliCare for College Students* app: (1) a mood rating and mood journal tool that allowed participants to rate their mood using an emoji-based scale and subsequently write a few sentences about their mood; (2) a calendar tool that allowed participants to access a history of their mood rating and mood journal entries; (3) a weekly symptom check that provided participants with personalized feedback, such as advice on managing stress and connecting with others when symptoms were elevated; (4) information about on-campus resources specific to participants' university along with links directing students to websites with more information; (5) short psychoeducational lessons on mental health and wellness topics (eg, *Self Care 101*); and (6) the suite of interactive skill–focused IntelliCare apps that were available for download. Screenshots of each of these features are available in Multimedia Appendix 1.

Measures

Participants were prompted to complete the PHQ-8 [15] and GAD-7 [13] on a weekly basis as part of the symptom check. The PHQ-8 was selected as the symptom check tool because the IntelliCare for College Students app was designed as a self-guided resource that, following this initial study, would be made freely available to all interested students at these universities. Although it is established that asking about suicide via self-report questionnaires does not increase the risk of suicidal thoughts or behavior, university administrators voiced a strong preference to avoid asking about suicidality within the app because it would not be possible to closely monitor the responses in the broader implementation of the program. At baseline, week 4, and week 8, participants completed the *Check my Knowledge Questionnaire* through the app, which included the Anxiety Literacy Questionnaire (ALQ) [16], Depression Literacy Questionnaire (DLQ) [17], Knowledge and Beliefs about Services Scale (KBSS) [18], and Cognitive and Behavioral Response to Stress Scale (CB-RSS) [19]. The ALQ and DLQ are designed to assess mental health literacy by presenting 22 true or false statements regarding anxiety and depression (eg, *Being easily fatigued may be a symptom of anxiety disorder*). Participants receive a score of 1 for each statement they correctly assign as either true or false. Scores for each questionnaire can range from 0 to 22, with higher scores indicating greater mental health literacy. The KBSS includes 5 questions designed to measure knowledge of campus mental health services (eg, "What have you heard from other students about the quality of mental health and psychological counseling services on your campus?"). Responses to each item on this measure are independently examined. The CB-RSS is an 18-item scale designed to measure the use and helpfulness of various cognitive and behavioral skills. There are 4 subscales included: cognitive skill frequency, cognitive skill usefulness, behavioral skill frequency, and behavioral skill usefulness. For each cognitive or behavioral skill, participants rate how often they used the skill and how helpful it was (eg, "During the past month, how often did you take a moment to notice things that made you feel good or grateful? How helpful was this in making you feel better?"). Scores for cognitive subscales range from 0 to 24, and scores for behavioral subscales range from 0 to 30.

At weeks 4 and 8, the participants completed 30-min semistructured user feedback interviews. Participants provided feedback on their experience using the app and suggestions for changes they would like to see be made to the app (example questions include, "What problems have you encountered using IntelliCare for College Students?" and "What changes would you make to IntelliCare for College Students?"). Interviews were audio recorded and conducted via telephone.

Participants were eligible to receive a total of US $70 for participating in the study, including US $10 for completing each of the monthly in-app assessments and US $20 for completing each of the user feedback interviews.

Data Analysis

We incorporated quantitative data from questionnaires and app usage logs and qualitative data from interviews for a mixed methods data analysis. This mixed methods approach was chosen because although quantitative data can identify usability issues and dissatisfaction with program components, qualitative data provide guidance to the root of those errors and methods for program optimization. App usage data were examined in the form of descriptive statistics. We recruited a balanced sample of participants who had *higher symptoms* (defined as a baseline PHQ-9 or GAD-7 score ≥10) and those who had *lower symptoms* (defined as baseline PHQ-9 and GAD-7 scores both <10). Owing to the small sample size of each group, we examined symptoms of depression and anxiety by subgroup in the form of descriptive statistics. Measures of our treatment targets (anxiety literacy, depression literacy, and cognitive and behavioral coping skills) were analyzed using Wilcoxon signed-rank tests across participants with higher symptoms and those with lower symptoms [20]. Qualitative data were analyzed using a thematic analytic approach [21] in which interviews were analyzed using iterative codes that were used to identify core concepts, from which we determined the needs, concerns, and impressions of our program.

Results

Participants

A total of 30 people initiated the web-based screening questionnaire. Overall, 2 potential participants did not proceed with the full screening questionnaire, one potential participant was ineligible because they were not a student, and the remaining 6 participants were ineligible because we had closed recruitment for their cluster (eg, University #1, higher symptom). Our target recruitment goal was 20 participants. Of the recruited participants, 1 withdrew from the study before installing the study app, and we enrolled an additional participant in her place, leaving us with a final sample of 21 consented students and 20 students who installed the study app and initiated the study procedures.

Of the total sample of consented participants (n=21), 11 (52%) participants identified as White, 4 (19%) participants as African American or Black, 4 (19%) participants as Asian, and 2 (9%) participants declined to report their racial identity. Moreover, 28% (6/21) participants indicated that they were more than one race. The mean age of the participants was 24.19 (SD 6.03) years. The majority of the sample was female (n=17), non-Hispanic (n=17), and seeking undergraduate degrees (n=14). Of the final sample (n=20), 19 participants completed the study, indicating a high rate of retention.

Of the total sample, 11 participants reported elevated symptoms for depression and/or anxiety (defined as a PHQ-9 or GAD-7 score ≥10), and we refer to this group of participants as the *higher symptom participants*. Of those participants, 6 reported elevated symptoms of both depression and anxiety. Participants without elevated symptoms of depression or anxiety are referred to as the *lower symptom participants*.

The average PHQ-9 score for participants with higher symptoms was 13, indicating moderate symptoms of depression (SD 5.63; range 7-27), and the average PHQ-9 score for participants with lower symptoms was 3.60, indicating few symptoms of depression (SD 2.59; range 0-8). The average GAD-7 score for participants with higher symptoms was 12.35, indicating moderate symptoms of anxiety (SD 4.74; range 7-21), and the average GAD-7 score for participants with lower symptoms was 3.50, indicating few symptoms of anxiety (SD 3.37; range 0-9).

App Usage

Across the sample, the IntelliCare for College Students program was used an average of 17.05 days over the 8-week study period (SD 8.12; range 4-25). Participants completed an average of 5.85 symptom assessments (SD 2.1; range 1-8). In examining the time between the first and last use of the app, we saw that the majority of participants (18/20, 90%) continued to use the app beyond the 8-week study period. Of the 2 participants who did not use the app beyond the 8-week study period, there was a 9-day period of use for 1 participant and a 42-day period of use for the other participant.

There were minimal differences in usage between students with higher symptoms and those with lower symptoms. Participants with higher symptoms used it an average of 18.91 (SD 9.83) days, and participants with lower symptoms used it an average of 14.78 (SD 5.02) days. Participants with higher symptoms completed an average of 6.09 symptom assessments (range 1-8), and participants with lower symptoms completed an average of 5.55 symptom assessments (range 2-8). Moreover, 1 participant from each group did not use the app beyond the 8-week study period.

Psychosocial Targets

In the full sample, significant improvements were observed in participants' scores on the ALQ (Z=−2.006; *P*=.045). We also observed significant increases in the frequency with which participants used both cognitive (Z=−2.091; *P*=.04) and behavioral (Z=−2.249; *P*=.03) coping skills, as measured by the CB-RSS. Significant changes were not observed for the DLQ (*P*=.23) or for the perceived usefulness of cognitive (*P*=.06) and behavioral coping skills (*P*=.09). Table 1 provides descriptive statistics on psychosocial targets for the full sample and by subgroup.

Although this study was not powered to detect differences between the participants with higher symptoms and lower symptoms, it appeared that the statistically significant improvements observed in the ALQ and the frequency subscales of the CB-RSS were driven by participants in the higher symptom group. Participants in the higher symptom group began the study with lower scores and at week 8 had scores more similar to those in the lower symptom group.

Minimal changes were observed over time for items on the KBSS. At baseline, 11 participants agreed or strongly agreed that they knew where to go if they needed to seek professional help for their mental health while attending their university, and at the 8-week follow-up, 13 participants agreed or strongly agreed with that statement. At baseline, nearly all participants (n=18) responded that they believed that therapy or counseling is *very helpful* or *quite helpful* for individuals their age who are clinically depressed, and this did not change at 8-week follow-up.

No meaningful changes were observed in the PHQ-8 or GAD-7 scores over time in either subgroup. At the week 1 symptom check, participants in the higher symptom group had a mean score of 11.63 (SD 6) on the PHQ-8 and a mean score of 10.82 (SD 4.12) on the GAD-7. By the week 8 symptom check, participants in the higher symptom group had a mean score of 9 (SD 6.53) on the PHQ-8 and a mean score of 10 (SD 3.83) on the GAD-7. Similarly, at the week 1 symptom check, participants in the lower symptom group had a mean score of 3.75 (SD 2.38) on the PHQ-8 and a mean score of 4.88 (SD 2.85) on the GAD-7. By the week 8 symptom check, participants in the lower symptom group had a mean score of 0.6 (SD 2.51) on the PHQ-8 and a mean score of 2.86 (SD 2.61) on the GAD-7.

Table 1. Descriptive statistics of psychosocial targets for the full sample and by subgroup.

Criteria	Full sample, mean (SD)		Higher symptom, mean (SD)		Lower symptom, mean (SD)	
	Baseline	Week 8	Baseline	Week 8	Baseline	Week 8
Anxiety Literacy Questionnaire	13.88 (3.67)	14.63 (3.45)	13.6 (3.91)	14.4 (3.97)	14.25 (3.62)	14.89 (2.98)
Depression Literacy Questionnaire	13.89 (4.26)	14.68 (3.83)	13.6 (3.34)	14.7 (3.68)	14.22 (5.31)	14.67 (4.21)
CB-RSS[a] cognitive usefulness	9.73 (6.23)	12.58 (6.86)	8.4 (6.24)	12.6 (7.17)	11.22 (6.22)	12.56 (6.93)
CB-RSS cognitive frequency	10.47 (4.03)	12.68 (4.49)	9.6 (4.81)	13.4 (5.02)	11.44 (2.92)	11.89 (3.98)
CB-RSS behavioral usefulness	17.74 (6.10)	19.68 (8.91)	16.2 (6.09)	18.6 (9.98)	19.44 (5.98)	20.89 (7.98)
CB-RSS behavioral frequency	14.42 (4.98)	16.52 (6.44)	13.9 (5.61)	16.5 (6.72)	15.0 (4.44)	16.56 (6.54)

[a]CB-RSS: Cognitive and Behavioral Response to Stress Scale.

Qualitative User Feedback

A total of 3 main themes were identified from student feedback on their experiences with the IntelliCare for College Students program: opportunities for self-reflection, access to information and resources, and convenience.

Opportunities for Self-Reflection

Students enjoyed having the space to write down how they were feeling and found the process of having an emotional check-in spot in the form of a mood journal, particularly useful. One student noted:

> *It's the first time I've ever used an app...to say what I'm feeling. I've never attempted to use apps or basically tell anyone how I feel [on] a certain day...But, actually like even typing it down, it feels kind of...relieving in some way.*

This highlights that the act of reflecting on and verbalizing one's emotional experiences was perceived as beneficial for stress management and self-care.

There was a similar appreciation voiced for the symptom checker, which guides users through an assessment of common depression and anxiety symptoms. As one student noted:

> *So I was, because I don't go for counseling and all that because I don't think I have super severe problems but...I have my days where I'm done and I think it's critically important for people to check in with themselves sometimes because most people don't do that often...it's kind of nice to open and app and, "How are you doing?" and "Do you feel this? Do you feel that?" it's like a check in kind of thing.*

Here, we observe that the app was seen as a way to check in with oneself and to prompt users to take note of specific symptoms and emotional experiences that they might be having and otherwise not be aware of.

Many students were interested in tracking their symptoms and connecting those symptoms to potential stressors and/or triggers. As one student commented:

> *I think what motivates me is to track my moods in general is just finding those connections with what I wrote and the things going on in my life.*

Students reflected on their process of self-discovery through using the mood journal, noting that they identified differences in how they felt based on place (eg, school vs home) and time (eg, different times of the month) and were able to use those identified differences to enact changes in their lives.

Access to Information and Resources

Students also valued being able to access information about mental health and stress through the IntelliCare for College Students app. When prompted about their experiences using the app, one student reflected that the app contained:

> *some useful information, like about depression and anxiety. Yeah some information that I wasn't familiar with. So yeah, maybe it gave me a better understanding of like some terms or maybe like some symptoms.*

Although the information included in IntelliCare for College Students app was not entirely novel to some participants, the consolidated delivery format and the ability for students to access this type of information conveniently within the app were seen as the strength of the program. One student reflected:

> *So, I like this because I think different at this point is so much better because even me as a Freshman we hear the same things like "Go to this" and "Go to that." And sometimes we just don't want to do it because we hear it so much and it takes so much effort even though sometimes it doesn't take a lot of effort but to many of us, it does. So much work, I have to go to the building, I have to call and schedule but this is like, this would be a good first step for many people and you don't have to be someone who's, who has depression or anybody, you could, it could work for people just as a self-check because checking in with yourself and how you handle situations is important.*

Here, we observe the multiple barriers that the student had faced to go to the counseling center and how she saw the app as a good entry point for any student to check in on their mental health status and learn about the resources available to them.

Convenience

Mobile mental health apps have historically been developed to increase convenient access to mental health information and tools, and convenience was a major theme in the user feedback interviews. Students indicated that they appreciated the ability

to use the program in short bursts of time. One student noted that she was able to engage with the app more continuously because of this design, as in:

> *It's like having a diary without having to do all of the writing. Because I was one of those people where I had a diary and I'd use it for like two days and then I'd stop. But it's...doing the work without putting in so much effort. So you're just answering general questions like 'Are you feeling this? Have you been feeling this?' I like that idea behind it because it's not super time-consuming.*

Another student commented:

> *I feel like when I use it, I don't really spend a lot of time on there, which is a good thing because it's very straight-forward too so I kinda know which app to open or like whatever needs I'm having that day. So it's really user-friendly.*

Similar comments highlight that the program was perceived as usable and convenient for students.

However, although students generally agreed that the program was quick and easy to use, many students identified a combination of lack of time and forgetfulness as barriers to program use. One student commented:

> *When I have a lot going on, the first thing on my mind isn't IntelliCare...So, these last 4 weeks, that's when my classes started. And so it was kind of hard to like, post something when I have so many other things to do. It kind of slips my mind sometimes.*

Although interactions within the app were relatively brief, several students noted that they deprioritized using the app when they were feeling strapped for time.

As one student commented:

> *Yeah, because honestly this really wasn't for me, or up to me, and if I had more time in my life I would probably like schedule out like a time and use it every single day. But, like because I have so much to do and it really gets in the way of that.*

When prompted about what got in the way of using IntelliCare for College Students, a student commented:

> *I'm mostly just like busy and forget like, "Oh, I have that." Because it's like on my phone and there's like so much stuff on my phone already.*

Although students noted that they spend a lot of time on their phones, the app often got lost in their long lists of other downloaded and infrequently used apps.

Through the course of this study, software bugs and glitches were identified, which were remedied either during or following the study. There were intermittent issues with questionnaires being deployed at appropriate intervals and with the user interface displaying and functioning properly on phones with various screen sizes. Of note, we learned that the in-app notifications were working inconsistently for our participants. We observed that many students valued the use of notifications to address issues related to forgetfulness. One student who received notifications throughout the study commented:

> *I feel like it's good to have um, a reminder about just kind of like to check in with myself basically. That it has the notifications and I like it. You know, I have to do the check in. I feel like it's been helping me on that. Like scheduled just thinking about my week.*

Another student, whose notifications were working inconsistently, noted that they put reminders in their own personal calendar on their phone to use the app, noting:

> *Like I do a lot of things and I'm also a full-time student and I work full time...So I, I, that's why I put reminders on my phone to use it but because I am so busy, like I only find myself going to it when I'm really going through a hard time.*

Although forgetfulness was a notable barrier for many students and notifications were desired and useful, receiving notifications did not prompt all students to engage with the app. Rather, there needed to be a perceived need for using IntelliCare (eg, *going through a hard time*) coupled with remembering that IntelliCare was an available option (eg, receiving a notification).

Although there was generally positive feedback around the format of the IntelliCare for College Students program, ideas for enhancing the convenience and accessibility of program use were shared in the feedback interviews. Specifically, some students were interested in incorporating less text and more videos in the lessons. As one student noted:

> *I read through quickly two of 'em...I feel like they should be videos recorded. But like, you know it's all just like reading, like reading and reading. Maybe just like a video, like someone just talking to you.*

Furthermore, a student noted that they might appreciate "maybe like an auditory style where it reads it to you." Although the decision to design lessons as text based was informed by privacy considerations identified in early user-centered design activities (eg, students are often in public spaces or shared living spaces and reading allows for more discrete access to potentially sensitive mental health information), this feedback highlighted that individual students have varying preferences on how to consume information. Future iterations of the program may examine user engagement with and feedback on information presented in text, audio, and audio-visual formats.

Discussion

Principal Findings

Given the ongoing challenges to delivering an array of mental health services on college campuses, there remains a need to use innovative solutions to address increasing college student mental health needs. In this pilot study of the IntelliCare for College Students program, we are provided with a glimpse into what seems to work, what issues come up, and what needs to be studied next when designing and disseminating digital tools for college student mental health.

First, the IntelliCare for College Students app was considered usable and engaging. Although there were suggestions made to

improve usability and there were some bugs and glitches identified during the study, the vast majority of participants (18/20, 90%) continued to use the app beyond the 8-week study period. In past trials of the IntelliCare platform for general adult populations, participants used the app beyond the 8-week study period at lower or similar rates (33.7% in one trial [6] and 84% in another trial [7]). This is particularly notable, given that mental health apps are frequently abandoned by users in a relatively short time frame. Although usage rates vary, in a review of real-world user engagement with 93 different mental health apps, Baumel et al [22] found that the median 30-day retention rates were just 3.9%. Thus, the usage rates observed in this study indicate that the program was engaging, as participants returned to the app beyond the period they had originally committed to the study.

There are often challenges in designing universally accessible mental health resources that can be used by individuals who are currently experiencing symptoms of mental illness and by individuals seeking support to promote their continued wellness. Individuals often prefer tools and resources that are perceived as personally relevant, and the tools and resources that appear personally relevant may be quite different for someone who is struggling with more significant symptoms of depression or anxiety than for someone who is looking to promote wellness through stress management practices. As individuals can fluctuate in their membership into these higher symptom and lower symptom groups over time, it is valuable to design tools that can reach individuals when they are highly symptomatic and distressed and can also support individuals when they are less symptomatic and well [23]. In our program, participants received feedback on their symptoms when they completed the symptom checker tool within the app, and we recognize that receiving feedback on symptoms could influence use. However, we observed minimal differences in usage between students with higher symptoms and those with lower symptoms, indicating that IntelliCare for College Students could be a broadly accessible program. By offering a simple workflow containing a wide variety of tools and resources for supporting mental health and wellness, participants were able to find the tools and resources that were personally relevant to them and continue to use them as needed.

We did not observe changes in symptoms of depression or anxiety during the course of this study. We note that the study was underpowered to detect changes in psychosocial targets, so we are unable to determine if the lack of change was because of chance. Compared with previous studies of IntelliCare in which participants were encouraged to use IntelliCare daily, participants in this study were not given this instruction and used IntelliCare less frequently during the 8-week study than had been observed in these previous studies [6-8]. Participants enrolled in this study during the summer months, and the 8-week follow-up for many participants took place after the fall semester began. Some fluctuations in mood may be attributed to the change from summer break to resuming coursework [24]. However, we observed improvements in psychological targets, suggesting that the program had its intended effects on behavior and condition. Improvements were observed in participants' scores on the ALQ, indicating that they experienced gains in their knowledge of anxiety symptoms and anxiety management strategies. As low mental health literacy is a commonly cited barrier to mental health treatment seeking among college students [25,26], increasing mental health literacy appears to be a particularly important pathway to support students in seeking appropriate mental health resources.

We also observed increases in the frequency with which participants reported using a variety of cognitive and behavioral coping skills, such as taking time to figure out how thoughts impacted emotions and planning positive activities. As the use of cognitive and behavioral coping skills is believed to lead to improvements in mood [27], this finding provides preliminary support for the effectiveness of IntelliCare for College Students as a mood management resource. Significant improvements were observed in the ALQ, and the frequency subscales of the CB-RSS appeared to be driven by participants in the higher symptom group, who had lower baseline scores on these measures than did participants in the lower symptom group. Future research will examine these potential differences in larger sample sizes.

Limitations and Future Directions

There are limitations to this study that must be considered when interpreting the results. First, this was a single-arm study design aimed at examining how students used the app over an 8-week period, the preliminary associations between app use and psychosocial targets, and usability issues that needed to be remedied before the larger implementation study. There was no control group, and the study was not powered to detect changes in psychosocial targets. Although the study sample was racially and ethnically diverse, the majority of participants were female. Although a predominantly female user base is common in studies of mental health apps [28,29] and depression is more commonly diagnosed in women than in men [24], it is unclear how generalizable the results would be to male students and additional design considerations may be needed to attract and engage a male user base. We also observed that our study sample consisted primarily of students who were already involved in their campus community through student leadership positions and past engagement in counseling services. This likely contributed to the relatively high rates of knowledge of where to seek mental health services in this sample as well as the lack of change in that knowledge over the 8-week study. Finally, because participants had committed to an 8-week study period, usage rates may have been higher than would have been in a more naturalistic study design [22]. We plan to examine and compare usage rates within this pilot study to those observed in the implementation of the IntelliCare for College Students app on 2 university campuses.

Conclusions

The results indicate that the IntelliCare for College Students program was perceived as largely usable and engaging to a sample of university students. The program demonstrated some preliminary psychosocial benefits to students, and further testing is needed to determine the program's utility in promoting symptom change and connecting students to other mental health resources.

Acknowledgments

This study was supported by a grant from the National Institutes of Health (K08 MH112878).

Conflicts of Interest

DM has an ownership interest in Adaptive Health Inc, which has a license from Northwestern University to commercialize IntelliCare. EL has received consulting fees from Actualize Therapy, LLC (last in June 2018), a company that formerly held the license to IntelliCare. DM has also received consulting fees from Apple Inc.

Multimedia Appendix 1
Screenshots of IntelliCare for college students.
[DOCX File , 19572 KB - mental_v7i10e21075_app1.docx]

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Abbreviations

ALQ: Anxiety Literacy Questionnaire
CB-RSS: Cognitive and Behavioral Response to Stress Scale
DLQ: Depression Literacy Questionnaire
GAD: Generalized Anxiety Disorder
KBSS: Knowledge and Beliefs about Services Scale
PHQ: Patient Health Questionnaire

Edited by J Torous; submitted 04.06.20; peer-reviewed by T McCall, J Schleider; comments to author 16.07.20; revised version received 05.08.20; accepted 23.08.20; published 10.10.20.

Please cite as:
Lattie E, Cohen KA, Winquist N, Mohr DC
Examining an App-Based Mental Health Self-Care Program, IntelliCare for College Students: Single-Arm Pilot Study
JMIR Ment Health 2020;7(10):e21075
URL: http://mental.jmir.org/2020/10/e21075/
doi:10.2196/21075
PMID:33037874

Original Paper

Evaluation of ReachOut.com, an Unstructured Digital Youth Mental Health Intervention: Prospective Cohort Study

Bianca Lorraine Kahl[1], BA; Hilary May Miller[1], MPH; Kathryn Cairns[1], PhD; Hayley Giniunas[1], BA; Mariesa Nicholas[1], BA

ReachOut Australia, Pyrmont, Australia

Corresponding Author:
Bianca Lorraine Kahl, BA
ReachOut Australia
Suite 2.04, Building B
35 Saunders Street
Pyrmont, 2009
Australia
Phone: 61 02 8029 7734
Email: bianca.kahl@reachout.com

Abstract

Background: Young people experience a disproportionate burden associated with mental illness that Australia's mental health care system is ill-equipped to handle. Despite improvements in the provision of mental health services, the rates of service utilization among young people remain suboptimal, and there are still considerable barriers to seeking help. Digital mental health services can overcome a number of barriers and connect young people requiring support; however, the evidence base of digital interventions is limited.

Objective: The aim of this study is to examine the effectiveness of a brief, self-directed, unstructured digital intervention, ReachOut.com (hereafter ReachOut), in reducing depression, anxiety, stress, and risk of suicide.

Methods: A cohort of 1982 ReachOut users participated in a 12-week longitudinal study, with a retention rate of 81.18% (1609/1982) across the duration of the study. Participants completed web-based surveys, with outcome measures of mental health status and suicide risk assessed at 3 time points across the study period.

Results: The results demonstrated that over the 12-week study period, young people using ReachOut experienced modest yet significant reductions in symptoms of depression, anxiety, and stress. Significant, albeit modest, reductions in the proportion of participants at high risk of suicide were also observed.

Conclusions: The findings of this research provide preliminary evidence of the promise of an unstructured digital mental health intervention, ReachOut, in alleviating symptoms of mental ill-health and promoting well-being in young people. These findings are particularly important given that digital services are not only acceptable and accessible but also have the potential to cater to the diverse mental health needs of young people at scale, in a way that other services cannot.

(JMIR Ment Health 2020;7(10):e21280) doi:10.2196/21280

KEYWORDS

digital mental health; digital intervention; youth; internet-based intervention; depression; anxiety; stress; suicide

Introduction

Background

Young people experience a high burden of disease attributable to mental ill-health, with approximately one in four young people (aged 15-24 years) experiencing a mental health problem every year [1]. Unfortunately, the prevalence of psychological distress in young people in Australia appears to be increasing [2], and suicide remains the leading cause of death for Australian youth [3]. Many mental health problems have their onset in adolescence or early adulthood, and if left untreated, can result in more frequent and severe episodes of ill-health throughout the lifespan [4-7]. There is limited capacity within the current mental health service system to meet the demands associated with youth mental health problems in a timely manner, and many young people are going without vital support [8].

Although there have been steady improvements in the provision and uptake of treatment services among young people in the

past decade, rates of service utilization among adolescents and young adults remain suboptimal; in the latest Australian Child and Adolescent Survey of Mental Health and Wellbeing, 21.4% of young people aged between 12 and 17 years had accessed a service for emotional or behavioral problems in the past 12 months [8,9]. Furthermore, despite increased provisions and extensive public destigmatization efforts, a significant proportion of young people are reluctant to access community services for their mental health problems [10,11]. Common barriers to help-seeking for young people include limited service availability (particularly in rural areas), accessibility issues (in terms of location and time), financial constraints, concerns about confidentiality, and fear of judgment or stigma [10,12,13]. A desire for autonomy in the help-seeking process and a preference for self-reliance are also salient barriers for young people [10,14,15]. In addition to these common barriers, there are a number of young people who report having unfavorable experiences with mental health professionals and are therefore hesitant to either return or seek further professional help [16]. In the light of these barriers, innovative approaches to reaching and engaging, or reengaging, young people with mental health support are required.

Digital mental health services have the potential to overcome common barriers to help-seeking experienced by young people [17]. Recent research indicates that young people perceive web-based mental health support to have many benefits over traditional face-to-face services, including greater accessibility, immediacy, interactivity, lower financial costs, and reduced embarrassment associated with the experience [18]. The use of internet among young people is prolific [19] and there is growing evidence that young people are turning to digital platforms to access mental health information and support [2]. Australian research indicates that approximately one in five 12 to 17-year-old adolescents, and one in three 18 to 25-year-old adults who have experienced a mental health problem have used internet search engines to access mental health information [20]. A national survey of young Australians conducted in 2018 [2] also found that young people were amenable to using the internet for mental health support. For example, 37% of those with psychological distress said that they would use the internet to source information about specific issues and 22% reported that they would use the internet to access information about available services [2]. Another recent study found that the majority of youth (72%) would access a web-based resource if they were experiencing a mental health problem, and a third (32%) would prefer a web-based resource over face-to-face therapy [18].

The flexible, freely accessible, and multicomponent nature of unstructured digital services may be appealing to young people experiencing issues more broadly; they may also be particularly attractive to young people with mental ill-health who are reluctant to engage with clinical services for several reasons. First, they can be accessed anonymously, whereas most structured programs require users to provide personal information, thereby circumventing concerns about confidentiality [2,10]. Second, they are self-directed and therefore responsive to young people's preference for autonomy by providing a range of resources to select from [10]. Third, they are able to deliver a service experience that is tailored to the needs and preferences of each individual young person through personalization [21]. Finally, there are many evidence-based digital mental health services that can be accessed for free or at a low cost, with no waiting period [22,23]. Digital services might also act as an alternative or adjunct intervention when young people have had previous negative experiences with mental health professionals. In such cases, digital services may be well-positioned to provide interim support and rebuild service readiness in young people who are in need of more intensive intervention but are dubious about returning to professional services [24].

The growth in the accessibility and uptake of digital technologies offers a cost-efficient and highly scalable alternative to reach young people needing mental health support when compared with traditional models of clinical care [25]. Digital services have the potential to reach and deliver positive outcomes across the mental health spectrum. Moreover, they can be appropriate for young people who experience subthreshold mental health problems and who may be ineligible for other supports, or those who are reluctant to seek professional help owing to minimization and/or self-stigma. Currently, several digital support services exist to support young people in managing their mental health, including web-based counseling services (eg, eheadspace), structured web-based therapies (eg, Moodgym), psychoeducational websites, and web-based blogs and forums [26]. There is also increasing evidence of the effectiveness of web-based counseling, therapies, and mobile self-monitoring tools in improving mental health outcomes and help-seeking [27-33]. Web-based positive psychology interventions have also been linked to increased well-being and decreased stress in nonclinical youth populations [34]. Not only is there evidence of the effectiveness of digital services in the prevention and early intervention space but there is also evidence that mobile apps designed to prevent suicide can bring about reductions in psychological distress among vulnerable populations (eg, Ibobbly, [35]). Moreover, web-based interventions may also prevent relapse in mental illness and support a process of recovery [36,37]. Given the flexibility and versatility of digital media, digital services are well placed to support the broad spectrum of unique mental health issues that young people, both well and unwell, experience.

Although there is substantial evidence for structured and clinician-led digital interventions, limited research has been conducted to investigate the effectiveness of unstructured digital mental health interventions, and there is a lack of ecologically valid research for digital interventions. Although randomized control trials (RCTs) represent the gold standard in research and provide important insights for many treatment outcomes, a reliance on these methods means that much evaluative research of digital programs is conducted under highly controlled and prescriptive conditions that rarely mimic the experience of users in the real world [38]. To adequately evaluate the effectiveness of digital interventions, it is imperative to examine these digital services in the environments in which they are intended to be used [38]. This study aimed to bridge this gap by exploring the impact of one unstructured digital mental health intervention, ReachOut.com (hereafter ReachOut), on mental health outcomes

of young people who used it over a 3-month period, in a naturalistic study.

This Research

Preliminary findings from previous cross-sectional evaluations of ReachOut have suggested that the service has a positive impact on well-being [39,40]; however, further research is needed to investigate its effectiveness in improving the mental health and well-being outcomes of young people. This research aims to add to the extant evidence base for digital mental health interventions by critically evaluating the impact of ReachOut on symptoms of depression, anxiety and stress, and suicidal ideation in a large cohort of users.

Methods

Overview

A longitudinal study was conducted over a 12-week period to explore whether participating in a brief, unstructured digital intervention would be associated with changes in symptoms of depression, anxiety, stress, and suicide risk. Outcome measures of mental health status and suicide risk were assessed at 3 time points across the 12-week study period. We also briefly explored the user experience ratings of the service. This study was approved by the University of Melbourne Human Research Ethics Committee.

Intervention

ReachOut is an unstructured, self-administered digital mental health service for young people aged 14 to 25 years. ReachOut resources are developed with the involvement of young people and are reviewed by a Clinical Advisory Group, composed of a diverse team of clinicians. ReachOut is accessed by more than 2 million people in Australia annually (based on visitation statistics from January 2020), which indicates that this unstructured digital service modality holds appeal for young people. ReachOut is a multi-layered service with components that vary in intensity. At the base level, it provides psychoeducational information, personal stories, quizzes, videos, and audio recordings. It also offers apps and tools, peer-support from both peers and trained moderators, pathways to clinical support, and customized recommendations to users through NextStep [41]. ReachOut is designed to support well-being affected by everyday stressors to more complex mental health issues, by providing evidence-informed self-help strategies, sharing stories of recovery, building knowledge of professional help, and increasing self-efficacy to seek help. We expected using ReachOut as part of this intervention to increase professional help-seeking behavior and reduce the impact of mental health symptoms.

Materials

Mental Health Status

The mental health status of participants was assessed using the short form of the Depression, Anxiety, and Stress Scale (DASS-21 [42]). The DASS-21 comprises 21 items, which are considered over the past week, and make up three subscales that measure levels of depression (eg, “I felt that life was meaningless”), anxiety (eg, “I felt I was close to panic”), and stress (eg, “I found it difficult to relax”). Items were scored on a 4-point scale, where lower scores indicated lower severity (0=*Did not apply to me at all* to 3=*Applied to me very much, or most of the time*). Each subscale was scored and classified as indicating normal, mild, moderate, severe, or extremely severe levels of depression, anxiety, and stress. The measure demonstrated good reliability on the subscales of depression (α=.93), anxiety (α=.86), and stress (α=.87) at baseline.

Suicide Risk

Suicidal ideation was assessed using 8 critical items from the Reynolds’ Suicidal Ideation Questionnaire (SIQ) [43]. The 8 critical items scale included statements such as “I thought about how I would kill myself,” and were measured on a 7-point scale (0=*I never had this thought* to 6=*Almost every day*). These 8 items have demonstrated ecological validity, having been significantly correlated with clinical assessments of suicidality (*P*=.05, [44]). A score of 5 or 6 on more than 3 items of the 8 critical items is considered to indicate a higher risk of suicide in adolescents [43].

User Experience

Participant impressions of ReachOut were assessed using bespoke measures that align with the user experience goals for the service, which have been co-designed with young people. These items addressed the relevance, availability, and accessibility of *ReachOut*, whether ReachOut had helped participants understand their own experiences and whether it had provided them with helpful strategies and tools. These statements were ranked on a 5-point scale (1=*strongly agree* to 5=*strongly disagree*). Participants were also asked to rate their satisfaction with ReachOut on a 4-point scale (1=*poor* to 4=*excellent*).

Recruitment

Participants were recruited through a pop-up notification on the ReachOut website. On clicking the notification, users were asked to complete an eligibility questionnaire. Participants were required to be residing in Australia, aged between 16 and 25 years, and to have used the ReachOut website previously, either to access information or support for themselves or for someone they knew. If eligible, participants were presented with an information statement for providing informed consent. Rolling recruitment occurred across two phases. Phase one recruitment commenced in November 2014 and ended in August 2015. Following this, phase two recruitment commenced in February 2016 and was completed in June 2016.

Procedure

Participants completed 4 surveys across a 3-month period. A baseline survey (T1) captured demographic characteristics, mental health, and suicide risk. Further surveys were administered 1 week post baseline (T2), 5 weeks post baseline (T3), and 12 weeks post baseline (T4). User experience, including satisfaction with and impressions of the ReachOut website, were assessed at T2, using bespoke measures taken from past ReachOut user studies. Mental health and suicide risk were not assessed at T2. T3 and T4 repeated all measures from the baseline survey, excluding demographics. Each survey took

15-40 min to complete: Baseline (30-40 min), T2 (10-15 min), T3 and T4 (20-30 min).

Statistical Analyses

Frequency and descriptive analyses were conducted to explore the characteristics of the participants. To explore whether participants experienced a reduction in depression, anxiety, and/or stress across the 12-week unstructured intervention study, a series of 3-way mixed analysis of variance (ANOVA) was conducted. These analyses were also used to determine whether the trends across time differed based on gender, sexual orientation, and age group. The assumption of sphericity was violated for all 3 analyses; therefore, the Greenhouse-Geisser correction was applied. The 3-way interactions were examined to explore whether reductions in depression, anxiety, and stress significantly differed between gender, sexual orientation, and age groups. We used Cochran's Q analysis to explore whether there was a reduction in the proportion of ReachOut users at high risk of suicide across the 12-week study period. Finally, to explore changes in the proportion of people at risk of suicide by gender, sexual orientation, and age group, data files were split by group, and analyses were run separately as above.

Results

Participant Characteristics

A final sample of 1982 young people aged between 16 and 25 years (mean 19.40, SD 2.98) was recruited. The study retention rate was 81.18% (1609/1982), with 1609 participants completing the 3-month follow-up survey. Characteristics of all participants compared with those included in the analysis are shown in Table 1. No major differences were observed between those included and those not included in the analysis. However, those participants who self-selected for this study may not be representative of all people who use ReachOut more broadly. The sample was predominantly female, and many had previously sought help from a mental health professional. Of the participants who had sought help, only 54.53% (656/1203) said they found the help they received from the professional to be helpful. A relatively large number also had a history of mental health-related hospital admissions. See Table 1 for a full description of participant characteristics.

Table 1. Participant baseline characteristics.

Characteristics	Full sample (n=1982), n (%)	Analyzed sample (n=1609), n (%)
Age (years)[a]		
16-18	915 (47.0)	759 (47.4)
19-21	523 (26.9)	437 (27.3)
22-25	509 (26.1)	406 (25.3)
Gender identity		
Female	1657 (83.6)	1352 (84.0)
Male	233 (11.8)	179 (11.1)
Other (gender diverse)	92 (4.6)	78 (4.8)
Sexual orientation[b]		
Heterosexual	1268 (65.0)	1050 (65.3)
Lesbian/gay	103 (5.3)	90 (5.6)
Bisexual	254 (13.0)	197 (12.3)
Unsure/questioning	166 (8.5)	141 (8.8)
Other/different	159 (8.2)	129 (9.0)
Previous help-seeking		
Previously seen a mental health professional	1487 (75.0)	1203 (74.5)
No	495 (25.0)	406 (25.2)
Mental health hospitalizations		
No hospitalization	1667 (84.1)	1366 (84.9)
Previous hospital admission for a mental health issue	289 (14.6)	223 (13.9)
Don’t know	26 (1.3)	20 (1.2)
User experience ratings of ReachOut (% agree or strongly agree)[c]		
ReachOut is relevant	1559 (82.3); N=1894	1327 (83.1); N=1597
ReachOut is available and accessible	1646 (86.7); N=1899	1396 (87.5); N=1596
ReachOut helps me to understand my own experiences	1361 (71.5); N=1903	1165 (72.9); N=1599
ReachOut has given me a range of practical self-help strategies and tools	1303 (68.6); N=1899	1103 (69.2); N=1595
Overall rating of ReachOut (% good or excellent)	1902 (99.0); N=1922	1588 (99.1); N=1602

[a]Not all participants reported age. Full sample (N=1947), analyzed sample (N=1602).

[a]Not all participants reported sexual orientation. Full sample (N=1950), analyzed sample (N=1607).

[c]Not all participants responded to the user experience *ratings*.

Changes in Depression, Anxiety, and Stress Over Time

ANOVA revealed a significant main effect of time, showing that there was a significant decrease in overall DASS-21 scores from baseline to follow-up. There was also a significant main effect of DASS-21, highlighting differences in scores between depression, anxiety, and stress. However, these main effects were superseded by significant 2-way interactions between DASS-21 and time. Although scores on depression, anxiety, and stress decreased over time, depression showed the largest decrease from baseline to the 3-month follow-up, when compared with anxiety and stress. See Table 2 for means and standard deviations for interaction effects of DASS and time, gender, sexual orientation, and age group from the ANOVA models described below.

Table 2. Means and standard deviation for depression, anxiety, and stress across time, gender, age group, and sexual orientation.

Parameter	Depression, mean (SD)	Anxiety, mean (SD)	Stress, mean (SD)
Time			
Baseline	22.55 (12.30)	16.53 (10.66)	21.96 (10.47)
Follow-up	17.70 (12.74)	13.75 (10.44)	19.09 (11.00)
Gender			
Male	20.07 (11.06)	13.47 (9.49)	18.81 (9.49)
Female	19.46 (11.07)	15.09 (9.47)	20.43 (9.47)
Other identity	22.52 (11.06)	16.86 (9.48)	22.53 (9.48)
Sexual orientation			
Heterosexual	18.06 (10.85)	13.86 (9.38)	19.33 (9.41)
Gay or lesbian	22.00 (10.85)	16.97 (9.37)	21.74 (9.40)
Bisexual	22.48 (10.86)	16.37 (9.37)	22.24 (9.40)
Unsure/questioning	23.04 (10.85)	17.39 (9.36)	21.90 (9.40)
Different sexual identity	23.32 (10.86)	18.31 (9.36)	22.34 (9.40)
Age (years)			
16-18	20.16 (11.07)	15.99 (9.46)	20.48 (9.49)
19-21	18.91 (11.06)	14.41 (9.44)	20.16 (9.51)
22-25	19.73 (11.05)	13.88 (9.45)	20.49 (9.49)

The 3-way interaction between gender, DASS-21, and time was not statistically significant (Table 3), nor was the 3-way interaction between sexual orientation, DASS-21, and time (Table 4). The 3-way interaction between age group, DASS-21, and time was also not statistically significant (Table 5). This demonstrates that the changes in depression, anxiety, and stress scores across time did not significantly differ with respect to gender, sexual orientation, or age group.

Table 3. Repeated measures effects of DASS across time, by gender.

Parameter	*F* test (*df*)	*P* value	η_p^2
DASS[a]	186.02 (1.78,2780.46)	<.001	0.106
Time	46.04 (1.93,3020.69)	<.001	0.029
Gender	3.21 (2.00,1565.00)	.04	0.004
DASS×Time	15.96 (3.75,5865.91)	<.001	0.010
DASS×Gender	5.53 (3.55,2780.46)	<.001	0.007
Time×Gender	0.28 (3.86,3020.69)	.89	0.000
DASS×Time×Gender	1.40 (7.50,5865.91)	.20	0.002

[a]DASS: Depression, Anxiety and Stress Scale-21

Table 4. Repeated measures effects of DASS across time, by sexual orientation.

Parameter	*F* test (*df*)	*P* value	η_p^2
DASS[a]	274.53 (1.77,2773.93)	<.001	0.150
Time	62.00 (1.93,3017.65)	<.001	0.038
Sexual Orientation	15.06 (4.00,1561.00)	<.001	0.037
DASS×Time	25.15 (3.75,5852.35)	<.001	0.016
DASS×Sexual Orientation	3.53 (7.11,2773.93)	.001	0.009
Time×Sexual Orientation	0.85 (7.73,3017.65)	.55	0.002
DASS×Time×Sexual Orientation	0.87 (15.00,5852.35)	.60	0.002

[a]DASS: Depression, Anxiety and Stress Scale-21.

Table 5. Repeated measures effects of DASS across time, by age group.

Parameter	*F* test (*df*)	*P* value	η_p^2
DASS[a]	539.53 (1.77,2752.98)	<.001	0.257
Time	155.33 (1.93,3010.53)	<.001	0.091
Age group	2.15 (2.00,1558.00)	.20	0.003
DASS×Time	38.34 (3.75,5843.55)	<.001	0.024
DASS×Age group	7.43 (3.53,2752.98)	<.001	0.009
Time×Age group	2.74 (3.87,3010.53)	.03	0.004
DASS×Time×Age group	1.08 (7.50,5843.55)	.37	0.001

[a]DASS: Depression, Anxiety and Stress Scale-21.

Although there were no statistically significant 3-way interactions, there were several statistically significant 2-way interactions. A statistically significant 2-way interaction was observed between the DASS-21 and gender. The differences between depression and anxiety ($F_{2,1565}$=6.51, P=.002, η_p^2=0.008) and between depression and stress ($F_{2,1565}$=7.94, P<.001, η^2=0.010) differed based on gender. Participants who identified with the *other* gender identity consistently scored the highest on depression, anxiety, and stress. However, while female participants scored higher on anxiety and stress compared with male participants, male participants scored higher on depression when compared with female participants (Table 2 for means and standard deviations).

Furthermore, although there was a statistically significant 2-way interaction between DASS-21 and sexual orientation, upon further inspection of the effect, there did not appear to be a meaningful interaction and it did not demonstrate clear patterns between sexual orientation and the DASS-21. That is, heterosexual young people consistently scored lower for depression, anxiety, and stress, while lesbian or gay and bisexual young people consistently scored lower than those with the *other* sexual orientation. However, there were no other consistent trends between participants who were identified as gay or lesbian, bisexual, or unsure or questioning in depression, anxiety, or stress scores (Table 2 for means and standard deviations). This lack of interaction could have been caused by low participant numbers in the various groups.

Moreover, there was a statistically significant 2-way interaction between age group and time, from baseline to follow-up ($F_{2,1558}$=3.06, P=.05, η^2=0.004). That is, although all age groups showed a decrease in overall DASS-21 scores from baseline to the 3-month follow-up, this decrease was most pronounced for participants aged between 19 and 21 years (baseline mean 20.17, SD 9.94; follow-up mean 15.94, SD 10.44) when compared with those aged between 16 and 18 years (baseline mean 20.46, SD 9.92; follow up mean 17.47, SD 10.44) and participants aged between 22 and 25 years (baseline mean 20.01, SD 9.93; follow-up mean 16.77, SD 10.44).

There was also a statistically significant 2-way interaction between the DASS-21 and age groups. Contrasts revealed that there were differences in scores between depression and anxiety across age groups ($F_{2,1558}$=5.70, P=.003, η_p^2=0.007) and between anxiety and stress across age groups ($F_{2,1558}$=18.44, P<.001, η_p^2=0.023). Although the trends across age groups were similar for depression and stress, they differed for anxiety. Participants aged 16 to 18 years scored the highest for anxiety, followed by those aged 19 to 21 years, while those aged 22 to 25 years scored the lowest on anxiety (Table 2 for means and standard deviations).

Changes in Suicidal Ideation Over Time

A total of 1577 participants completed the SIQ at baseline, 5 weeks postbaseline, and at the 3-month follow-up. There was a statistically significant difference between the proportions of participants at high risk of suicide across the different time

points (χ^2_2=23.1, *P*<.001). About 12.30% (194/1577) were at high risk of suicide at baseline, 10.53% (166/1577) at 5 weeks postbaseline, and 8.50% (134/1577) at the 3-month follow-up. Pairwise comparisons were performed using Dunn's procedures with a Bonferroni correction for multiple comparisons, presenting adjusted *P* values. Compared with the baseline percentage of participants at high risk of suicide, there was a statistically significant decrease in the percentage of those at high risk at the 3-month follow-up (*P*<.001). There was no statistically significant difference between the baseline and 5-week postbaseline values (*P*=.08) but there was a statistically significant reduction from the 5-weeks postbaseline value to the 3-month follow-up (*P*=.01).

Changes in Suicidal Ideation by Demographics

Significant reductions in the proportion of people experiencing suicidal ideation were observed at follow-up among female and gender-diverse participants, heterosexual and unsure or questioning participants, and those aged 16-18 years and 19-21 years (Multimedia Appendix 1 for full details).

User Experience

Participants favorably rated their user experience of ReachOut, agreeing that it was relevant and accessible and that it helped them to understand their experiences and gave them practical help strategies and tools. See Table 1 for the percentages of endorsement for each user experience goal.

Discussion

Principal Findings

This study aimed to explore the impact of ReachOut, an unstructured digital mental health intervention, on mental health outcomes and risk of suicide over time. The findings demonstrate that over a 3-month period, young people using ReachOut experienced a significant reduction in symptoms of depression, anxiety, and stress. Significant reductions in the proportion of participants at high risk of suicide were also observed.

The findings indicate that despite being a prevention and early intervention service designed for young people in mild-to-moderate levels of distress, the service is, in fact, also attracting young people in high levels of distress and with more complex presentations. A relatively large number of participants in this study had a history of mental health-related hospital admissions, which was substantially higher than the population estimates [45]. Further, 12.30% (194/1577) and 8.50% (134/1577) of the sample were at high risk of suicide at baseline and follow-up, respectively. ReachOut is not designed to be a crisis service or to meet the particular needs of young people at risk of suicide. However, we recognize that these young people are visiting ReachOut, perhaps unaware of our extent of service, and we acknowledge our duty of care to them. It is also probable that some visitors to ReachOut are aware of our extent of service but have had negative experiences with crisis support services. In these instances, there is an opportunity to leverage our position as a trusted support service to bridge the gap and build on their readiness to reengage with the support that is matched to their needs.

An important consideration for open-access websites and other eHealth tools is that while they can be targeted at particular levels of need, this does not necessarily mean that users will engage with them in the prescribed way. This gives rise to duty of care implications. As such, ReachOut is supported by a Clinical Advisory Group that supports the organization in implementing the duty of care and risk management framework. ReachOut is undertaking a program of continuous improvement, research, and partnerships with specialist support services to ensure young people with more complex presentations, particularly those at risk of suicide, are directed to the support that best matches their needs. A machine learning tool [46] has been developed to assess the risk within ReachOut's peer support community. It triages and escalates posts that are deemed to be high-risk, whereupon staff moderators follow up and work closely with the young person and appropriate partner organizations (including emergency services) to keep them safe. Where deemed necessary, moderators edit or remove high-risk posts where there is a risk to the safety of the broader community. This triaging tool has been running successfully since 2016 and has been increasingly accurate in triaging posts in the community forum to support efforts to keep the community and moderators safe. A direct referral from ReachOut to Lifeline's web chat service is currently being piloted and we are also undertaking a research project that explores the level of risk as a function of browsing behaviors, to support the automatic identification of young people who could benefit from more intensive support and targeting a persuasive intercept that encourages them to do so.

Although the improvements seen in mental health outcomes and suicide risk were relatively modest, they should not be discounted given the significant mental health needs of this cohort and the pronounced burden associated with mental illness during this developmental phase more broadly [47]. Reduction of symptoms of depression and anxiety of a similar magnitude has been reported in other published evaluations of mental health prevention programs [48-51], many of which are more resource-intensive, typically delivered face-to-face and often within school settings. Although the methodological differences of these studies prevent direct comparison of effects, the overall effects of ReachOut, a self-directed, brief, unstructured, and relatively inexpensive intervention, are promising alongside these more resource-intensive programs.

Many of the young people who participated in this study had previously sought help from a mental health professional, and a number of them had previous mental health hospital admissions. However, many did not rate their experience with mental health professionals as helpful. Digital interventions are uniquely positioned to provide alternative interim support to young people who may have had previous unfavorable experiences with traditional modes of care and to encourage them to reengage with more specialist support where appropriate. Although previous help-seeking experiences were poorly evaluated, participants rated their experience of ReachOut more favorably. These positive ratings can likely be attributed to the flexible and accessible mode of delivery, which mitigates

a number of common barriers to help-seeking, and in part to the co-design methods employed in service and content development. ReachOut takes a participatory approach, co-designing services with diverse groups of current and/or prospective users, and adopts user-led experience goals to ensure that services are tailored for people with different needs. These findings, coupled with existing literature [35,52,53], present a strong argument for employing co-design methods in the development of youth mental health services. Furthermore, the positive ratings of ReachOut highlight the demand for web-based services among young people in high distress and underscore the importance of web-based services across the spectrum from early intervention to crisis services. Although more intensive, face-to-face treatment service modalities clearly have their place, it is important that early intervention and prevention are also prioritized to help reduce the incidence of common mental disorders early in the lifespan and maximize the efficiency of the limited resources available [54].

The participants in this study rated their user experience favorably in terms of both the relevance and accessibility of the program, and the *usefulness* of the intervention in providing them with a range of practical strategies and helping them understand their own experiences; however, the latter were not as positive as the former. As an open-access and completely self-directed service that services young people of varying ages, backgrounds, and levels of distress, it is likely that young people have varying levels of success in finding content that is relevant to their personal circumstances, given the vast array of issues and experiences covered in the site. ReachOut is currently exploring how personalization can optimize the experience of visitors to the site, helping them rapidly navigate to the most relevant information and support for them based on their needs and preferences, without having to wade through content that is not relevant or helpful. We hypothesize that a more personalized user experience may in turn result in higher ratings of usefulness in future evaluations of ReachOut.

Given the considerable health burden of mental health conditions in young people and the established barriers to accessing support [10,12,13], web-based mental health services offer a unique opportunity to address the needs of young people. Digital services are making rapid gains in the delivery of health and mental health care and are recognized for their acceptability, scalability, and reach [55]. Digital services can overcome common barriers faced by young people when accessing mental health services, including stigma and preference for self-reliance [10], provide support to large numbers of young people in a highly accessible and youth-friendly manner, and offer a unique opportunity to access hard-to-reach groups. Compared with traditional services, digital services, provided they are effective and accessed by large numbers of people, are cost-effective and may provide relief from symptoms in their own right, while also facilitating onward referral when required [55]. We found similar improvements in mental health symptoms across various demographic groups, including by age, gender, and sexual orientation. We hypothesize that the lack of notable differences between these groups is related to the involvement of diverse young people in the development of service resources and the flexibility and self-directed nature of the intervention. Young people from all backgrounds are involved in the co-creation of information, support, and tools for ReachOut. In addition, the unstructured nature of ReachOut allows young people to navigate and select information and/or support that may be relevant to them from a wide variety of topics and diverse perspectives. The result is a flexible intervention that is adaptable to the individual, and yet can be scaled up to reach large numbers of young people in need.

Limitations and Future Directions

Overall, the study provided valuable insights into the potential of an unstructured digital intervention; however, this study is not without its limitations. First, participants self-selected into the study, and there were minimal eligibility criteria other than age, location, and current use of ReachOut. Although all participants were ReachOut users, there was no minimum requirement of usage for the duration of the study. Therefore, it is difficult to specifically attribute dosage patterns to improvement in mental health and suicide risk. Furthermore, one goal of the intervention was to facilitate access to professional help, and as such, the use of professional mental health services alongside ReachOut may have resulted in greater reductions observed in mental health scores over time. The possible impact of other help-seeking avenues reduces our confidence in the attribution of causality to the intervention. In addition, this sample had complex mental health needs that may not be representative of young people across the mental health spectrum but rather of those in high distress. Self-report measures were used to capture mental health status and no observer-rated assessments were used. The majority of participants in the study were female, thus limiting generalizability; however, there is also a skew toward young female users within the wider ReachOut user population and the profile of young people who seek help for psychological distress in Australia [13].

Furthermore, while the results indicate significant improvements in mental health and suicide risk among young people, the lack of a control group precludes the definitive attribution of these outcomes to their use of ReachOut. Although RCTs represent the gold standard in evaluating some treatment outcomes, there can be challenges in implementing these studies within the context of a brief, unstructured, and self-directed digital intervention that operates within a dynamic service environment and is rapidly responding to the changing needs of young people. Further, the pace at which digital technology is evolving requires a faster delivery of research and evaluation insights to ensure that these are timely and relevant; the significant time investment of RCT designs is often not conducive to the fast-paced innovation cycle. More rapid sources of evidence are therefore required in addition to RCTs to support interventions to adapt to new technologies and evolving user needs. Further, as others have noted, a favorable outcome in an RCT does not always imply that the intervention will have a meaningful impact in the real world, especially in the digital space [38]. There have been a number of web-based and app-based interventions that have demonstrated favorable results through RCTs [56-58]; however, there has been little consideration of the application of these interventions in the natural environment, in which usage patterns and dosages are unknown, and the environments in

which these are implemented are uncontrolled [38,59]. Despite these challenges, discrete components of the ReachOut service offering have been subjected to controlled trials [41]. Future evaluation research that includes a control group would be valuable for drawing more definitive conclusions regarding the attribution of any observed changes to the intervention.

It is also important to consider that *spontaneous* remission (ie, remission of symptoms that are not related to a given treatment) may account for a proportion of the improvements in mental health and suicide risk observed over the 3-month study period. Without a control group, it is difficult to estimate the influence of spontaneous remission on these findings. There is currently limited evidence regarding the rates of spontaneous remission in young people. However, a meta-analysis that examined *remission* in untreated depression, defined as 'clinically significant improvement', found that 23% of adults remitted at 3 months, with a higher remission rate (not mentioned in the paper) observed in children and adolescents [60]. On the basis of this, we might conservatively estimate that between 20% and 30% of adolescents with an affective disorder spontaneously remit with the passage of time, and it is therefore possible that a proportion of the cases that experienced improvements in mental health outcomes would have experienced it anyway, even in the absence of the support they accessed from ReachOut. However, the level of reduction in symptoms that was observed, coupled with the young people's positive endorsement of user experience goals as well as a self-report of the subjective impact (ie, how ReachOut helped them) in the qualitative data (see [61]), suggests that ReachOut did contribute to the improvements seen in mental health and suicide risk, although different research designs are required to establish more definitively the extent of this contribution. As noted above, a study design that involves a matched control group would allow for a more thorough investigation of the potential impact of spontaneous remission on the observed effects. This would also allow for an exploration of whether there were any possible study effects associated with completing the evaluation surveys, as opposed to engaging with the intervention per se.

A final limitation of the study is the lack of objective data on the young people's activity on ReachOut, which precludes the examination of engagement variables as a potential mediator of impact. Future research on ReachOut will build on this study by capturing the users' browsing data to explore the impact of different components of the intervention on mental health outcomes and the dosage effects. It is hoped that this research will further elucidate the critical factors of unstructured interventions that lead to improvements, including any influences of dose (frequency and duration of use), modality of delivery, and content format.

Despite these possible limitations, this study provided preliminary evidence of promise for a brief, unstructured, self-directed digital intervention to support young people's mental health and well-being. The large potential for digital interventions for youth mental health and well-being is widely acknowledged [62], and given the substantial evidence of the acceptability, effectiveness, and cost-effectiveness of digital interventions, there is a clear rationale to invest in the development and evaluation of evidence-based digital services for youth mental health.

Conclusions

Digital mental health interventions can address barriers to access and provide services to young people in need at a population level, and there is growing evidence that they are effective in improving mental health outcomes among youth. Specifically, these findings demonstrate the promise of an unstructured digital mental health intervention, ReachOut, in reducing depression, anxiety, and stress symptoms, and risk of suicide in young people. Although ReachOut is primarily intended for prevention and early intervention, the findings from this study highlighted that the service is attracting young people in high levels of distress. Despite the considerable mental health needs of this cohort, significant improvements in all outcomes were observed and young people rated their experience of using ReachOut highly. Our findings, coupled with existing research, indicate that unstructured digital mental health services are not only accessible and acceptable but also have the potential to cater to the diverse mental health needs of young people, in a way that other services are unlikely to be able to do because of limited resources and ability to scale. Future research that involves a comparison group and the collection of user data to explore dose-response effects is needed to confirm and expand on these findings.

Acknowledgments

The authors would like to acknowledge the contribution of Associate Professor Phil Kavanagh, University of Canberra for peer review of the results and interpretation of this research. The authors also thank Dr. Atari Metcalf, Dr. Sylvia Kauer, Professor Lena Sanci, and Dr Coralie Wilson for their contribution to the design of this research. The authors acknowledge that this study was conducted on the lands of the Gadigal people of the Eora Nation and pay respect to the traditional owners.

Conflicts of Interest

The authors are employed (BK, HM, KC, and MN) or were formerly employed (HG) by ReachOut Australia, the organization that operates ReachOut.com, the web-based service that is the subject of this evaluation and which funded the research.

Multimedia Appendix 1
Changes in risk of suicide over time split by gender, sexual orientation, and age group.
[DOCX File , 16 KB - mental_v7i10e21280_app1.docx]

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Abbreviations

ANOVA: analysis of variance
DASS-21: Depression, Anxiety and Stress Scale-21
RCT: randomized control trial
SIQ: Suicidal ideation Questionnaire

Edited by J Torous; submitted 10.06.20; peer-reviewed by L Farrer, T Fleming; comments to author 15.07.20; revised version received 06.09.20; accepted 09.09.20; published 15.10.20.

Please cite as:
Kahl BL, Miller HM, Cairns K, Giniunas H, Nicholas M
Evaluation of ReachOut.com, an Unstructured Digital Youth Mental Health Intervention: Prospective Cohort Study
JMIR Ment Health 2020;7(10):e21280
URL: http://mental.jmir.org/2020/10/e21280/
doi:10.2196/21280
PMID:33055066

Original Paper

Performance, Cost-Effectiveness, and Representativeness of Facebook Recruitment to Suicide Prevention Research: Online Survey Study

Sylvia Lee[1*]; Michelle Torok[1*], PhD; Fiona Shand[1], PhD; Nicola Chen[1], PhD; Lauren McGillivray[1], PhD; Alexander Burnett[1], MPH; Mark Erik Larsen[1], PhD; Katherine Mok[1], PhD

Black Dog Institute, University of New South Wales, Sydney, Australia

[*]these authors contributed equally

Corresponding Author:
Michelle Torok, PhD
Black Dog Institute
University of New South Wales
Hospital Road
Sydney, 2031
Australia
Phone: 61 0415677477
Email: m.torok@unsw.edu.au

Abstract

Background: Researchers are increasingly using social media advertisements to recruit participants because of their many advantages over traditional methods. Although there is growing evidence for the effectiveness and cost-effectiveness of social media recruitment in the health sciences, no studies have yet examined this in the context of suicide prevention, which remains to be a highly stigmatized and sensitive topic.

Objective: This study aims to recruit a general community sample to complete a survey on suicide literacy, stigma, and risk via Facebook advertisements. Specifically, we aim to establish the performance of the advertisements, cost-effectiveness, sample representativeness, and the impact of gender-specific advertising on recruiting men into the study.

Methods: From June 2017 to March 2019, we released Facebook advertisements targeted at adults 18 years or older, residing in the New South Wales (NSW) trial or control regions, and involved in the LifeSpan suicide prevention trial. Cost-effectiveness was examined descriptively using metrics provided by Facebook. Chi-square analyses were conducted to determine demographic differences between our sample and the general NSW population as well as the impact of gender-specific advertisements on gender engagement.

Results: The 14 Facebook advertisement campaigns reached a total of 675,199 people, yielding 25,993 link clicks and resulting in 9603 individuals initiating the survey (7487 completions) at an overall cost of Aus $2.81 (US $2.01) per participant. There was an overrepresentation of younger (P=.003), female (P=.003), highly educated (P<.001) participants and mental health conditions (P<.001) compared with the total NSW population. The use of male-specific advertisements resulted in a significantly higher proportion of men completing the survey relative to gender-neutral advertisements (38.2% vs 24.6%; P<.001).

Conclusions: This study demonstrates the potential of Facebook to be an effective, low-cost strategy for recruiting a large sample of general community participants for suicide prevention research. Strategies to improve sample representativeness warrant further investigation in future research.

(JMIR Ment Health 2020;7(10):e18762) doi:10.2196/18762

KEYWORDS

research subject recruitment; social media; suicide

Introduction

Suicide is a significant and complex public health issue, with more than 800,000 deaths per annum [1]. It remains to be a largely unspoken and stigmatized topic in many countries, and this stigma may, in part, prevent individuals not only from seeking help [2-4] but also from participating in research which may advance our understanding of risk and protective factors.

To develop suicide prevention initiatives that address the needs of individuals and communities, measuring risk, suicide literacy, and stigma is necessary [5,6]. However, recruiting community-based participants into health survey research, specifically mental health, has historically been challenging [6-9]. Challenges include logistical barriers, such as geography, transportation, and time constraints [7], but also more complex personal factors, such as mistrust in research programs, concerns about privacy and confidentiality [10], and stigma surrounding mental health issues [11].

The growing reach of web-based social media platforms offers a new opportunity to enhance recruitment for suicide prevention research purposes [12]. For example, as of November 2019, Facebook had 2.45 billion active users per month [13], of which 15 million are Australians [14], positioning it as the largest social media platform globally. A systematic review conducted by Thornton et al [15] reports that more than 100 health-focused research studies have used Facebook as a recruitment strategy in the past decade, demonstrating its emerging appeal. Previous studies have used Facebook to not only recruit participants from the general community [9] but also to target audiences based on specific demographics, regional characteristics, or user interests [12,16]. Owing to Facebook's added advantages of anonymity and confidentiality, it has demonstrated potential in recruiting hard-to-reach individuals for research surrounding highly sensitive and stigmatizing issues, such as human immunodeficiency virus [17], mental health [9,12], sexuality [18], and substance use [19].

Another advantage of social media recruitment is its potential cost-effectiveness. A review of health research studies recruiting via Facebook advertisements found this approach to be considerably more affordable (an average of US $12.53, SD $23.16 per participant) [15] than traditional recruitment strategies, such as flyers, newspaper advertising, or face-to-face recruitment [9] and other web-based (non–social media) advertising strategies (up to US $66.15 per participant) [15,19,20]. However, the literature on cost-effectiveness has largely focused on substance use and smoking cessation [12], and no research studies have yet examined whether Facebook is a cost-effective recruitment approach in the field of suicide prevention. There may be variability in the cost-effectiveness of Facebook recruitment across research areas, particularly those perceived as more stigmatized, warranting the replication of such findings in the context of suicide prevention research.

Although Facebook has many potential advantages over traditional methods of participant recruitment, there is limited research examining the representativeness of participants recruited via Facebook [15,16]. Characteristics or populations that were most often reported to be overrepresented included younger participants [9,21,22], women [15,23], and those who were well educated [8,21,24]. The issue of representativeness is particularly pertinent in the conduct of a suicide prevention study, as certain populations (eg, men, older adults, and those from cultural and linguistically diverse minority groups) have a higher risk of suicide [25,26] but are less likely to participate in research [12,23]. The lower levels of research participation among these groups may be due to higher levels of stigma of suicide [27], perceived nonrelevance, or poorer internet access and social media usage [28]. Given that the use of Facebook recruitment in mental health research is increasing, it is important to investigate sample representativeness and whether specific advertising strategies can enhance representativeness, such as the use of gender-specific wording or imagery. To the best of our knowledge, this is the first study to report on whether the use of male-specific advertisements increases the response rates of men in mental health research.

Aims

To date, no studies have examined whether targeted, paid Facebook advertising can be used to recruit a large sample of community participants into suicide prevention research. Accordingly, this study aims to advance our understanding of the usefulness of Facebook advertising as a means of recruiting a general community sample into a survey on suicide risk, literacy, and stigma. The survey was delivered as part of a multilevel suicide prevention trial known as LifeSpan in New South Wales (NSW) [29]. LifeSpan is being implemented at 4 sites (Newcastle, Illawarra Shoalhaven, Central Coast, and Murrumbidgee), with 3 corresponding control sites: South Western Sydney, Nepean Blue Mountains, and Western NSW. The study addresses gaps in our understanding of how to improve sample representativeness by testing gender-specific advertisements against gender-neutral advertisements to examine whether this approach results in an increased rate of survey participation by men. The specific aims of this study were to (1) determine the cost-effectiveness of Facebook as a recruitment tool for suicide prevention research in the general population; (2) determine the performance of Facebook advertisements with respect to reach, views, and survey initiations and completions; (3) examine whether a representative community sample can be recruited through Facebook; and (4) examine whether gender-specific advertisements increase the rate of male participation.

Methods

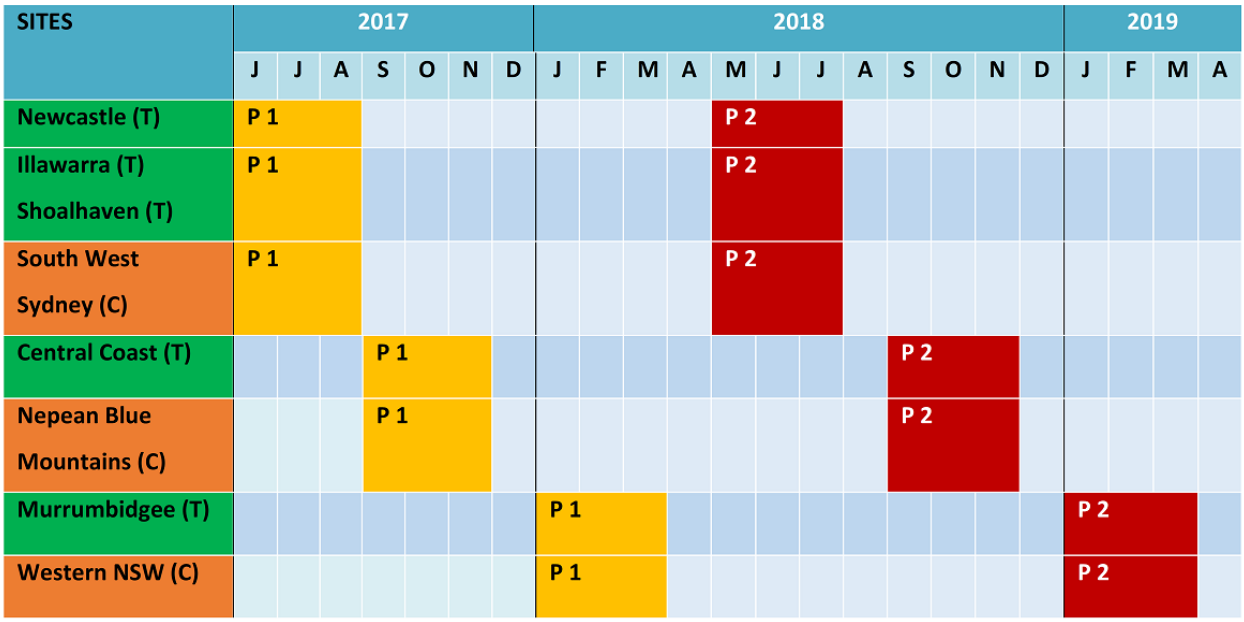
Study Design

The survey was delivered using a longitudinal panel design in which a group of community members at the LifeSpan intervention and control sites were followed up for over 2 years at multiple time points based on the formal implementation period of the trial (T0: baseline recruitment at 3 months before LifeSpan being delivered, T1: at 12 months postbaseline, and T2: at 24 months postbaseline). To account for potential attrition in the first panel, a second panel was recruited at the T1 time point of the first panel. This study examines the cost-effectiveness and feasibility of Facebook recruitment based on data from the baseline recruitment time point (T0) of the first and second panels.

Participants

In total, 14 unique Facebook advertisement campaigns were used to recruit participants from June 2017 to March 2019, over a 68-week recruitment period. The duration of each campaign ranged from 4 weeks to 16 weeks (Figure 1), and the duration was determined by an algorithm in Facebook based on the advertisements that were being viewed.

Figure 1. Baseline recruitment for Panel 1 and Panel 2 trial (T) and control (C) sites.



The Facebook advertisements were targeted at individuals whose profiles matched the following inclusion criteria: (1) 18 years or older, (2) residing in LifeSpan NSW trial regions or corresponding control regions, and (3) able to competently read and understand English.

There were no specific exclusion criteria.

Procedure

For the first panel (June 2017 to March 2018), targeted, paid Facebook advertisements containing a short headline (eg, "Lend a Voice to Suicide Prevention" or "Share a Voice to Help Out") were displayed to all users aged 18 years and older residing in one of the targeted locations. These advertisements included a generalized image and a brief description of the study.

For the second panel (May 2018 to March 2019), an additional set of Facebook advertisements was included with male-focused imagery (eg, photo of a man) and male pronouns in the advertisement wording ("voice of local blokes to help make it better"). The advertisements were also targeted specifically at men in each recruitment location according to Facebook user profiles. In panel 2, a Facebook pixel was also configured in the entry page of the survey link to improve conversion rates by tracking target user activity and remarketing the advertisements to those who were interested (clicked on survey link but did not complete the survey).

Once individuals clicked on the Facebook advertisements, they were directed to a web-based study portal where interested persons completed a brief eligibility screener. Eligible participants were directed to read a participant information sheet, and by starting the web-based survey, individuals consented to being involved in the study. Eligibility was determined by participants' age, postcode, and suburb, which had to map to the trial or control sites. Participants who were eligible to participate were provided with a link to a web-based survey. The survey included questions about basic demographic parameters (eg, age, gender, highest level of education, employment status, language spoken at home, marital status, ethnicity) and a series of suicide and help-seeking scales (Suicidal Ideation Attributes Scale, Distress Questionnaire-5, Stigma of Suicide Scale, Literacy of Suicide Scale, and Actual Help-Seeking Questionnaire) to measure the primary outcomes of interest for the broader LifeSpan study. At the end of the survey, participants were asked to provide their email ID if they consented to being contacted for follow-up research. No incentives were offered to the participants. To prevent duplicate entries, only one survey per internet protocol address per panel was accepted.

Participant Safety

Given the potentially distressing nature of the study, in the consent process, participants were provided with a clear outline of the aims of the research and the types of questions they would be asked as well as a list of helplines and help resources. These help resources were listed again at the end of the survey. Participants were reminded periodically throughout the survey that if they felt distressed at any time, they could immediately discontinue and contact their GP, one of the help resources provided, or a member of the research team for further assistance. This safety procedure was approved by the Hunter New England Local Health District Human Research Ethics Committee (approval number 16/09/21/4.05) and is consistent with the 2007 National Statement on Ethical Conduct in Human Research [30].

Measures

For the purposes of this study, the primary outcomes of interest were cost-effectiveness of Facebook recruitment, sample representativeness, and gender-specific engagement.

The effectiveness of the Facebook advertisements across the first and second panels at baseline (T0) recruitment was assessed using the following performance metrics provided by Facebook:

- *Reach:* number of Facebook users who saw the advertisement.
- *Link Clicks:* number of clicks the advertisement received.
- *Click through rate (CTR):* percentage of link clicks per reach.
- *Surveys started:* the total number of people who initiated the survey (partial survey completions+completions).
- *Completions:* number of completed surveys.
- *Conversion rate:* percentage of surveys started per link click.
- *Completion rate:* percentage of surveys completed per link click.
- *Cost per completion:* total costs of advertisements divided by number of survey completions (cost-effectiveness metric).

Cost-effectiveness was defined as the cost per completed survey and reported in Australian dollars. This was calculated by dividing the total cost spent on advertising across the entire recruitment period by the number of survey completions.

The representativeness of our sample was evaluated based on the self-reported sociodemographic characteristics, such as gender, age, language spoken at home, and highest level of education. These characteristics were compared with those of the total NSW population using nationally representative 2016 Australian census data [31] and mental health data from the NSW results of the 2017-2018 National Health Survey [32].

The performance of the gender-specific advertisements was measured by comparing the proportion of men and women who partially completed or completed the survey in panels 1 and 2.

Statistical Analysis

The results were analyzed using IBM SPSS statistical software version 25.0 [33]. Data were treated as missing if a question was skipped or not answered. The effectiveness and cost-effectiveness of the Facebook advertisements were analyzed descriptively using the performance metrics described earlier and by calculating the cost per completed survey, adopting a methodology similar to that of an earlier seminal study in this area [9]. Sample representativeness was assessed by comparing the demographic characteristics of participants who completed our survey with those of the general NSW population. Differences in proportions of characteristics were analyzed using the chi-square goodness-of-fit statistic to determine whether the survey initiators in our sample were consistent with the expected distribution in the NSW population. Differences between advertisement illustrations and the gender of participants were analyzed using the chi-square tests of independence, with odds ratio and 95% CIs reported. The alpha value was set at .05 for all analyses.

Ethics Approval

The Hunter New England Human Research Ethics Committee (HREC/16/HNE/399) approved this study. The privacy of all participants was maintained throughout the study. Participant data were not accessible to Facebook, and participants' Facebook data were not accessible to the researchers. The data provided by Facebook to the research team were at an unidentifiable aggregate level. For example, researchers were able to see the (ie, demographics [age, gender]) characteristics of the people who clicked on the advertisements. Any identifiable information collected was only used for the purposes of contact for follow-up. No individuals were identified in the reporting of results.

Results

Facebook Advertising Campaign—Recruitment Rate

During the recruitment period (June 2017 to February 2019), the Facebook advertisements reached a total of 675,199 people, yielding 25,993 link clicks (CTR=3.85%). Of those who clicked on the link, 7478 (77.88%) people completed the web-based survey (n=3224 in panel 1; n=4254 in panel 2) and 2125 (22.12%) people partially completed the survey (n=786 in panel 1; n=1339 in panel 2. Table 1 describes the performance of the advertisements according to Facebook metrics across the first and second panels of recruitment.

Table 1. Facebook recruitment advertisement performance across all sites.

Facebook metrics	Panel 1	Panel 2	Overall
Reach, n (%)	413,742 (61.28)	261,457 (38.72)	675,199 (100)
Link clicks, n (%)	15,291 (58.83)	10,702 (41.17)	25,993 (100)
Click through rate, %	3.70	4.09	3.85
Surveys started[a], n (%)	4010 (41.76)	5593 (58.24)	9603 (100)
Surveys completed, n	3224 (43.11)	4254 (56.89)	7478 (100)
Conversion rate, %	26.22	55.26	36.94
Completion rate, %	21.08	39.75	28.77

[a]Survey started=partially completed surveys+completed surveys; click through rate=percentage of link clicks divided by reach; conversion rate=percentage of completions divided by link clicks; completion rate=percentage of completions divided by link clicks.

Cost-Effectiveness

Table 2 displays the cost-effectiveness of Facebook advertisements in this study and provides comparisons with earlier studies. The overall expense was Aus $20,997.97 (US $15,055.97), with an average cost per participant of Aus $2.81 (US $2.01), with specific costs per panel described in Table 2. The costs reported for this study were commensurate with those of other studies that have recruited Australian general community adults (R: Aus $0.55-Aus $9.82 [US $0.39-$7.04]) but lower than those of studies that were conducted primarily overseas [12,27,28]. The Australian-based studies all recruited samples from the general population, whereas two of the international studies [12,27] recruited specific populations where subthreshold or full diagnostic mental health symptoms were the eligibility criteria.

Table 2. Cost-effectiveness comparison of this study with prior mental health studies using social media recruitment methods.

Studies	Recruitment target	Country from which the participants were recruited	Total cost of advertisements Aus $ (US $)	Completed surveys (n)	Cost per participant Aus $ (US $)
This study					
First panel	Suicide in adults aged ≥18 years from general community	Australia/NSW	14,497.97 (US $10,388.17)	3224	4.50 (US $3.23)
Second panel	Suicide in adults aged ≥18 years from general community	Australia/NSW	6500.00 (US $4,660.63)	4254	1.53 (US $1.10)
Prior studies					
Batterham (2014)—round 1 recruitment [9]	Mental health; adults aged ≥18 years from general community	Australia	12,600 (US $9034.45)	1283	9.82 (US $7.04)
Batterham (2014)—round 2 recruitment [9]	Mental health; adults aged ≥18 years from general community	Australia	920 (US $659.66)	610	1.51 (US $1.08)
Choi et al (2017) [34]	Mental health in men aged ≥18 years from general community	Australia	500 (US $358.50)	398	0.55-3.85 (US $0.39-$2.76)
Chu and Snider (2013) [35]	Posttraumatic stress disorder in Canadian youth (aged 15-24 years) affected by violence	Canada	1508.26 (US $1081.45)	88	17.13 (US $12.28)
Morgan et al (2013) [12]	Adults with subthreshold symptoms of depression	Australia, New Zealand, the United Kingdom, Ireland, Canada, the United States	696.15 (US $499.15)	35	19.89 (US $14.26)
Youn et al (2013) [36]	Depression in students across 5 colleges	The United States	338.8 (US $242.93)	20	16.94 (US $12.15)

Sample Representativeness

Table 3 compares the characteristics of our sample with those of the total NSW population from which the survey respondents were recruited. Those who completed the survey (*completers*) and the survey initiators differed significantly on all variables compared with the referent NSW population. Compared with the NSW population, our sample had a significantly higher proportion of women (66.5%) and an underrepresentation of older adults (≥60 years) in our sample (14.2%). Our samples were also significantly more likely to have tertiary qualifications and to primarily speak English at home than the broader NSW population. Significantly elevated rates of mental health conditions were reported by our sample.

Table 3. Demographic and mental health characteristics of survey respondents compared with those of the New South Wales general population.

Characteristics	Partial completers, n %	Completers, n %	Survey initiators[a], n %	NSW[b] general population, %	Completers versus NSW		Survey initiators versus NSW	
					Chi-square (*df*; number of participants included in the sample)	*P* value	Chi-square (*df*)	*P* value
Gender					10.24 (1, n=8821)	.002	9.01	.003
Female	894 (62.5)	4971 (67.31)	5,865 (66.49)	3,794,217 (50.72)				
Male	537 (37.5)	2419 (32.69)	2,956 (33.51)	3,686,014 (49.28)				
Age (years)					11.75 (1, n=8839)	.003	11.75	.003
18-34	448 (31.1)	2,139 (28.91)	2,587 (29.27)	1,647,194 (27.5)				
35-59	757 (52.6)	4,241 (57.32)	4,998 (56.54)	2,450,605 (43.5)				
≥60	235 (16.3)	1,019 (13.77)	1,254 (14.18)	1,637,690 (29.0)				
Language at home					9.47 (1, n=9524)	.002	7.67	.006
English only	2,122 (100)	7,274 (98.27)	9,396 (98.66)	5,126,633 (87.45)				
Language other than English	0	128 (1.7)	128 (1.3)	735, 563 (12.55)				
Highest education[c]					22.76 (1, n=8885)	<.001	19.38	<.001
Less than year 12	220 (15.2)	759 (10.2)	979 (11.0)	1,479,305 (32.54)				
Year 12	240 (16.6)	962 (12.9)	1,202 (13.52)	930,654 (20.47)				
Tertiary qualification	986 (68.2)	5,718 (76.86)	6,704 (75.45)	2,135,805 (46.98)				
Mental health condition					149.71 (1, n=8884)	<.001	145.54	<.001
Yes	976 (67.5)	4,969 (66.79)	5,945 (66.9)	1,428, 724 (19.09)				
No	469 (32.5)	2,470 (33.21)	2,939 (33.08)	6,051,507 (80.91)				

[a]Survey initiators=partial completers+completers.

[b]NSW: New South Wales.

[c]Year 12 is the final year of high school equivalent according to the Australian education system; note: for all categories missing or unknown responses were excluded from percentage calculations.

Gender-Specific Advertisement Effects

Multimedia Appendix 1 shows an example of the gender-neutral advertisements used in panel 1 recruitment (advertisement 1 and advertisement 2) as well as examples of advertisements targeted toward men using different language and imagery (advertisement 3 and advertisement 4) in panel 2.

Table 4 shows the proportion of male and female participants recruited for each of the 2 panels (panel 1: gender-neutral advertisements; panel 2: gender-focused advertisements). The chi-square analysis showed significant gender differences in recruitment responses across the 2 panels for survey completions and for partial completions, with an increase observed in the proportion of male respondents in panel 2 and a decrease in female respondents relative to panel 1.

Table 4. Gender of participants across panels of recruitment.

Survey completion status	First panel recruitment: gender-neutral advertisements	Second panel recruitment: gender-specific advertisements	Chi-square (*df*; number of participants included in the sample)	*P* value	OR (95% CI)
Survey completers, n (%)			159.4 (1, n=7390)	<.001	1.92 (1.25-1.35)
Male	793 (24.6)	1626 (38.22)			
Female	2402 (74.50)	2569 (60.39)			
Other/unknown[a]	29 (0.9)	59 (1.4)			
Total	3224 (100)	4254 (100)			
Partial completions, n (%)			17.21 (1, n=1431)	<.001	1.63 (1.30-2.05)
Male	157 (20.0)	380 (28.4)			
Female	360 (45.8)	534 (39.9)			
Other/unknown[a]	269 (34.2)	425 (31.7)			
Total	786 (100)	1 339 (100)			

[a]This group is not included in chi-square analyses; partial completions=started surveys but did not finish.

Discussion

Performance and Cost-Effectiveness Findings

This is the first study to examine the cost-effectiveness and representativeness of Facebook as a recruitment medium for suicide prevention research. Facebook was found to be an effective platform for recruiting a large sample of community members at a relatively low cost (average cost of Aus $2.81 [US$2.01] per survey completed). The overall cost per participant compared favorably with prior mental health studies that recruited similar populations, that is, adults from the general population [9,35], and costs were much lower than those of studies that recruited more specialized populations, with more stringent eligibility criteria, such as the presence of a particular health condition. Smaller pools of participants from which to draw from may prolong recruitment periods, resulting in larger advertising expenses over longer durations to meet recruitment targets. The estimated costs per survey completion were also lower than those reported for traditional recruitment methods, such as postal surveys or telephone calls, which are reported to range in cost from Aus $19.10 [9] to Aus $24.75 [37] per survey. This study adds to a growing body of evidence that supports the cost-effectiveness of social media recruitment strategies, particularly for general community samples.

The advertising campaign also had strong positive engagement, with more than 25,000 people clicking on the survey link. This resulted in a substantially higher CTR than the average Facebook advertising rate of 0.90% and the benchmark rate for health care industry standards (0.83%) [38], potentially highlighting the salience of the research topic. However, the large number of link clicks did not translate to a large number of survey initiations or completions, with just over two-third starting the surveys and approximately one-fourth completing them. This divergence between link clicks and survey completion is consistent with prior research, which has found that Facebook users tend to click advertisement links on impulse and lack the commitment to see the task through to its end [16,39]. In our second panel, however, we observed an increase in conversion rates and lower cost per participant, despite the lower total cost spent compared with the first panel. This could partly be because of an increased interest in, or awareness of, the LifeSpan trial, which was in its second year of implementation at the time of recruitment of the second panel. This improved result could also be because of the installation of a Facebook pixel during the second panel of recruitment, which tracks user activity after they see the Facebook advertisement and retargets users who are interested (ie, visited the Facebook page or clicked on the survey link but did not complete the survey). The pixel also optimizes conversions by automatically allocating more money to advertisements with greater success rates (higher conversions) and less money to advertisements that are performing poorly. As such, the use of Facebook pixels may be a promising approach to social media recruitment strategies in future studies.

Representativeness

The findings from this study indicated that there were significant differences in demographic and mental health characteristics of our sample and those of the target general population in NSW. Our participants were more likely to be younger, female, better educated, and less culturally diverse (eg, most participants could only speak English) compared with the overall NSW population. These findings are largely consistent with findings from prior research on general population samples [9,16,21]. Although Facebook mainly constitutes younger users, there is evidence that Facebook is gaining popularity among older user groups [40,41], suggesting that there is potential to increase engagement with older adult populations in web-based surveys over time.

The higher education levels seen in our sample are not only consistent with those reported in prior samples recruited via Facebook [42] but also similar to patterns of educational attainment in participants recruited through traditional recruitment strategies [42,43]. This suggests that, generally, people with higher education levels tend to engage in health research studies, potentially because of greater levels of health literacy and increased awareness of their importance. Although the high levels of English-speaking participants in this sample

could indicate that those from culturally and linguistically diverse backgrounds may experience barriers engaging in health research, it may also simply be an artifact of our eligibility criteria, which required proficiency in English.

There were also significantly higher rates of mental health conditions in our sample compared with the general NSW population. Previous mental health research has similarly observed elevated rates of mental health problems among participants relative to the general Australian population [9]. Such overrepresentation may reflect a potential self-selection bias, with individuals experiencing mental health problems more inclined to participate in mental health research because the subject matter interests or concerns them. The degree to which these differences will have significant implications for the validity of the study depends on the research topic and design. As suicide is one of the leading causes of death among young depressed people [1], having overrepresentation of young people and people with mental health disorders may be useful in understanding risks and help-seeking behaviors for suicidality. However, in community research that is intended to understand the prevalence of stigma and awareness of suicide in the general community, such overrepresentation may be a shortcoming of the study.

The final aim was to evaluate the impact of gender-specific advertisement content on recruitment rates. Consistent with recent studies, our findings from the first panel of recruitment suggest that men are more difficult to recruit than women and are underrepresented in health research studies. The introduction of targeted, gender-specific advertisements (using colloquial language such as *blokes* in text captions) appeared to appeal to Australian men, with significant improvement in the number of men responding to the survey in panel 2 compared with panel 1. The effectiveness of using male- or female-specific imagery and/or wording has been demonstrated in only a few previous studies of social and health factors [24,35] but suggests that men are more likely to participate when they are specifically called to action. As suggested by Fenner and Garland [8], Facebook recruitment has a great potential to yield a demographically representative sample by oversampling specific subgroups of the population. In research studies where men present a higher risk of a health problem, consideration should be given to allocating a budget for the design and development of male-specific advertisements. In addition, novel techniques such as machine learning, which analyzes patterns of how men use social media compared with women and how they engage in health content on the web, might provide valuable new insight into reaching men for health research purposes using Facebook advertisements.

Limitations

As with all studies, this study is not without limitations. Our study recruited a general population sample from selected trial and control sites in NSW, Australia. As such, the findings of this study may not be generalizable to different populations and settings. Relatedly, we acknowledge that we have only captured and reported on very few demographic and mental health factors in this study as measures or *representativeness*. The decision regarding what factors to report on for representativeness was limited by the availability of matched NSW population-level data; however, we fully acknowledge that these variables are a limited measure of *representativeness*. To fully describe the representativeness of Facebook or social media recruited samples, future studies should look to capture precise measures of socioeconomic variables, employment, sexuality, and cultural and linguistic diversities, giving careful consideration to measures that are consistent with census data or national surveys for comparability. In addition, although the advertisements had high levels of reach (exposure), comparatively fewer people went on to initiate the survey. Without person characteristic data on the group exposed (vs the survey initiators), we are not able to determine whether representativeness issues are an artifact of the archetypal Facebook user (ie, are younger, better educated persons) and therefore underrepresented groups are not seeing the advertisements (eg, older people, less educated people) or whether underrepresented groups do not want to participate in research studies. If representativeness issues are to be addressed, future research should seek to determine whether underrepresentation is because of exposure, motivational, or access-related reasons.

Furthermore, when determining the feasibility of using Facebook advertisements to recruit participants, it is worth considering that we do not know if the participants who clicked on the advertisements and completed the survey were the same people who were exposed to the Facebook advertisement campaigns. This is because Facebook recruitment is liable to uncontrolled snowballing, as participants could *share* the survey link or *tag* Facebook friends that they think would be interested in the study. Future studies that examine Facebook's advertising to recruit participants should collect information about how an individual was exposed to the study and implement pixels to further study participant conversion patterns.

Finally, the strategy we used to improve gender (specifically male) representativeness in this study (ie, male-centric wording and masculine imagery) may not be appropriate to redress imbalances in the participation of other demographic groups, such as the poorly educated or older adults. For such groups, access to social media itself might be a key barrier to participation in web-based surveys. Strategies to improve engagement with these groups might include targeting the family or peer social media networks of these groups to promote research studies and assist these groups in participating. Understanding what strategies work to improve participation in groups of interest is an area that warrants investigation in future studies.

The findings indicate that advertising suicide prevention research using Facebook is a feasible and cost-effective way to recruit a community-based sample. Preliminary evidence suggests that gender-specific advertisements improve male participation in the study, and this gain warrants further replication and investigation in future evaluations of social media recruitment strategies, particularly to better understand individuals' motivations for participating in research studies. Such information could assist in developing strategies to optimize the recruitment and representativeness of samples; this might be particularly important for studies where higher levels of participation of a known *high risk* group is important. As the

functionality of Facebook is advancing rapidly, emerging marketing features such as Facebook pixels or machine learning algorithms could be tested in future studies to advance the optimization and cost-effectiveness of recruitment.

Acknowledgments

This study was supported by a philanthropic grant from the Paul Ramsay Foundation for the LifeSpan suicide prevention trial.

Authors' Contributions

All authors have made significant contributions to the manuscript. KM, MT, FS, ML, and LM designed the study and planned the statistical analysis. SL analyzed the data, with assistance from NC and AB. SL wrote the first draft of the manuscript. All authors contributed to the interpretation and subsequent editing of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of advertisements across panels and advertisement performance metrics.
[DOCX File , 240 KB - mental_v7i10e18762_app1.docx]

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Abbreviations

CTR: click through rate
NSW: New South Wales

Edited by G Eysenbach; submitted 17.03.20; peer-reviewed by W Guo, R Melia, S Ferguson, K Reuter; comments to author 18.08.20; revised version received 20.09.20; accepted 21.09.20; published 22.10.20.

Please cite as:
Lee S, Torok M, Shand F, Chen N, McGillivray L, Burnett A, Larsen ME, Mok K
Performance, Cost-Effectiveness, and Representativeness of Facebook Recruitment to Suicide Prevention Research: Online Survey Study
JMIR Ment Health 2020;7(10):e18762
URL: http://mental.jmir.org/2020/10/e18762/
doi:10.2196/18762
PMID:33090115

Original Paper

Preliminary Outcomes of a Digital Therapeutic Intervention for Smoking Cessation in Adult Smokers: Randomized Controlled Trial

Jamie Webb[1], BSc (Hons), MRes; Sarrah Peerbux[2], BA (Hons), MSc; Peter Smittenaar[1], BSc, MSc, PhD; Sarim Siddiqui[1], BSc (Hons), MBBS; Yusuf Sherwani[1], BSc (Hons), MBBS; Maroof Ahmed[1], BSc (Hons), MBBS; Hannah MacRae[1], BA, DClinPsych; Hannah Puri[1], BSc (Hons); Sangita Bhalla[1], BSc (Hons); Azeem Majeed[2], MD, FRCP, FRCGP, FFPH

[1]Digital Therapeutics Inc, San Francisco, CA, United States

[2]Imperial College London, London, United Kingdom

Corresponding Author:
Jamie Webb, BSc (Hons), MRes
Digital Therapeutics Inc
2443 Fillmore St
San Francisco, CA, 94115
United States
Phone: 1 650 684 5503
Email: jamie@quitgenius.com

Abstract

Background: Tobacco smoking remains the leading cause of preventable death and disease worldwide. Digital interventions delivered through smartphones offer a promising alternative to traditional methods, but little is known about their effectiveness.

Objective: Our objective was to test the preliminary effectiveness of Quit Genius, a novel digital therapeutic intervention for smoking cessation.

Methods: A 2-arm, single-blinded, parallel-group randomized controlled trial design was used. Participants were recruited via referrals from primary care practices and social media advertisements in the United Kingdom. A total of 556 adult smokers (aged 18 years or older) smoking at least 5 cigarettes a day for the past year were recruited. Of these, 530 were included for the final analysis. Participants were randomized to one of 2 interventions. Treatment consisted of a digital therapeutic intervention for smoking cessation consisting of a smartphone app delivering cognitive behavioral therapy content, one-to-one coaching, craving tools, and tracking capabilities. The control intervention was very brief advice along the Ask, Advise, Act model. All participants were offered nicotine replacement therapy for 3 months. Participants in a random half of each arm were pseudorandomly assigned a carbon monoxide device for biochemical verification. Outcomes were self-reported via phone or online. The primary outcome was self-reported 7-day point prevalence abstinence at 4 weeks post quit date.

Results: A total of 556 participants were randomized (treatment: n=277; control: n=279). The intention-to-treat analysis included 530 participants (n=265 in each arm; 11 excluded for randomization before trial registration and 15 for protocol violations at baseline visit). By the quit date (an average of 16 days after randomization), 89.1% (236/265) of those in the treatment arm were still actively engaged. At the time of the primary outcome, 74.0% (196/265) of participants were still engaging with the app. At 4 weeks post quit date, 44.5% (118/265) of participants in the treatment arm had not smoked in the preceding 7 days compared with 28.7% (76/265) in the control group (risk ratio 1.55, 95% CI 1.23-1.96; P<.001; intention-to-treat, n=530). Self-reported 7-day abstinence agreed with carbon monoxide measurement (carbon monoxide <10 ppm) in 96% of cases (80/83) where carbon monoxide readings were available. No harmful effects of the intervention were observed.

Conclusions: The Quit Genius digital therapeutic intervention is a superior treatment in achieving smoking cessation 4 weeks post quit date compared with very brief advice.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN) 65853476; https://www.isrctn.com/ISRCTN65853476

(JMIR Ment Health 2020;7(10):e22833) doi:10.2196/22833

KEYWORDS

digital; smoking; cessation; mobile; randomized controlled trial; app; mobile phone; mHealth

Introduction

Background

Smoking is a leading cause of preventable and premature death worldwide. It is an important risk factor for serious health problems and life-threatening diseases [1]. Globally, tobacco use causes more than 8 million yearly deaths [2]. Moreover, the total global economic cost of smoking is more than $1.4 trillion a year [3]. Smoking is, therefore, a major worldwide economic and public health concern [1-3].

In the United Kingdom, very brief advice (VBA) is the recommended clinical practice for smoking cessation for all health care practitioners [4,5]. It is designed to promote quit attempts and to be used opportunistically in virtually any situation [4,5]. Those interested in quitting are referred to their local stop smoking service [4], which typically combines face-to-face behavioral support with the option of pharmacotherapy, offered as nicotine replacement therapy (NRT) or varenicline. Similarly, in the United States, smokers can access free telephone services and tobacco cessation websites that provide access to pharmacotherapy and additional behavioral support [6].

Despite traditional smoking cessation programs demonstrating efficacy, they only help about 8% of smokers to quit long-term [7]. Such programs have been shown to have limited utilization due to scheduling, time, and financial constraints [8,9]. Telephone support can overcome these barriers but reaches only about 1% of smokers annually [10]. Given that support may be difficult to access, there is an urgent need for alternative solutions that are cost-effective, convenient, and scalable.

Technological advancements have led to new approaches that aim to overcome the drawbacks of conventional smoking cessation programs. Smartphone apps are one new approach with the potential to support behavior change [11,12]. They have been used successfully across a multitude of therapeutic areas, including chronic conditions [13-15] and the promotion of healthy behaviors [16-22].

Smartphone apps have advantages over traditional approaches, including ease of accessibility, personalization of interactions with real-time feedback, scalability to large populations, and cost-effectiveness [23]. In 2018, the number of mobile phone subscriptions topped 8 billion globally [23]. Smartphone apps have the potential to reach smokers who would not or are unable to use traditional services.

However, there is a paucity of data that examine the efficacy of smartphone apps for smoking cessation. A review of mobile phone–based smoking support identified only 5 randomized controlled trials (RCTs) that tested the effectiveness of smartphone apps with low-intensity support, with each showing limited efficacy [23]. Furthermore, a recent content analysis revealed low adherence of existing smartphone apps to evidence-based treatment guidelines [24], while a review of the 50 most downloaded cessation apps found only 2 with scientific support [25].

Digital therapeutic interventions are a new wave of smartphone apps that can deliver high-intensity evidence-based therapeutic programs. Emerging evidence is encouraging and suggests that high-intensity support delivered via digital therapeutic interventions can aid smoking cessation. However, many promising early studies suffer from limitations, such as using single-arm cohorts or solely relying on self-reported abstinence without biochemical verification to assess intervention efficacy [19-22]. To date, very few RCTs have been conducted on digital therapeutic interventions for smoking cessation [26-28].

Objectives

This study had several objectives. The first objective of this study was to test the preliminary effectiveness of the digital therapeutic intervention Quit Genius (QG) by measuring 7-day point prevalence abstinence at 4 weeks post quit date. Other objectives included assessing user engagement with QG, as well as testing its effect on cognitive, attitudinal, and emotional outcomes.

Methods

Design

We conducted a 2-arm, single-blinded, parallel-group, preregistered randomized controlled trial with 4-week, 6-month, and 12-month follow-up. This trial report is in accordance with the Consolidated Standards of Reporting Trials (CONSORT) checklist. Here we report the primary outcomes at 4 weeks only, as data collection for later time points is still ongoing. Approval was granted by the Health and Social Care Research Ethics Committee A (reference 18/NI/0171) and this research complies with the Declaration of Helsinki.

Participants

Participants were recruited in the United Kingdom between January and November 2019. Adult smokers (aged 18 years or older) were invited to participate if they had been smoking at least 5 cigarettes a day for the past year, were not using any other form of stop smoking support, and had sufficient mobile phone functionality (fifth generation or higher for Apple iPhone or version 18 or higher for Android). The exclusion criteria were not speaking English, pregnancy, chronic obstructive pulmonary disease, psychiatric medication, and a serious health condition that would substantially hinder completion of the intervention or control, as determined by the study team. Participants with serious health conditions or using psychiatric medication were ruled out as a safety consideration.

Participants were recruited offline from primary care practices across London via SMS text messaging campaigns. Posters and leaflets at local community venues and advertisements on social media were also used. Recruitment advertisements and study information given to participants described the opportunity of being allocated to one of 2 possible behavioral interventions,

in addition to optional NRT. No mention of a digital intervention was made to the participants before randomization. Participants randomized into the study received £10 (US $12.82) to offset travel expenses. Participants completed a questionnaire online or via the telephone at 4 weeks after their quit date and were paid £20 (US $25.63) for completion.

Registration

The trial was registered in the International Standard Randomized Controlled Trial Number (ISRCTN) database (ISRCTN65853476) on December 18, 2018. On July 24, 2019, we adjusted the primary outcome to equate it with the majority of trials on smoking cessation. Specifically, the time window for assessing whether the participant had successfully quit was reduced from 2 weeks to 1 week. The previously approved primary outcome related to the Russell Standard (ie, self-reported abstinence in the past 2 weeks at 4 weeks post quit date). This was changed to capture self-reported 7-day point prevalence abstinence at 4 weeks. This decision was informed in part by a recent Delphi study, which found only partial compliance with the Russell Standard, as reported by smoking cessation experts [29]. Although we acknowledged a lack of consensus relating to outcome criteria in smoking cessation research, it was our opinion that the use of 7-day point prevalence is preferable to 14-day point prevalence, as it allows for greater comparability with other studies. Amending the primary outcome to 7-day point prevalence allowed for greater comparison with other studies of face-to-face, digital, and other low-intensity intervention smoking cessation trials (full justification is available on the ISRCTN page). This decision was made without having analyzed trial outcomes. The 14-day point prevalence was added as a secondary outcome. Another secondary outcome (number of quit attempts up to week 4 post quit date) is reported here as "any additional quit attempt after the quit date" because a continuous test was not appropriate on the distribution, which was predominantly 1 quit attempt. All other adjustments to the trial registration only concerned start and end dates of recruitment and publication to account for unexpected challenges in recruitment.

Randomization and Masking

Participants were randomized 1:1 (treatment:control) using a block size of 4 participants through the trial management system Curebase (Curebase Inc) [30]. Researchers randomizing participants were blind to allocation until they had performed the randomization.

Procedures

At first contact (via phone or online), participants were provided with study information and completed a questionnaire to determine eligibility. If eligible, participants were invited to attend an in-person baseline session where eligibility was reconfirmed and informed consent and baseline data were collected. Participants were then randomized. All participants were recommended to set their quit date within 2 weeks of randomization, but this was not a mandatory requirement for study participation. All participants were offered NRT in addition to their allocated intervention. At 4 weeks post quit date, participants were invited to complete the follow-up survey (via phone or online).

Treatment Intervention: Quit Genius

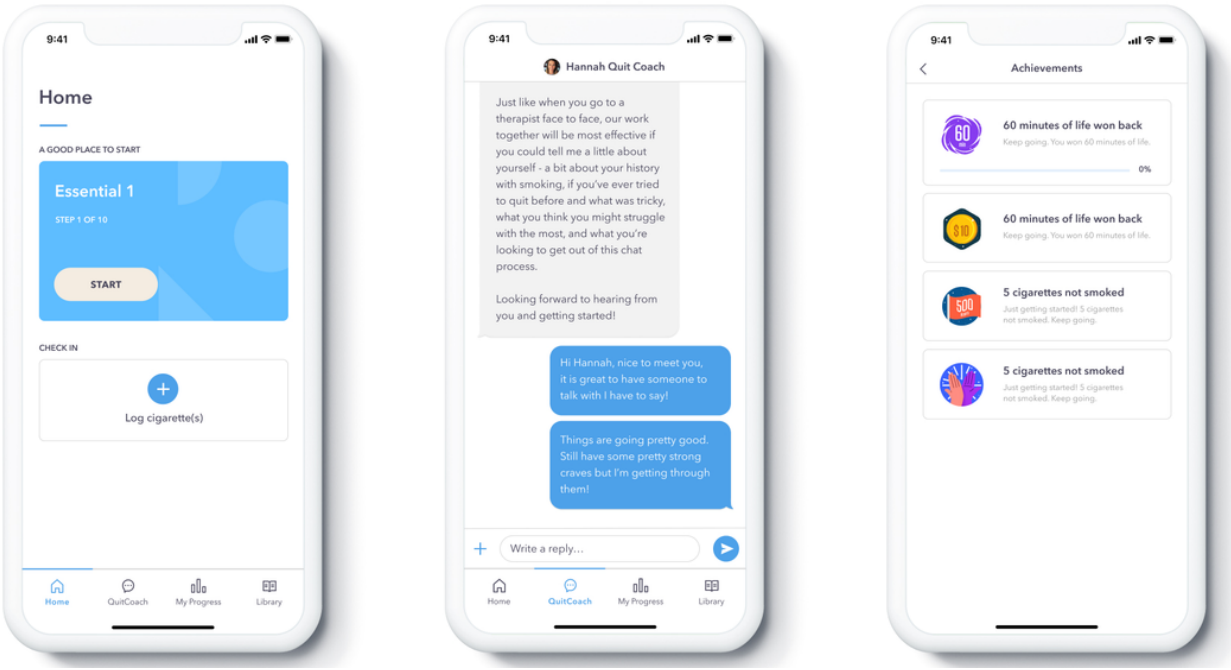
Quit Genius is a digital therapeutic intervention comprising a smartphone app informed by the principles of cognitive behavioral therapy (CBT) [31]. It is a year-long program designed to support the user both before and after their quit date. Quit Genius delivers intervention components that have demonstrated efficacy in promoting smoking cessation, including self-monitoring, goal setting, encouraging medication adherence, and providing feedback on progress. QG was developed over many iterations, including engagement with smokers, patient representatives, and scientific advisors. The app collects data on users through in-app metrics to help personalize the program. Metrics include usage, session completion, program completion, and quit date. Additional data are collected based on user participation and feedback following CBT exercises, providing information such as the user's reasons for quitting smoking and the reasons why they continue to smoke.

Content is tailored to the user and delivered in the form of animated videos, audio sessions, reflective exercises, and quizzes. The user is prompted to complete a series of self-paced steps on their smoking cessation journey, with each new step (and content) unlocking only once the previous step has been completed. The program content is divided into 2 stages. The "Essentials" stage, in which the user is prompted to complete a series of different steps before their quit date, covers aspects such as preparing for the quit date, using nicotine replacement therapy, and thinking about the reasons for quitting. The "Sustain" stage, which the user completes once they quit smoking, focuses on the general principles of relapse prevention and helps the user to stay smoke free in the long-term. In the time leading up to their quit date, users are encouraged to monitor their smoking habits daily by logging the number of cigarettes smoked, their triggers (how they felt when they wanted to smoke), and the intensity of their craving. Once the user has quit smoking, they are encouraged to log whether they are currently smoking.

As part of the QG digital therapeutic intervention, participants also have access to a quit coach, an advisor qualified by the National Centre for Smoking Cessation and Training (NCSCT). The coach provides personalized CBT-based support via a digital chat interface and the phone. Typically, participants partake in an initial phone call, with the rest of the quit coach interaction mediated through the in-app digital chat interface. Users can monitor their progress via the app, which details improvements to health and any financial benefits gained from being a nonsmoker since their quit date. Finally, users can access the "Craving Toolbox," which comprises audio content of short breathing exercises, mindfulness exercises, and meditation exercises designed to help the user manage their cravings to smoke. The QG app uses CBT to target not only smoking cessation but also skills and strategies to promote improved mental health and well-being. While the QG app does not substitute professional care for mental health concerns, the app specifically addresses common mental health concerns such as

low mood, anxiety, stress, self-esteem, and social skills. The app also specifically targets general health and well-being concerns, such as diet, exercise, and self-care techniques. Specific skills and techniques used include goal setting, cognitive restructuring, graded exposure, progressive muscle relaxation, mindfulness, assertiveness and communication training, and problem-solving skills. QG users receive push notifications to serve as reminders to engage with the app. All participants in the treatment group received free access to the QG intervention (screenshots shown in Figure 1).

Figure 1. Screenshots of the digital therapeutic intervention Quit Genius.



Control Intervention: Very Brief Advice

VBA is a simple form of advice designed to be used opportunistically. It follows the Ask, Advise, Act structure, as recommended by the UK government. Participants were advised to contact their local stop smoking service to access support and medication to quit smoking. Trial assistants were trained in the delivery of VBA, as per NCSCT guidelines. For the control group participants allocated a carbon monoxide (CO) device, a nonbranded mobile app (ASH app) was also provided to visualize CO readings for the participant. The control group mobile app was only used in conjunction with the CO device and contained no other content for participants.

Nicotine Replacement Therapy

All participants had the option to receive nicotine replacement products (2-mg or 4-mg gum and 16-hour or 24-hour patches) free for 12 weeks, with the first 2-week supply issued at the baseline visit. Participants were allowed to purchase alternative forms of oral NRT.

Carbon Monoxide Monitor

Half of all participants were given a CO monitor (Smokerlyzer; coVita Inc) to measure levels of carbon monoxide in their breath and to validate self-reported smoking abstinence. Participants were selected pseudorandomly to ensure 50% of each group was assigned a device. Devices were provided to 50% of participants for cost considerations and to explore if being assigned a CO monitor would affect quit rates between subgroups. CO levels were collected via self-reporting at 4 weeks post quit date. The CO devices plugged into the headphone or charging slot of participants' smartphones and were used in conjunction with the QG and control app. At the follow-up time point, participants were asked to give a reading from their device via the phone or online. NCSCT guidelines of a CO reading less than 10 ppm were used to validate participants' self-reported abstinence [32].

Engagement

Engagement with the digital therapeutic intervention was measured via app opens, weeks actively using the app (defined as logging in to the app), stage progression through education and CBT components, number of messages sent between the participant and quit coach, check-ins (defined as a self-report of smoking status, that is, yes or no smoking after quit date), and diary entries (defined as registration of a cigarette before or after quit date using the in-app diary).

Outcomes

Measurements were taken at baseline and at the 4-week follow-up. The following variables were collected at baseline: demographic details, smoking status, smoking history, expired carbon monoxide level, Fagerström Test for Nicotine Dependence [33], Smoking Abstinence Self-efficacy Questionnaire (SASEQ) [34], Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [35], short version of the World Health Organization Quality of Life (WHOQOL-BREF) [36], and the service use questionnaire [37]. At 4 weeks post quit date, smoking status, changes in attitudes and perceptions of smoking, SASEQ, WEMWBS, and WHOQOL-BREF were collected. Expired carbon monoxide level was collected only

in those participants who were assigned their own device. Measurements were collected via online questionnaires.

The primary outcome was self-reported 7-day point prevalence abstinence at 4 weeks post quit date. Secondary outcomes at week 4 were 14-day point prevalence abstinence, any additional quit attempts after the quit date, self-reported changes in confidence levels, knowledge, attitudes and perceptions related to smoking cessation, changes in SASEQ and WEMWBS, and satisfaction with the treatment intervention (treatment group only).

Data Analysis

At 4 weeks, we expected to observe a 7-day abstinence rate of 25% in the treatment group and 10% in the control group. At a type I error rate of 5% and power of 90%, we required 133 participants per group (266 total). At 6 months, a conservative estimate would be a 10% quit rate in the treatment group and 3% quite rate in the control group. To detect a difference with 80% power and 5% type I error, we needed to randomize 194 participants per group (388 total). Assuming a 20% dropout, we aimed to recruit at least 500 participants.

We performed both intention-to-treat (ITT) [38] and per-protocol (PP) analyses. ITT included all participants assigned to treatment and control. ITT analysis assumed that participant data were not missing at random. PP included the subset of participants that provided answers to the self-reported outcomes at week 4.

We used chi-square tests for binary outcomes and 2-sample 2-tailed *t* tests for continuous outcomes. Those lost to follow-up at 4 weeks were considered as currently smoking for the primary outcome and 2-week abstinence. They were also considered as making no additional quit attempts after the quit date; not choosing “strongly agree” to improvements in confidence, knowledge, or attitude; and showing no change in self-efficacy or mental well-being from baseline. We used logistic regression to estimate the main effect of being assigned a CO device on likelihood of quitting, with treatment assignment as a covariate in the model. We made no corrections for multiple comparisons.

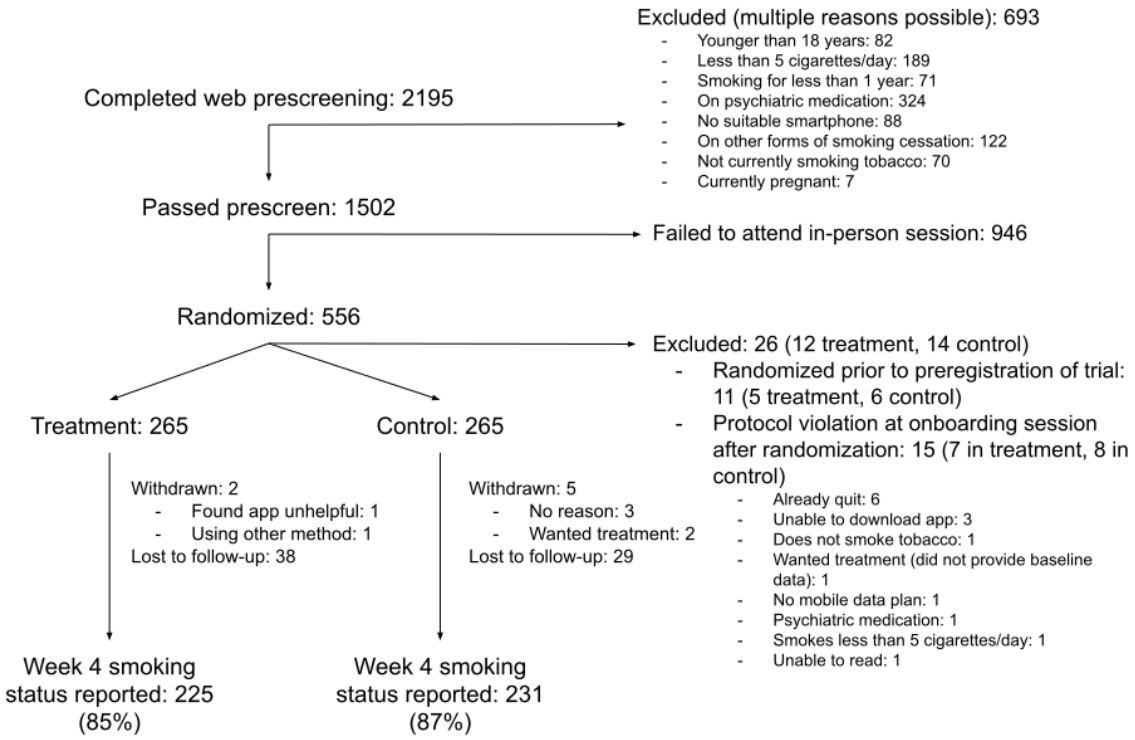
All data processing and analysis was performed in R (R Foundation for Statistical Computing) using the tidyverse package family and the fmsb package [39-41].

Results

Participant Flowchart

Figure 2 shows the CONSORT flowchart for the RCT.

Figure 2. CONSORT flowchart.



Participants

A total of 556 participants were randomized (treatment: n=277; control: n=279). The intention-to-treat analysis included 530 participants (n=265 in each arm; 11 excluded for randomization before trial registration and 15 for protocol violations at baseline visit). Participants came from a wide age range (treatment: 19-73 years; control: 20-78 years), there were slightly more men than women, and about 2 in 3 self-identified as White (Table 1). Educational attainment ranged uniformly from secondary education to postgraduate education, and 80.0% (424/530) were in paid employment, of which over half were in managerial or professional roles. Participants were smoking on average 14 (treatment) or 15 (control) cigarettes per day, with nicotine dependence of 4 out of 10 on the Fagerström Test for Nicotine Dependence. Most participants (451/530, 85.0%) had previously made quit attempts, primarily by going “cold turkey” or with the help of e-cigarettes and NRT. No substantial differences between treatment and control groups were introduced through randomization.

Table 1. Demographics and smoking history of treatment and control groups.

Characteristic	Treatment	Control
Participants, n	265	265
Age (years), mean (SD)	40 (12)	42 (12)
Female, n (%)	123 (46.4)	116 (43.8)
Ethnicity, n (%)		
White	183 (69.1)	164 (61.9)
Black/Caribbean/African	25 (9.4)	30 (11.3)
Asian	18 (6.8)	25 (9.4)
Arab	3 (1.1)	4 (1.5)
Mixed	24 (9.1)	23 (8.7)
Other	7 (2.6)	11 (4.2)
Prefer not to say	5 (1.9)	8 (3.0)
Education, n (%)		
GCSE[a] or lower	57 (21.5)	61 (23.0)
A-level	65 (24.5)	51 (19.2)
Undergraduate degree	76 (28.7)	77 (29.1)
Postgraduate degree	44 (16.6)	51 (19.2)
PhD	6 (2.3)	2 (0.8)
Prefer not to say	17 (6.4)	23 (8.7)
In paid employment, n (%)	209 (78.9)	214 (80.8)
Type of employment (if employed), n (%)		
Managerial or professional	126 (60.5)	113 (53.0)
Routine or manual	22 (10.5)	33 (15.3)
Intermediate	21 (10.0)	20 (9.3)
Other	38 (18.1)	41 (19.1)
Prefer not to say	2 (1.0)	7 (3.3)
Cigarettes per day, mean (SD)	14 (6)	15 (7)
Fagerström Test for Nicotine Dependence (range 0-10), mean (SD)	4 (2)	4 (2)
Any past attempt to quit smoking, n (%)	223 (84.2)	228 (86.0)
Method previously used (if past attempts), n (%)		
Cold turkey	104 (46.8)	113 (49.4)
E-cigarettes	93 (41.5)	95 (41.5)
NRT[b]	68 (30.6)	64 (27.9)
Prescription medication	24 (10.9)	34 (15.1)
Smartphone app	20 (9.1)	22 (9.8)
Hypnotherapy	8 (3.8)	16 (7.2)
Psychological therapy	3 (1.5)	4 (1.9)

[a]GCSE: General Certificate of Secondary Education.

[b]NRT: nicotine replacement therapy.

Engagement

Engagement with different facets of the digital therapeutic intervention is shown in Table 2. By the quit date (an average 16 days after randomization), 89.1% (236/265) of those in the treatment arm were still actively engaged. At the time of primary outcome, 74.0% (196/265) of participants were still engaging with the app. The content consisting of education and cognitive

behavioral therapy (Essentials 1 and 2) were completed by 55.1% (146/265) and 35.8% (95/265) of participants, respectively. In addition, 69.1% (183/265) of participants sent at least one in-app message to their coach, and on average, people messaged their coach about once per week. On average, participants reported 12 diary entries to report cigarettes smoked before their quit date and 6 check-ins to report cravings or lapses after their quit date.

Table 2. Engagement with the digital therapeutic intervention in the treatment group (intention-to-treat participants, n=265).

Engagement	Value
App opens up to week 4, mean (SD), IQR	37 (52), 9-43
Days between randomization and quit date, mean (SD), IQR	16 (21), 9-23
Still active by quit date, n (%)	236 (89.1)
Still active 4 weeks after quit date, n (%)	196 (74.0)
Completed Essentials 1[a], n (%)	146 (55.1)
Completed Essentials 2[b], n (%)	95 (35.8)
Sent 1+ messages to coach, n (%)	183 (69.1)
Messages to coach before quit date, mean (SD), IQR	3.3 (5.9), 0-4
Messages to coach from quit date to week 4, mean (SD), IQR	4.2 (7.5), 0-6
Messages from coach before quit date, mean (SD), IQR	6.6 (6.3), 2-9
Messages from coach from quit date to week 4, mean (SD), IQR	6.2 (5.8), 2-9
Number of diary entries[c] before quit date, mean (SD), IQR	12 (27), 1-12
Number of check-ins[d] from quit date to week 4, mean (SD), IQR	6 (10), 0-9

[a]Essentials 1: program content aimed at preparation for the quit date.

[b]Essentials 2: program content intended for just after the quit date.

[c]Diary entry: registration of a cigarette smoked before and after the quit date.

[d]Check-in: self-report of smoking status after the quit date.

Outcomes

Table 3 shows the primary outcome and secondary outcomes for intention-to-treat and per-protocol analyses. In the intention-to-treat analysis, those in the treatment arm were 55% more likely to report 7-day abstinence 4 weeks after their quit date compared to those in the control group (risk ratio 1.55, 95% CI 1.23-1.96; 118/265, 44.5% vs 75/265, 28.3% quit rate). In participants that were pseudorandomly assigned a CO device (treatment: 138/265; control: 142/265), 97.1% (134/138) in treatment and 97.9% (139/142) in the control group provided a CO reading at baseline, and 60.9% (84/138) in treatment and 66.9% (95/142) in the control group provided a reading at 4 weeks (including those who did not complete the week 4 questionnaire). CO completion was 88% (50/57) and 89% (33/37), respectively, in participants that claimed abstinence at 4 weeks. For these abstaining participants, the CO measurement was below 10 ppm for 96% (48/50) and 97% (32/33) of participants in treatment and control, respectively. Whether or not a participant was provided with a CO device did not significantly predict quit rate (P=.29 in logistic regression with CO device and intervention main effects). There was no difference in NRT use in treatment (133/225, 59.1%) and control (146/231, 63.2%) in those that completed the week 4 questionnaire (risk ratio 0.94, 95% CI 0.81-1.08), nor in electronic cigarette use in treatment (29/225, 12.9%) and control (23/231, 10.0%) groups (risk ratio 1.29, 95% CI 0.77-2.17).

Table 3. Outcomes at 4 weeks after quit date.

Outcome and group	Treatment	Control	Chi-square test (*df*)	*t* test (*df*)	*P* value	RR[a] (95% CI)	Group difference (95% CI)
Primary outcome							
7-day abstinence, n (%)							
ITT[b] (n=530)	118 (44.5)	75 (29.3)	13.7 (1)	N/A[c]	<.001	1.55 (1.23 to 1.96)	N/A
PP[d,e] (n=456)	118 (52.4)	75 (32.5)	17.8 (1)	N/A	<.001	1.62 (1.29 to 2.02)	N/A
Secondary outcomes							
14-day abstinence, n (%)							
ITT (n=530)	91 (34.3)	62 (23.3)	7.2 (1)	N/A	.007	1.47 (1.12 to 1.93)	N/A
PP[e] (n=456)	91 (40.4)	61 (26.4)	9.5 (1)	N/A	.002	1.53 (1.17 to 2.0)	N/A
Any additional quit attempt beyond initial quit date, n (%)							
ITT (n=530)	68 (25.6)	86 (32.5)	2.6 (1)	N/A	.10	0.79 (0.6 to 1.03)	N/A
PP[f] (n=443)	68 (30.9)	86 (38.6)	2.5 (1)	N/A	.11	0.8 (0.62 to 1.04)	N/A
Knowledge improved, n (%)[g]							
ITT (n=530)	104 (39.2)	77 (29.1)	5.7 (1)	N/A	.02	1.35 (1.06 to 1.72)	N/A
PP[f] (n=443)	104 (47.3)	76 (34.1)	7.5 (1)	N/A	.006	1.39 (1.1 to 1.75)	N/A
Confidence improved, n (%)[g]							
ITT (n=530)	84 (31.6)	65 (24.5)	3.0 (1)	N/A	.08	1.29 (0.98 to 1.7)	N/A
PP[f] (n=443)	84 (38.2)	64 (28.7)	4.1 (1)	N/A	.04	1.33 (1.02 to 1.74)	N/A
Attitude improved, n (%)[g]							
ITT (n=530)	100 (37.7)	103 (38.8)	0.0 (1)	N/A	.86	0.97 (0.78 to 1.21)	N/A
PP[f] (n=443)	100 (45.5)	101 (45.3)	0.0 (1)	N/A	>.99	1 (0.82 to 1.23)	N/A
Change in SASEQ[h] (24-point scale), mean (SD)							
ITT (n=530)	4.2 (7.0)	3.1 (6.7)	N/A	1.7 (527)	.09	N/A	1.0 (–0.161 to 2.17)
PP[i] (n=440)	5.1 (7.4)	3.6 (7.0)	N/A	2.0 (436)	.04	N/A	1.4 (0.052 to 2.75)
Change in WEMWBS[j] (56-point scale), mean (SD)							
ITT (n=530)	0.7 (7.0)	0.6 (6.5)	N/A	0.2 (525)	.83	N/A	0.13 (–1.02 to 1.28)
PP[i] (n=440)	0.9 (7.7)	0.8 (7.0)	N/A	0.2 (433)	.88	N/A	0.11 (–1.26 to 1.48)
Unregistered outcomes							
Cigarettes per day in those that failed to quit, mean (SD)							
PP (n=222)	7.9 (6.4)	7.5 (5.9)	N/A	0.5 (180)	.65	N/A	0.39 (–1.29 to 2.06)

Outcome and group	Treatment	Control	Chi-square test (*df*)	*t* test (*df*)	*P* value	RR[a] (95% CI)	Group difference (95% CI)
% reduction in cigarettes per day in those that failed to quit, mean (SD)							
PP (n=222)	48.1 (28.2)	48.9 (29.3)	N/A	–0.2 (194)	.83	N/A	–0.83 (–8.57 to 6.91

[a]RR: risk ratio.

[b]ITT: intention to treat.

[c]N/A: not applicable.

[d]PP: per protocol.

[e]Treatment: n=225; control: n=231.

[f]Treatment: n=220; control: n=223.

[g]As measured by percentage of participants reporting "strongly agree."

[h]SASEQ: Smoking Abstinence Self-efficacy Questionnaire.

[i]Treatment: n=219; control: n=221.

[j]WEMWBS: Warwick-Edinburgh Mental Well-being Scale.

For secondary outcomes, 14-day abstinence showed greater efficacy of treatment compared with control (risk ratio 1.47, 95% CI 1.12-1.93). Those in treatment were no more or less likely to have made an additional quit attempt after the initial quit date (risk ratio 0.79, 95% CI 0.60-1.03). Those in the treatment arm were more likely to strongly agree that their knowledge of their smoking habit had improved (risk ratio 1.35, 95% CI 1.06-1.72), but no such effect was observed regarding their confidence in their ability to stay smoke free (risk ratio 1.29, 95% CI 0.98-1.70) or in terms of whether their attitude toward stopping smoking had become more positive (risk ratio 0.97, 95% CI 0.78-1.21). The treatment was also not superior to control in terms of the increase in smoking self-efficacy (*P*=.09) or mental well-being (*P*=.83). However, in the per-protocol analysis, which included only participants that completed their week 4 outcomes, several secondary outcomes were significantly better in treatment compared with control; confidence improved more (risk ratio 1.33, 95% CI 1.02-1.74), as did self-efficacy (*P*=.04).

Participant satisfaction with the treatment intervention was high (213/265 in the treatment group that completed the questionnaire at week 4). On a scale from 0 (least satisfied) to 3 (most satisfied), mean quality of the smoking cessation service was 2.4 (SD 0.7), program meeting needs was 2.2 (SD 0.8), helpfulness of information was 2.6 (SD 0.6), helping to deal with smoking effectively was 2.4 (SD 0.7), and likelihood of coming back if needing to quit in the future was 2.5 (SD 0.7). When asked whether the participant would recommend the digital therapeutic intervention to a friend, 92.0% (196/213) would do so. Most participants considered the quit coach (72/213, 33.8%) and the education and CBT content (62/213, 29.1%) to be the most helpful. Some participants considered self-monitoring (28/213, 13.1%), the smoking diary (19/213, 8.9%), the craving toolbox (15/213, 7.0%), or other features (13/213, 6.1%) to be the most helpful. The community element of the digital therapeutic intervention was considered the least helpful, with only 1.9% (4/213) of participants considering it as the most helpful.

Finally, we examined 2 outcomes unregistered at trial registration. First, cigarettes smoked per day by those who failed to quit showed no difference between treatment and control groups (treatment: 7.9 cigarettes per day; control: 7.5 cigarettes per day). Similarly, the average percent decrease in cigarettes per day, though substantial in both groups, showed no difference between groups (48.1% decrease in treatment vs 48.9% decrease in control; *P*=.83).

Discussion

Principal Findings

In this RCT, we assessed the preliminary efficacy of Quit Genius, a digital therapeutic intervention for smoking cessation. The primary outcome of self-reported 7-day abstinence at 4 weeks post quit date was significantly higher (*P*<.001) for the treatment group compared with a control group using VBA.

Principally, this shows the superiority of the digital therapeutic intervention compared with the United Kingdom's typical first-line intervention for smoking cessation [4,5]. We show that the digital therapeutic intervention is an effective method for short-term behavior change. The treatment group demonstrated a pseudorandomly CO-verified 4-week quit rate comparable with high-intensity face-to-face smoking cessation programs used by health care services in the United Kingdom [42]. Our results support previous literature illustrating that high-intensity behavioral support combined with pharmacotherapy is an effective means of quitting smoking [42].

Compared with other digital therapeutic interventions, the 44.5% (118/265) and 52.4% (118/225) 7-day abstinence rates 4 weeks after the quit date (for ITT and PP, respectively) compare favorably with previous digital intervention studies. Pivot, another digital therapeutic intervention, achieved an end-of-study CO-verified 7-day abstinence rate of 32% (ITT) and 37% (PP) [20]. An acceptance and commitment therapy intervention by Smartquit achieved 21% 7-day abstinence at 2 months post enrollment [22]. Clickotine's 7-day abstinence rate of 45% at 8 weeks post enrollment was similar to that observed in the current study [21]. However, all these studies used single-arm designs rather than RCTs and were therefore unable

to distinguish the causal effect of treatment, placebo, or underlying differences in propensity to quit in the study population [43]. Finally, both Smartquit and Clickotine studies used non–CO-verified self-reported abstinence as their primary means of assessing intervention efficacy, leaving a possibility of falsely reported smoking status [21,22]. This study largely avoided such limitations by using a 2-arm parallel-group RCT design with pseudorandom biochemical verification. While this study pseudorandomly verified the CO of ITT and PP participants, we found a near-perfect agreement (80/83, 96%) between the CO monitor and self-reported abstinence, suggesting that self-report can be taken at face value. The preliminary abstinence rates of the digital therapeutic intervention studied here are promising both in absolute terms and compared with the control group. Nevertheless, 6- and 12-month abstinence rates will be needed to confirm whether the intervention is also efficacious in the longer term.

Cognitive, Attitudinal, and Emotional Improvements

Education and confidence are integral mechanisms in eliciting successful smoking cessation [44,45]. In this study, treatment caused a greater improvement in knowledge of personal smoking habits compared with control. Similarly, confidence in ability to stay smoke free was higher in treatment than control, though only statistically significant in participants that completed the study per protocol (P=.04). No effect was found on the attitude of participants toward stopping smoking. This suggests that the digital therapeutic intervention is an effective tool for making people aware of their habit and instilling some degree of confidence but fails to improve a commonly negative attitude toward stopping smoking. Given that smoking cessation interventions may be enhanced by incorporating strategies that target attitude change [46], the intervention could be further improved to engender a more positive attitude toward quitting.

Self-efficacy is a robust indicator of future successful smoking abstinence [45]. We observed the digital therapeutic intervention to be superior to the control in improving self-efficacy in participants who completed the study per protocol but not when analyzed by intention to treat. This resembles the increase in reported confidence, indicating that the digital therapeutic intervention enhanced users' beliefs in their capacity to quit successfully but that further developments on the intervention should focus on strengthening these outcomes.

We observed no benefit of the digital therapeutic intervention compared with the control in terms of mental well-being. In a retrospective study of the same intervention, we observed a correlation between hedonic well-being and quit rates [47]. In line with this, smoking cessation is typically associated with improved mental health, with evidence illustrating a reduction in anxiety, depression, and stress after quitting [48]. Given the higher quit rates in the treatment group, we expected treatment to be superior in terms of mental well-being. However, improvements are usually demonstrated in longer-term follow-ups than the 4 weeks reported here [48]. As such, changes in mental well-being might not yet have manifested, and our 6-month and 12-month outcomes will shed light on the longer-term impact of the digital therapeutic intervention on mental well-being. There are both positive and negative effects associated with smoking and smoking abstinence that could impact mental well-being. Evidence suggests that smokers who reduce their smoking but fail to quit show more pronounced mood deterioration than those who succeed [48]. Conversely, there is evidence illustrating the negative sequelae of smoking cessation, such as anxiety, insomnia, and weight gain [49]. Therefore, it is possible that simultaneous effects could have been active within groups, resulting in no net effect on mental well-being.

Nicotine addiction is a condition that rarely exceeds a lifetime abstinence rate greater than 50% per treatment. For this reason, many smokers take 30 or more quit attempts before being successful [50]. Nonetheless, a reduction in daily cigarette use predicts future behavior change; individuals who reduce their cigarette use by about 50% are more likely to see future quit attempts and greater odds of successful quitting [50]. Among treatment participants who had not quit smoking, there was an average reduction of 48% in their cigarette use compared to baseline, similar to control. Digital therapeutic interventions can, perhaps more easily than traditional programs, leverage such data to continue to engage and encourage specific participants after a failed quit attempt, identifying an optimal time to engage when chances of quitting are highest.

Engagement

To elicit the success of any noninvasive digital therapeutic intervention, users must actively partake in the treatment [15,22]. We assessed engagement across several elements of the intervention and observed 89.1% (236/265) of the participants using the app until their quit date, with 74.0% (196/265) still using the app 4 weeks after their quit date. One differentiating aspect of this digital therapeutic intervention from typical smartphone apps is the presence of human coaching. We found a consistent bidirectional flow of communication between quit coach and participant from baseline to quit date and from quit date to 4-week follow-up. Of all the elements of treatment offered by the intervention, coaching was considered the most helpful. This reflects previous notions that smoking cessation programs that use health coaching as a means of support are effective in eliciting successful smoking abstinence [51]. Thus, the high level of engagement observed in this study may reflect the combination of in-app human coaching and other engagement features, such as push notifications, check-ins, and keeping a diary.

Strengths and Limitations

Particular strengths of this study are the randomized controlled design, preregistration of the trial and its outcomes, pseudorandom biochemical verification despite the remote nature of the intervention, and high 4-week follow-up rate. The key limitation of this study is the short follow-up period of 4 weeks. It is known that relapse occurs over a longer time frame [52-54], and the current findings do not speak to the digital therapeutic intervention’s ability to prevent longer-term relapse.

Another limitation is that participants may have exaggerated their self-reported smoking abstinence. To combat this, participants were informed from study outset that regardless of smoking abstinence, they could remain on the trial and would

be eligible for remuneration. Another preventative measure was the use of a measurement device to assess CO levels in the exhaled breath of the individual. Due to cost considerations, these devices were provided pseudorandomly to 50% of each study arm. The near-perfect agreement (80/83, 96%) between the CO monitor and self-reported abstinence suggests that, at least in the context of this digital therapeutic intervention, self-report can be taken at face value.

A further limitation was that the digital therapeutic intervention was not compared with another multifaceted intervention. VBA was chosen due to its use as the United Kingdom's typical first-line intervention for smoking cessation, and for those participants not assigned a CO device, no app was provided. Therefore, it is plausible that participants may have guessed that they were assigned the control intervention due its limited functions.

There were also several limitations of the study sample. While the exclusion of participants with serious health conditions or using psychiatric medication was enforced as a safety consideration, it limits the generalizability to a smoking population that largely has other health and psychiatric conditions. Additionally, it is important to acknowledge that the study largely consisted of a sample of White, educated, and employed participants. Participants were required to attend an in-person baseline visit, so they had to live within a commutable distance to London. Therefore, the participant sample used in this study may be more reflective of an urban population, limiting the generalizability to more rural and remote-based populations.

Lastly, the lack of experimenter blinding to participant group allocation may have introduced bias into data interpretation. To avoid this, standardized questionnaires, participant interaction scripts, and standard operating procedures were used across treatment groups so that any effect on participant outcome data was minimized. In addition, the trial outcome measures and sample size were preregistered, and data were only analyzed after data collection had been completed.

Conclusions

A digital therapeutic intervention for smoking cessation was superior to very brief advice in achieving smoking cessation after 4 weeks in a pseudorandomly biochemically verified RCT. The digital therapeutic intervention examined here is an effective option for short-term smoking cessation. Participants were actively engaged and satisfied with the intervention. Nevertheless, opportunities exist to improve mental well-being and attitudinal outcomes. A critical open question pertains to the long-term efficacy, which will be reported in a subsequent paper.

Acknowledgments

The authors thank the participating National Health Service primary care practices located across the London districts of Barnet, Camden, Ealing, Hammersmith and Fulham, Islington, Kilburn, and North Kensington for their support in participant recruitment. AM is supported by the Northwest London National Institute for Health Research Applied Research Collaboration.

Conflicts of Interest

The study was funded by the company that produced the Quit Genius digital therapeutic intervention (Digital Therapeutics Inc). PS is a paid statistical consultant. JW, SP, SS, YS, MA, HM, HP, and SB either received a salary from or own equity in Digital Therapeutics Inc.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2059 KB - mental_v7i10e22833_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
CO: carbon monoxide
CONSORT: Consolidated Standards of Reporting Trials
ISRCTN: International Standard Randomized Controlled Trial Number
ITT: intention to treat
NCSCT: National Centre for Smoking Cessation and Training
NRT: nicotine replacement therapy
PP: per protocol
QG: quit genius
RCT: randomized controlled trial
SASEQ: Smoking Abstinence Self-efficacy Questionnaire
VBA: very brief advice
WEMWBS: Warwick-Edinburgh Mental Well-being Scale
WHOQOL-BREF: short version of the World Health Organization Quality of Life

Edited by G Eysenbach; submitted 07.08.20; peer-reviewed by K Garrison; comments to author 28.08.20; revised version received 17.09.20; accepted 19.09.20; published 06.10.20.

Please cite as:
Webb J, Peerbux S, Smittenaar P, Siddiqui S, Sherwani Y, Ahmed M, MacRae H, Puri H, Bhalla S, Majeed A
Preliminary Outcomes of a Digital Therapeutic Intervention for Smoking Cessation in Adult Smokers: Randomized Controlled Trial
JMIR Ment Health 2020;7(10):e22833
URL: https://mental.jmir.org/2020/10/e22833
doi:10.2196/22833
PMID:33021488

Viewpoint

Therapist-Supported Online Interventions for Children and Young People With Tic Disorders: Lessons Learned From a Randomized Controlled Trial and Considerations for Future Practice

Liam R Chamberlain[1], BSc; Charlotte L Hall[1], PhD; Per Andrén[2,3], MSc; E Bethan Davies[1], PhD; Joseph Kilgariff[4], RMN; Natalia Kouzoupi[5,6], MSc; Tara Murphy[5,6], DClinPsy; Chris Hollis[1,7,8], BSc, MBBS, DCH, PhD, FRCPsych

[1]NIHR MindTech Medtech Co-operative, Institute of Mental Health, University of Nottingham, Nottingham, United Kingdom
[2]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden
[3]Stockholm Health Care Services, Region Stockholm, Stockholm, Sweden
[4]Nottinghamshire Healthcare NHS Foundation Trust, Nottingham, United Kingdom
[5]UCL Great Ormond Street Institute of Child Health, University College London, London, United Kingdom
[6]Great Ormond Street Hospital for Children NHS Foundation Trust, London, United Kingdom
[7]Division of Psychiatry and Applied Psychology, Institute of Mental Health, University of Nottingham Innovation Park, Nottingham, United Kingdom
[8]NIHR Nottingham Biomedical Research Centre, Nottingham, United Kingdom

Corresponding Author:
Chris Hollis, BSc, MBBS, DCH, PhD, FRCPsych
Division of Psychiatry and Applied Psychology
Institute of Mental Health, University of Nottingham Innovation Park
Triumph Road
Nottingham, NG7 2TU
United Kingdom
Phone: 44 115 8230258
Email: Chris.Hollis@nottingham.ac.uk

Abstract

In recent years, research into internet-based cognitive behavioral therapy (iCBT) has suggested that therapist-guided digital interventions have greater engagement, adherence, and effectiveness than self-directed digital therapies. While research has focused on the effectiveness of, and adherence to, these interventions, less attention has been paid to their implementation in practice and what aspects of the therapist role support success. An understanding of the key factors related to the therapist role and intervention delivery is required if these iCBTs are to be applied in routine clinical care and outcomes optimized. In light of the coronavirus disease 2019 (COVID-19) pandemic, there is greater emphasis on allowing patients access to remote therapies. We report the experiences and reflections of 4 therapists and their 2 supervisors in delivering an online, therapist-supported intervention in a randomized controlled trial for children and young people with tic disorders (the Online Remote Behavioural Intervention for Tics [ORBIT] trial). Themes discussed include the importance of training, supervision, creating support documents/manuals, and record keeping. Alongside this are communication strategies used by therapists to encourage patient adherence and treatment effectiveness. These include rapport building, treatment personalization, and suggestions for overcoming non-engagement. These reflections offer important considerations for the delivery of iCBTs as well as implications associated with the implementation of these interventions in existing services and future research studies. We share thoughts on where iCBTs may sit in a stepped care model, how services may deal with comorbid conditions, and the potential role of iCBTs in collecting clinical data.

(JMIR Ment Health 2020;7(10):e19600) doi:10.2196/19600

KEYWORDS

Tourette syndrome; tic disorders; internet-based cognitive behavioral therapy (iCBT); remote therapy; therapist support

Introduction

Background

Tic disorders are associated with significant clinical impairment. Although behavioral therapies are an effective and acceptable treatment for these conditions, they are not always available due to a shortage of trained therapists [1].

As demonstrated in clinical trials, therapist-guided internet-based cognitive behavioral therapy (iCBT) is an efficacious format that has been successfully tested within various conditions [2]. These treatments are potentially cost-effective and can improve current service delivery by transcending barriers of time and geography. They are likely to be particularly useful when there is a clear lack of trained therapists, as is the case with tic disorders. Furthermore, it is the case that many low-to-middle-income countries have limited access to mental health services, and it is likely that iCBTs could provide cost-effective interventions that can be widely distributed [3]. Similarly, in light of the coronavirus disease 2019 (COVID-19) pandemic, there is an increasing need to offer psychological or behavioral interventions remotely to ensure continuity of care for existing patients and provide an avenue of support for the increasing mental health pressures as a result of the pandemic [4]. If therapist-supported iCBTs are to be integrated into standard clinical care, there needs to be consideration around the delivery of treatment, including the role of the therapist.

This viewpoint reports on the experiences of therapists who delivered an online, therapist-supported intervention in a randomized controlled trial for children and young people with tic disorders [5]. This paper also summarizes the lessons learned based on thoughts, reflections, and discussions between those in the therapist role and their supervisors in the trial. A more in-depth account of therapist and patient experiences is being formally evaluated [6]. We detail procedures used by the therapists within this trial that go beyond the method described in the original protocol paper [5], and suggest implications of applying iCBTs in existing services. These experiences are likely to be generalizable to other therapist-supported iCBTs, especially those set in child and adolescent mental health services and community pediatric settings.

The ORBIT Trial

The Online Remote Behavioural Intervention for Tics (ORBIT) is a randomized controlled trial delivered in England between 2017 and 2021 [5]. In ORBIT, two 10-week, therapist-supported, internet-delivered behavioral interventions have been trialed: (1) *BIP TIC*, which is based on exposure and response prevention (ERP) principles [7]; and (2) psychoeducation on tics. In both treatments, child patients and an assigned supporter (usually a parent or caregiver) log in to an internet treatment platform and each work through 10 chapters of treatment content (Table 1). The chapters can be completed independently, but the supporter is encouraged to assist with the child's comprehension of the material (ie, making sure they actually understand the chapters as they are being read).

Table 1. Chapters of the ORBIT treatments.

Chapter number	ERP[a] treatment content		Psychoeducation treatment content	
	Young Person	Supporter	Young person	Supporter
1	Learn about tics	Introduction	Introduction	Introduction
2	More about tics	Thoughts and behaviors of supporters	Tics and Tic list	Praise
3	Practicing stopping your tics	Praise	Learning about tics	Prompts
4	Making the practice more challenging	Prompts	More than tics	More than tics
5	Continued practice	Situations and reactions	Healthy habits	Healthy habits for your child
6	School	Troubleshooting	School	School
7	Talk about your tics	Continued practice	Talking about tics with your class	Thoughts and behaviors of supporters
8	Continued practice	Continued practice	Risk and protective factors	Risk and protective factors
9	The final sprint	Continued practice	Tics and the future	Looking after yourself
10	Plan for the future	Plan for the future	Plan for the future	Plan for the future

[a]ERP: exposure and response prevention.

All patients were between the ages of 9 and 17 at the time of their baseline assessment. A formal diagnosis of tic disorder is not necessary for participation—rather they have to meet the threshold for having tics on the Yale Global Tic Severity Scale (YGTSS) [8]; further details can be found in the study protocol [5]. Differences in severity of tics is not formally considered during therapy. All patients and supporters are assigned to 1 of 3 therapists educated to at least a bachelor's degree in a psychology-related discipline—with the highest qualification being a PhD. Typically, patients would meet their therapist once in person during their assessment appointment and would be allocated the same therapist throughout (except for absences). Contact with their therapist is asynchronous and predominantly through text-based communication within the platform (eg,

messages resembling email, comments on completed worksheets). Therapists aimed to have approximately 10-20 minutes of contact per week with each dyad of child and supporter; this time was logged (by the platform) to measure the amount of support patients were needing and would help the therapists devote comparable time to each patient. This amount of contact is significantly less than might be expected in face-to-face behavioral therapy for tics (manualized as 1 hour per week for 10-12 weeks). Treatment is occasionally supplemented with telephone calls and emails outside of the platform, if the child or supporter was not accessing the treatment platform regularly—and these times were manually logged and combined with the times recorded by the platform.

The treatment content of ORBIT is delivered by the online platform (through text, illustrations, and videos), so the therapist role was twofold: (1) maximizing the adherence to and uptake of the treatment content (via problem-solving and content application); (2) offering first-line technical support. For other interventions, the role of the therapist may also involve delivering the actual intervention content, but this is not the case for the ORBIT interventions.

Methods

Procedure

The information reported in this paper derives from the shared experiences and insights had by the ORBIT therapist team.

The therapist team consisted of 4 ORBIT therapists and 2 supervisor therapists (TM and JK). Therapists EBD and LRC were active throughout the entirety of the treatment period of ORBIT, with therapist NK joining approximately 1 year into the treatment period following the departure of a previous therapist. Therapists EBD and LRC were assigned to supervisor JK and were based at the Nottingham site, and therapist NK (and her predecessor) was assigned to supervisor TM and was based at the London site. The supervisors would host weekly supervision sessions with their respective therapist(s), with the session minutes written electronically and distributed via email to the other therapists.

Reflections of therapist experience were collected throughout the course of the trial within these supervision records. The lead author (LRC) summarized these key reflections and this summary was approved by the remaining therapist team.

Reflections

Therapist Training and Supervision

Before treatment, the therapists were familiarized with the interventions and background literature on tic disorders. However, no formal or manualized training was given for treating or managing tic disorders as the ORBIT treatments were largely designed as self-help programs. Therapists were shown the basic functions of the internet platform and given access to “how-to” guides which highlighted how to complete the necessary tasks (eg, unlocking chapters). As the therapists were not required to be specially trained in therapy delivery, standard operating procedures were designed during the initial set up of the ORBIT trial to aid the therapist’s effectiveness and efficiency (Table 2).

Table 2. Standard therapist procedures used in the ORBIT[a] trial.

Procedure	Perceived benefit(s)
Logging interactions between therapist and patients	• Keeping track of progress and change over time. • Able to manage larger caseloads. • Improve therapeutic rapport.
Using a bank of standardized responses	• Optimizing therapist time. • Therapists responses remain aligned and treatment integrity maintained.
Recording patient feedback	• Encourages reflective practice. • Identifies strengths and weaknesses of current delivery practice to inform service improvement.
Patient face-to-face meeting with their therapist at baseline assessment	• Rapport building and “humanizing” of therapist. • An opportunity to ask questions (not treatment advice as pre-randomization) and improve perceived treatment credibility.
Including photos and audio of therapists within treatment platform	• Rapport building and “humanizing” of therapist.
Using a standard protocol to prompt non-engaging patients (ORBIT messages→emails→telephone calls)	• Motivates patients to engage with treatment. • Stepped approach to contacting patients. • Consistency in therapist contact time.

[a]ORBIT: Online Remote Behavioral Intervention for Tics (trial).

As the ORBIT treatments are delivered on standardized webpages, there is less room for therapist drift. However, as therapist attitudes and behaviors seem to influence patient outcomes [9], it is important to ensure therapists coordinate their approaches when delivering iCBTs. Author TM developed technical treatment manuals, to ensure the same standard and

procedure of care be given to all patients regardless of allocated therapist. The therapists also had clinical supervision with 2 qualified and clinically experienced behavioral therapists (JK and TM). This maintained the fidelity of the treatment, while also giving direction on how to respond to patients when their queries went beyond the ORBIT interventions. For additional support, monthly peer supervision occurred between the therapists. This further aligned therapist attitudes and encouraged intertherapist consistency in content and amount of support.

Post-treatment peer and clinical supervision sessions were conducted to evaluate the impact of the therapist role and to highlight considerations for future implementation. Notable reflections within the ORBIT trial were that all patients were supported appropriately to their level of investment, indicating good overall engagement with high levels of patient motivation. Furthermore, the standard of care is believed to have been consistent throughout the trial and between patients. The therapists used these insights, alongside reflections recorded during the trial, to revise the original manuals and support documents. Revisions typically included updated motivational statements, common text communications, and ideas for troubleshooting both common and uncommon problems.

Engaging Patients in Therapy

To promote adherence to a therapy, therapists should balance between patients feeling supported (ie, not alone) and empowering the individual to take action (ie, not passive) [10]. This can be harder to achieve in iCBT: therapists tried to balance support by giving direction without excessive pressure. In order to achieve this, patients initially devised an engagement plan, which would typically be what days they planned to log in each week. Therapists attempted to refine this week-by-week by adding detail of what they could be doing during this time. The patients' self-report on their weekly worksheets would inform these refinements; therapists would send messages capturing significant elements for potential improvement and offering advice on how to tackle these. For example, a patient who struggled to talk about tics may be advised to attempt this task before their next date of logging in or before the next chapter would be opened. The therapist encouraged a collaborative process, asking whether they agreed with the proposed plan and requesting feedback on how they found completing the work. This was important as it seems that patients prefer iCBTs that are sensitive to their needs [10]. Furthermore, the therapists wanted to prepare the dyad to continue creating plans in the future without therapist input.

There was little discrimination in the therapists messaging patterns for the child and his/her supporter(s)—often when one was sent a message the other would be sent one shortly after. For example, if a child received a message encouraging the completion of a task, this would also be explained to the supporter with guidance on how they can support him/her with this task. The therapists thought this to be important with regard to keeping both users aware of the current plan of action, as well as maintaining the idea that their chapters were linked and should be completed collaboratively. It is notable, however, that some older children (mid-teens) had made it clear to the therapist that they wanted a degree of independence from their supporter throughout the treatment, and in these cases the collaboration was less emphasized. The content of the messages were also very similar, with slight differences being that the child would tend to receive more motivational statements (ie, praise) while the supporter would often receive more instructional messages; however, there was often a significant overlap. This same difference could also be seen between the younger and older children—older children would seem to do more work independently and therefore sought greater instructional advice, which would normally be requested by the supporter. When families (or child/supporter independently) became disengaged with the interventions, attempts to promote re-engagement were typically aimed at the supporter. Some examples of common phrases used within therapist messages include "You have done brilliantly with this, keep up the excellent work!," "I just wanted to check in as I can see you have not logged in for a few days - how are you getting on with your chapter X task? Let me know if you need anything my end!," "Thank you for your comments, it is very interesting to hear more about your personal experience," and "I am sorry to hear that you have been struggling with your tics at the moment, have you spoken to your [Supporter] about this?".

Alongside making the treatment content more applicable to patients, therapists tried to personalize their communication style. Therapists achieved this by remembering particular details, such as their hobbies or pets and using emojis that patients had used previously. Reciting these details later can reassure that the therapist is listening, which may be particularly important in iCBT, where intonation and body language are not evident. The ORBIT therapists believed that these strategies helped build a genuine therapeutic alliance in several cases.

Future Considerations

Below we outline some of the implications of using iCBTs in routine clinical care, including where they can fit into established frameworks and how they can improve the collection of health care data, as well as outlining areas for future development.

Implications of Applying iCBTs in Existing Services

The provision of iCBTs have a range of potential applications to improve current service delivery globally; they are a feasible way to bridge the mental health treatment gap in low-to-middle-income countries [3], as well as potentially being used as method to ensure continuity of care and delivery of mental health interventions during pandemics such as COVID-19 [4]. In standard care, they can be integrated into a stepped care model as a first-line or wait-list intervention, where they may reduce delays to accessing high-fidelity evidence-based interventions; however, this does require further evaluation. Furthermore, iCBTs offer a unique way of collecting data by containing clinically relevant outcome measures within their systems. This can improve the therapist's ability to monitor the patient's safety and well-being during treatment, and services can be greater informed of the needs of their users. However, to utilize the benefits of iCBT, considerations are needed on

how the use of iCBTs can be incorporated into clinical training for health care practitioners.

Therapists need to be aware of the limitations of the iCBT they are delivering to ensure they stay within the boundaries of the specific treatment goals: for example, the ORBIT treatments only targeted tic conditions and do not offer targeted treatment for common co-occurring symptoms and conditions. During the trial, the therapists would advise patients to seek help from other health care professionals regarding concerns beyond the remit of the ORBIT interventions. In the future, ICBT therapists can be based within community mental health services, as this may offer opportunities for integrated care that allows for direct referrals to the relevant professionals locally. Another possibility is to operate in a more "hub and spoke"-based model: local services would refer to a central point for the specific intervention and integration back to local services for other co-occurring conditions, either during or after treatment completion, would need consideration. In translation to clinical practice settings, a broader menu of digital tools and interventions targeting a range of co-existing conditions will be needed and be accessible to the therapist and the patients from a single platform.

Implications for Future Research

It will be important to assess which components in the therapeutic process (Table 2) mediate successful outcomes for digital interventions. A potential approach for future research would be to randomize these components using a multiphase optimization strategy [11].

A future study involving a digital platform for treatment delivery could randomize participants into slightly different versions of the same interventions where there are multiple assignment arms (intervention versions) with just 1 individual component (eg, content, duration, graphics, gamification, level of human support) differing between each. Further information related to identifying active components, which may be useful to evaluate in digital health interventions, has been published previously [12]. An important research task would be to see whether therapeutic alliance differs between therapies delivered with asynchronous support such as that offered in ORBIT and more synchronous support such as that offered in videoconferencing. Although there are existing measures of therapeutic alliance (see Himle and colleagues [13], for example), an additional research task will be to develop reliable and valid measures of the digital therapeutic alliance, its effect on outcome, and which therapist and patient factors influence this. This line of enquiry has been identified as a research priority in digital technology [14].

Conclusion

This paper reflects on the therapist role within a randomized controlled trial currently being run in the United Kingdom with the aim of sharing guidance on the successful use of a therapist role in iCBTs. Importantly, in an attempt to promote adherence to and increase effectiveness of such therapies, this paper highlights important points for consideration when delivering remote iCBTs, including adequate therapist training, clinical supervision, flexibility, and organization. We further suggest how therapist-guided iCBTs could fit into pre-existing services. The ORBIT treatments have to date been evaluated within the context of a randomized controlled trial delivered at specialist centers. The findings of this trial are required to understand the clinical and cost-effectiveness of this approach and feasibility and acceptability among patients.

Ethical Information and Trial Registration

This manuscript reflects on experiences from the ORBIT trial, which was approved by North West Greater Manchester Research Ethics Committee (REC reference 18/NW/0079). The ORBIT trial was prospectively registered with ISRTCN (ISRCTN70758207) and ClinicalTrials.gov (NCT03483493).

Acknowledgments

We acknowledge the on-going support of Angela Summerfield. Additionally, we thank the wider ORBIT team including Sophie Bennett, Bev Brown, Sue Brown, Mike Craven, Amber Evans, Cris Glazebrook, Isobel Heyman, Rachael Hunter, Rebecca Jones, Kareem Khan, Louise Marston, David Mataix-Cols, Caitlin McKenzie, Elizabeth Murray, Charlotte Sanderson, and Eva Serlachius. We also thank members of the ORBIT trial Steering Committee: Professor Edmund Sonuga-Barke (Chair), Mrs Neelam Gurav, Dr Prathiba Chisabesan, Dr Kim Goldsmith, Dr David Manley and Dr Cara Verdellen. We also thank members of The ORBIT Data Safety and Monitoring Committee: Professor Stephen Scott (Chair), Dr Uttom Chowdhury, and Professor Richard Emsley. Authors EBD and CH acknowledge the support of NIHR MindTech MedTech Co-operative. TM acknowledges support from the National Institute for Health Research Biomedical Research Centre at Great Ormond Street Hospital for Children NHS Foundation Trust and University College London. This research was funded by the National Institute for Health Research (NIHR) Heath Technology Assessment (HTA) (Ref 16/19/02). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and social care. CH acknowledges the financial support of the NIHR Nottingham Biomedical Research Centre.

Authors' Contributions

CH is the chief investigator and takes final responsibility for the ORBIT trial. CLH is the trial manager for ORBIT. LRC wrote this manuscript with approval and contribution from all authors (CLH, PA, EBD, JK, NK, TM, and CH). TM led the development of the therapy. JK and TM supervised the therapists. LRC, EBD, and NK delivered the therapy support. PA advised on processes and conducted the initial Swedish investigation. All authors critically revised the manuscript for its important intellectual content. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

COVID-19: coronavirus disease 2019
ERP: exposure and response prevention
iCBT: internet-based cognitive behavioral therapy
ORBIT: Online Remote Behavioural Intervention for Tics
YGTSS: Yale Global Tic Severity Scale

Edited by J Torous; submitted 24.04.20; peer-reviewed by J Firth, J van de Griendt, F Gonot-Schoupinsky; comments to author 15.05.20; revised version received 21.05.20; accepted 22.05.20; published 23.10.20.

Please cite as:
Chamberlain LR, Hall CL, Andrén P, Davies EB, Kilgariff J, Kouzoupi N, Murphy T, Hollis C
Therapist-Supported Online Interventions for Children and Young People With Tic Disorders: Lessons Learned From a Randomized Controlled Trial and Considerations for Future Practice
JMIR Ment Health 2020;7(10):e19600
URL: http://mental.jmir.org/2020/10/e19600/
doi:10.2196/19600
PMID:33095180

Original Paper

Instagram as a Window to Societal Perspective on Mental Health, Gender, and Race: Observational Pilot Study

Kierstin Utter[1], BA; Eva Waineo[1], MD; Capricia M Bell[1], BSc; Harrison L Quaal[1], BSc; Diane L Levine[1], MD

Department of Internal Medicine, Wayne State University School of Medicine, Detroit, MI, United States

Corresponding Author:
Diane L Levine, MD
Department of Internal Medicine
Wayne State University School of Medicine
Suite 2E
4201 St Antoine
Detroit, MI, 48201
United States
Phone: 1 313 993 7835
Email: DLLevine@med.wayne.edu

Abstract

Background: Gender and race are known to impact attitudes toward mental health topics and help-seeking behavior. Men and minorities are more likely to cite stigma as a reason for not seeking help for mental health concerns, which is of particular relevance given the high rate of suicide in men and challenges of historic proportion currently facing minority communities. Instagram provides a platform to discuss mental health, though a lack of male and minority representation may further alienate these populations.

Objective: We aimed to investigate whether men and nonwhite individuals are underrepresented in Instagram photos tagged with #mentalhealth (compared to photos tagged with #health) to better understand how gender and race-based representations are manifested on this popular social media platform and discuss the implications.

Methods: Three investigators of different genders and racial backgrounds met on nine different days via teleconference to analyze a total of 215 publicly available Instagram photos tagged with #mentalhealth and 215 with #health. These photos were generated using Instagram's search function, and search results were sorted by most recently published at the time of data collection. For each photo, the three investigators recorded their observations about the gender (male versus female) and race (white versus nonwhite versus racially unclassifiable) of subjects featured in the photo, which they did not discuss with other investigators. Chi-squared analysis was performed on each investigator's data set to compare the frequency of male versus female and white versus nonwhite subjects identified in each hashtag category. Kappa interrater agreement was calculated for each investigator pair, category (gender or race), and hashtag.

Results: All three investigators observed significantly more female as compared to male subjects in photos tagged with #mentalhealth (X^2=14.4, P<.001 for all investigators) while observing no significant difference between numbers of male and female subjects in photos tagged with #health (X^2=1.533, P=.22; X^2=1.241, P=.27; X^2=0.096, P=.76). All three investigators identified significantly more white than nonwhite subjects in photos tagged with both #health and #mentalhealth (X^2 values range from 11.912 to 98.927, P<.001 for all). Kappa interrater agreement revealed almost perfect agreement for gender (kappa=0.908-0.992) with the agreement for race ranging from 0.614 to 0.822, depending on hashtag and rater pair.

Conclusions: Women are featured more frequently than men in Instagram photos tagged with #mentalhealth. The topic of #health, meanwhile, is not gendered this way. Low visibility of mental health among men may both represent and exacerbate existing stigma and barriers to care. White subjects are featured significantly more frequently than nonwhite subjects in photos tagged with both #mentalhealth and #health. Directed interventions using the Instagram platform may be indicated to increase the visibility of underrepresented groups and break the cycle of stigma.

(JMIR Ment Health 2020;7(10):e19171) doi:10.2196/19171

KEYWORDS

mental health; Instagram; social media; stigma; gender; race; depression

Introduction

With over 1 billion users [1], Instagram is one of the most widely used social media platforms in the world. It is, first and foremost, a visual platform, centered around sharing user-generated photos and videos accompanied by captions. Instagram allows users to search for photos by "hashtag." A hashtag is a word or phrase preceded by the pound (#) symbol, which, when typed in the caption of the photo, makes the photo searchable by that term. Importantly, Instagram users have the option to make their photos private or public. Public photos are visible to anyone—even those without an Instagram account. Without an Instagram account, site visitors can only scroll through approximately 30 photos before either logging in or refreshing the page and starting anew. Visitors without accounts are likewise prohibited from clicking on photos returned in a search to access poster usernames or photo captions.

In addition to its popularity for social networking, Instagram is a growing forum for discussing health-related topics. The medical community has become interested in these discussions, such as those regarding HIV, cancer, vaping, alcohol, and self-harm behavior [2-6]. As of September 2020, there are 20.7 million posts tagged with #mentalhealth on Instagram and 123 million tagged with #health [7,8]. Instagram provides insight into the beliefs and attitudes circulating amongst users and allows health care providers to understand the social influence on health-related behavior.

We aimed to investigate whether men and nonwhite individuals are underrepresented in Instagram photos tagged with #mentalhealth (versus photos tagged with #health) to understand better how gender and race-based representations present on this popular social media platform and to discuss the implications. The rationale for this project stems from decades of research—on gender, race, and mental health stigma—and is twofold. We are interested first in whether historical patterns of gender and race-based stigma make themselves manifest in the influential social media realm, and in anticipating potential consequences of underrepresentation on this platform in particular.

Several risk factors known to be positively associated with symptoms of depression and anxiety are experienced more frequently by racial minorities, chief among which is discrimination [9]. Race also affects the rate at which patients receive treatment for mental illness, compounding these risks. Compared to 49.1% of non-Hispanic white patients that receive treatment, African American or non-Hispanic Black patients are treated at a rate of 30.6%, Hispanic or Latino patients 32.9%, and non-Hispanic Asian patients 24.9% [10]. Many implicate greater stigma in treatment discrepancies, especially among Asian and African American individuals. For example, in a study of attitudes toward mental health treatment in a college-aged student population, 63% of African American students and 52% of white students perceived stigma toward seeking care [11]. These figures are even more concerning in the current global climate when minority communities face a disproportionate death toll from the COVID-19 pandemic [12] and are leading a historic civil rights movement that brings intense focus to past personal traumas and injustice [13]. All these factors have created a sense of urgency in supporting the mental health of Black communities.

Mental health stigma is of particular relevance to men as well. A large historical body of research on gender, stigma, and mental health has shown that men associate mental illness and help-seeking with a deviation from the masculine ideal [14]. The development of this phenomenon may date back to the mid-1900s when the word "depression" first appeared in the Diagnostic and Statistical Manual [14]. It has been noted that male patients were "conspicuously absent" from the process of developing diagnostic criteria for depression and that early antidepressant clinical trials focused largely on women [14]. As a result, the tearful female patient became almost synonymous with depression [14].

The idea of depression and other mental health concerns as a "woman's problem" is alive and well today. The most troubling evidence that diagnostic criteria may overlook men is the high rate of suicide in men despite a low rate of depression [15]. It is thought that men cover up emotional turmoil for fear of stigma; men are less likely than women to report symptoms of mood disorders, and when they do, they report their symptoms as less severe compared to women's self-reports [15,16]. Additionally, men are more likely than women to list stigma as a reason for not seeking care [17]. Relying on negative male stereotypes to explain a lack of help-seeking behavior creates what some have described as a culture of "victim-blaming" [15]. Victim-blaming ignores cultural, societal, economic, and personal factors that may in fact play a large role in influencing men's behavior around mental health, including norms set by society, peers, and today, social media.

Given its ubiquity, social media may affect users' beliefs and attitudes toward mental health, and because it is a visual platform, gender and race feature prominently in Instagram posts. The gender and race of individuals in photos may influence how viewers feel about certain topics. For example, the gender and race of individuals in photos tagged with #mentalhealth may influence user attitudes on mental health—their beliefs regarding who talks about it, and who cares about it. In a recent qualitative study about men's discourse surrounding mental health, one participant expressed awareness that there is a lack of "manly men" discussing mental health problems in public, while women do so more freely, creating space for other women to do the same [14].

Described in this introduction is a vicious cycle; stigma may lead to underrepresentation on Instagram, and this underrepresentation may lead to even greater alienation of men from discussions about mental health unless directed interventions are made. With this background in mind, we first predicted that women would be featured more frequently than men in photos tagged with #mentalhealth. Second, we predicted that white subjects would be featured more frequently than nonwhite subjects in photos tagged with #mentalhealth. These hypotheses are based on the assumption that experiencing more stigma in the "real world" would make individuals less likely to associate themselves visually with the topic of mental health on social media.

The hashtag #mentalhealth was chosen as a topic that, unlike #depression or #anxiety, lacks epidemiologic bias. It is well established that more women are diagnosed with depression and anxiety than men [14]. Mental health is not a diagnosis but describes the totality of emotional, social, and psychological factors that impact behavior, and therefore as a concept, is superimposable on all individuals regardless of gender or race. #Mentalhealth was also chosen to facilitate simple control. Our analysis included an identical data collection process for photos tagged with #health. Because "mental health" falls under the umbrella of "health," we considered the number of men and women in photos tagged with #health to more closely reflect baseline Instagram representation. We hypothesized that equal numbers of male and female and white and nonwhite subjects would be featured in photos tagged with #health.

Methods

In planning this project, investigators established that in order to investigate the research question of whether men and minorities are underrepresented in photos tagged with #mentalhealth as compared to #health, they would first have to generate a large pool of Instagram photos for each of these hashtags. The investigators would then look together at each photo, and each investigator would record the gender(s) and race(s) of subjects in these photos based on individual investigator's interpretations. Because investigators predicted that they would disagree on gender or race for some subjects, data would need to be collected so that kappa agreement scores could be calculated.

This plan came to fruition in a multistep process with three investigators of different genders and racial backgrounds involved in data collection. The investigators met on nine separate days in July 2020 via teleconference. One investigator shared their screen and performed two internet searches in two separate tabs: one for "#mentalhealth Instagram" and another for "#health." This search returned the respective links to access Instagram.com galleries of photos tagged with #mentalhealth and #health. Notably, the investigator was not logged into Instagram, such that only publicly available photos were visible. For both groups, photos were sorted such that the most recently posted appeared first, to avoid the bias of seeing the most "popular" photos. Photos featuring real human subjects and not meeting exclusion criteria were included for analysis. A detailed description of exclusion criteria is outlined in Multimedia Appendix 1.

One by one, eligible images were assigned a unique image ID, and investigators individually recorded the number of males, females, white, nonwhite, and racially unclassifiable subjects in each photo in separate excel sheets. During this process, investigators would be prompted to log in to Instagram, at which point the team would switch to data collection for the opposite hashtag after refreshing the page—this method avoids the need to log in. The popularity of these hashtags allowed this process to continue in a back-and-forth fashion, as dozens of new photos were added to each collection every few minutes.

On the first 8 data collection days, investigators recorded 25 photos from each hashtag. On the ninth data collection day, an additional 15 were added in each category if any data had to be removed after data collection. Investigators did not share their opinions about the gender or race of individuals in photos and did not share their data spreadsheets until data collection was complete.

Throughout this process, the authors used the term "gender" to describe the expressed gender identity of individuals in Instagram photos as investigators perceive it when forced to categorize as male or female. The term "white" was used among investigators to refer to individuals appearing to be of European descent. The term "nonwhite" refers to any individuals not meeting this definition, including Native and Indigenous populations.

Chi-squared analyses were used to determine the significance of differences between the total number of men versus women and white versus nonwhite subjects featured in each hashtag category. Investigators decided to analyze a minimum of 200 photos for each hashtag to have an 80% power to determine a 12% difference with alpha .05 or *P* value. In calculating chi-square analyses for race, individuals deemed to be "unclassifiable race" were excluded such that only a white versus nonwhite comparison was performed. Cohen kappa was used to calculate agreement between each pair of raters for each type of rating (gender or race) in each hashtag. Racially unclassifiable individuals were removed from this analysis, such that agreement focused on subjects whom raters deemed to be white or nonwhite. Chi-square values, *P* values, and kappa agreement scores were calculated using GraphPad Prism.

Out of respect for Instagram user privacy, included photos were not clicked on to reveal usernames or any other information about the posters. Only publicly available photos were included, and photos were not saved in any way. No identifying information was recorded or collected from individuals featured in photos. No one was contacted, and informed consent was waived. This research was exempted by the Institutional Review Board of Wayne State University (protocol #083519B3X).

Results

Following data collection, ten mental health photos and six health photos were removed from all three investigators' data sets due to transcription errors committed by at least one rater. For example, one rater may have marked a subject as both white and nonwhite, forgot to record gender, or missed a subject in a photo altogether. In order to calculate kappa scores accurately, these photos were removed from data analysis. As such, a total of 205 mental health photos and 209 health photos were analyzed. Raters categorized a total of 250 subjects in mental health photos and 261 subjects in health photos. Total numbers of males, females, white, nonwhite, and racially unclassifiable subjects observed by each investigator for #mentalhealth and #health are shown in Tables 1 and 2.

Table 1. Data summary by rater for #mentalhealth photos.

Rater	A	B	C
Female, n	155	155	155
Male, n	95	95	95
White, n	154	171	140
Nonwhite, n	96	73	87
Unclassifiable, n	0	6	23

Table 2. Data summary by rater for #health photos.

Rater	A	B	C
Female, n	141	140	133
Male, n	120	121	128
White, n	177	201	170
Nonwhite, n	83	45	59
Unclassifiable, n	1	15	32

Rater A

In 205 photos tagged with #mentalhealth, rater A identified 155 females and 95 males and 154 white and 96 nonwhite individuals. In 209 photos tagged with #health, rater A identified 141 females and 120 males, and 177 white subjects, 83 nonwhite subjects, and 1 subject of unknown race.

Rater B

In 205 photos tagged with #mentalhealth, rater B identified 155 females and 95 males, 171 white subjects, 73 nonwhite subjects, and 6 subjects of unknown race. In 209 photos tagged with #health, rater B identified 140 females, 121 males, 201 white subjects, 45 nonwhite subjects, and 15 subjects of unknown race.

Rater C

In 205 photos tagged with #mentalhealth, rater C identified 155 females, 95 males, 140 white subjects, 87 nonwhite subjects, and 23 subjects of unknown race. In 209 photos tagged with #health, rater C identified 133 females, 128 males, 170 white subjects, 59 nonwhite subjects, and 32 subjects of unknown race.

All three investigators identified significantly more females than males in photos tagged with #mentalhealth while observing no significant difference between genders in photos tagged with #health (Table 3). All three investigators identified significantly more white than nonwhite individuals in photos tagged with both #mentalhealth and #health after removing individuals of unknown race.

Table 3. Chi-square analyses by rater, comparison, and hashtag.

Rater	Comparison	Hashtag	Chi square	*P* value
A	F[a] vs M[b]	MH[c]	14.4	<.001
A	W[d] vs NW[e]	MH	13.456	<.001
A	F vs M	H[f]	1.533	.22
A	W vs NW	H	33.985	<.001
B	F vs M	MH	14.4	<.001
B	W vs NW	MH	39.361	<.001
B	F vs M	H	1.241	.27
B	W vs NW	H	98.927	<.001
C	F vs M	MH	14.1	<.001
C	W vs NW	MH	11.912	<.001
C	F vs M	H	0.096	.76
C	W vs NW	H	53.803	<.001

[a]F: female

[b]M: male

[c]MH: #mentalhealth

[d]W: white

[d]NW: nonwhite

[e]H: #health

Interrater agreement for gender across both hashtags ranged between 0.908 and 0.992, representing almost perfect agreement (Table 4). Interrater agreement for race in #mentalhealth photos ranged from 0.784 to 0.822. Interrater agreement for race in #health photos was the lowest, ranging from 0.614 to 0.688.

Table 4. Kappa interrater agreement by rater pair, category, and hashtag.

Rater 1	Rater 2	Category	Hashtag	Kappa
A	C	Gender	MH[a]	0.983
A	B	Gender	MH	0.949
C	B	Gender	MH	0.966
A	C	Race	MH	0.822
A	B	Race	MH	0.784
C	B	Race	MH	0.805
A	C	Gender	H[b]	0.908
A	B	Gender	H	0.992
C	B	Gender	H	0.916
A	C	Race	H	0.688
A	B	Race	H	0.662
C	B	Race	H	0.614

[a]MH: #mentalhealth

[b]H: #health

Discussion

Principal Findings

Our study highlights several important points about the visual representation of #mentalhealth on Instagram. First, females are represented significantly more often than males. This difference is not seen in photos tagged only with #health. Therefore, we believe the gender difference observed in #mentalhealth photos is not simply due to greater Instagram usage by women but is an extension of the long-observed tendency for men to withhold from public discussions of mental health [14-17].

It is thought that this tendency is motivated by stigma and the desire to conform to the hegemonic masculine ideal, in which men are expected to hide emotional turmoil and only seek help after experiencing significant pain or physical injury [14]. Much of the work on this topic has focused on men and topics with negative or health-impairing connotations, such as depression and anxiety [14,15,18]. Our study focused on mental health generally—a phrase that may arise in discussions about depression but may also arise in discussions of happiness, recovery, or wellness. Real-world stigma is, therefore, not only replicated in the social media realm but perhaps exposed even further; it is possible that beyond mental illness and help-seeking, men also face barriers when it comes to discussing wellness.

Perhaps the most troubling interpretation of our data is that social media may propagate the idea of "mental health" as a woman's cause. Previous research on stigma and men's mental health has demonstrated that when certain health behaviors, such as health care utilization, are performed more frequently by women, men associate these behaviors with deviation from the masculine ideal and become stigmatized [19]. Discussion of mental health topics on social media may play out similarly. Unfortunately, what results is a self-propagating cycle in which stigma may decrease the visibility of men's mental health, which intensifies the stigma.

Our results also highlighted a disproportionate representation of white individuals in photos in both #health and #mentalhealth categories, representing a departure from our hypothesis. We expected to see more white and nonwhite subjects in #mentalhealth photos, but equal numbers of white and nonwhite subjects in #health photos. These results may reflect a real phenomenon of greater engagement with *both* health and mental health topics by white users. However, it is also important to consider that the majority (60.1%) of the US population is white [20].

Future Interventions and Directions

Our findings suggest an opportunity for intervention using the Instagram platform. Disruption of the underrepresentation of men and minorities in conversations about mental health (and health, in the case of minorities) may slow the perpetuation of stigma by helping Instagram users see mental health as a cause for everyone. Interventions may take the form of Instagram campaigns designed to reach men and minorities, focusing on circulating images of individuals from these groups tagged with #mentalhealth and #health.

Intervention may also be warranted in the health care setting, as our observations underscore the importance of patient education and patient-centered care. That is, physicians have a unique opportunity to engage male and minority patients in discussions about their health that may be stigmatized or not discussed in their personal lives. Further, demonstrating an understanding that different demographic groups discuss health to varying degrees contributes to cultural competence and the delivery of empathic care.

The methods described here have the potential for reproducibility across a wide array of disciplines within and outside of medicine. Instagram as research tool is a relatively new concept, and methodology remains a challenge in this field. In a study published in the Journal of Medical Internet Research in 2017, Carrotte et al stated, "No best practice tools are available for systematically searching social media, and various websites' default search algorithms do not allow systematic searching [21]." Though this remains true today, our methods are similar to those of previously published works in the field and are, in some ways, more rigorous.

Carrotte et al, for example, used two coders to analyze 476 social media posts from Instagram, Tumblr, Facebook, and Twitter tagged with #fitspo using the respective sites' search engines [21]. Images were collected over ten minutes. These authors coded images on 28 different variables, and only included categorical variables in the analysis if the kappa agreement met a minimum value of .60. Tiggemann and Zaccardo used Instagram's search function to identify photos tagged with #fitspiration [22]. One coder analyzed 600 images, assigning categorical variables to the image content such as food (healthy versus not healthy), gender (male, female, or both), and adiposity (thin, average, or overweight). A second independent coder assessed 10% of the included images. Santarossa et al used the Netlytic program to download Instagram photos tagged with #fitspo over 4 days [23]. This method yielded 128 photos coded by two investigators into photo categories (action, objectification, selfie, supplement, or other). Naftali et al used two coders (an experienced social media user and a social media expert) to analyze 300 photos from Facebook, Instagram, and YouTube, using the search term #plastic_surgery on Instagram [24]. Variables analyzed by coders included the poster's identity, photo subject (self-promotional, educational, commercial, or personal), and whether the photo featured "shaming."

Like our study, these works utilized hashtags to generate their database of photos and multiple human coders [21-24]. Our project's methods are more robust in that three human coders were utilized, and data were collected over 2 weeks to create a more randomized data set. Moreover, our sample size falls within the range of all these published studies, and our kappa agreement scores all fall above .60, the acceptable minimum used by Carrotte et al [21].

We believe our work adds to research related to mental health representations in social media, but it is only a starting point. This methodology can be used to study other hashtags related to specific mental health illnesses (eg, depression or anxiety) and even hashtags related to recovery. Future studies may also examine what other hashtags are commonly associated with photos tagged with #mentalhealth that may provide further insight into posters' attitudes toward mental health.

Limitations

The findings outlined in this study, particularly as it pertains to gender, are reliable in that three different raters of different racial and gender backgrounds individually identified statistically significant patterns with almost perfect agreement. Agreement scores for race determination were lower than that for gender, suggesting that race was predictably more subjective than gender, perhaps due to individual bias regarding physical

features and racial categories. Notably, because racially unclassifiable individuals were removed from this analysis, there were fewer data points used to calculate kappa scores for race as compared to gender.

As noted in the methods section, subjects deemed to be of "unclassifiable race" were also excluded from chi-squared calculations. Initially, there were concerns about the effect of excluding these individuals, as it could falsely inflate the representation of one race. However, despite recording different numbers of unclassifiable race subjects (see Tables 1 and 2), the three investigators observed the same patterns regarding gender and race discrepancy when the chi-squared analysis was performed (Table 3).

The social and political environment impacts the content of Instagram photos. To mitigate bias that may occur from collecting data at one specific time point coinciding with the circulation of a "viral" topic, investigators collected data on nine separate occasions over two weeks. Although photo inclusion and exclusion criteria were established at the time of data collection to focus the research question and prevent bias from the selection of photos, several photos meeting the inclusion criteria were noted to pose a challenge for raters (eg, taken from several meters away, in low lighting, or with faces/heads obstructed). Future studies may implement even stricter inclusion criteria to focus data collection even more closely.

The investigators are aware of a blind spot in this design in assessing the number of transgender, gender fluid, and non-binary individuals, and also of the fundamentally flawed nature of gender categorization based on physical appearance. However, this study is interested in binary categorization to explore the stigma resulting from a binary system. It is also possible that the individuals featured in photos were of different gender and race of the individual posting the photo, but for this study focusing on visibility, the focus remains on the photo itself. As a minor point, several video thumbnails were included in analyses. The videos may have featured individuals not seen in the thumbnail. Finally, hashtags were English words, and searching for photos with #health and #mentalhealth translated into other languages may impact data, particularly racial data.

Conclusions

This observational pilot study found that women are featured more frequently than men in public Instagram photos tagged with #mentalhealth, while there is no significant difference in the number of men and women featured in photos tagged with #health. Past research suggests these findings may be due to hegemonic gender norms and stigma. White subjects appear more frequently than nonwhite subjects in photos tagged with both #health and #mentalhealth. These disparate findings lay bare the need to promote the visibility of underrepresented groups in discussions surrounding mental health on social media and provide an emerging platform for health care providers to do so.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Photo inclusion and exclusion criteria.
[DOCX File , 14 KB - mental_v7i10e19171_app1.docx]

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Abbreviations

H: #health
MH: #mentalhealth
NW: nonwhite
W: white

Edited by T Rashid Soron; submitted 19.04.20; peer-reviewed by JP Allem, N Spencer, C Nwoke, D López López, B Liu, A Louren; comments to author 29.05.20; revised version received 31.07.20; accepted 12.09.20; published 27.10.20.

Please cite as:
Utter K, Waineo E, Bell CM, Quaal HL, Levine DL
Instagram as a Window to Societal Perspective on Mental Health, Gender, and Race: Observational Pilot Study
JMIR Ment Health 2020;7(10):e19171
URL: http://mental.jmir.org/2020/10/e19171/
doi:10.2196/19171
PMID:33107831

Review

Smartphone-Based Self-Monitoring, Treatment, and Automatically Generated Data in Children, Adolescents, and Young Adults With Psychiatric Disorders: Systematic Review

Sigurd Melbye[1], MD; Lars Vedel Kessing[1], MD, DSMc; Jakob Eyvind Bardram[2], MSc, PhD; Maria Faurholt-Jepsen[1], MD, DMSc

[1]The Copenhagen Affective Disorder Research Center (CADIC), Psychiatric Centre Copenhagen, Rigshospitalet, København Ø, Denmark

[2]Department of Applied Mathematics and Computer Science, The Technical University of Denmark, Lyngby, Denmark

Corresponding Author:
Sigurd Melbye, MD
The Copenhagen Affective Disorder Research Center (CADIC)
Psychiatric Centre Copenhagen, Rigshospitalet
Blegdamsvej 9
København Ø, 2200
Denmark
Phone: 45 28966634
Email: sigurd.arne.melbye@regionh.dk

Abstract

Background: Psychiatric disorders often have an onset at an early age, and early identification and intervention help improve prognosis. A fine-grained, unobtrusive, and effective way to monitor symptoms and level of function could help distinguish severe psychiatric health problems from normal behavior and potentially lead to a more efficient use of clinical resources in the current health care system. The use of smartphones to monitor and treat children, adolescents, and young adults with psychiatric disorders has been widely investigated. However, no systematic review concerning smartphone-based monitoring and treatment in this population has been published.

Objective: This systematic review aims at describing the following 4 features of the eligible studies: (1) monitoring features such as self-assessment and automatically generated data, (2) treatment delivered by the app, (3) adherence to self-monitoring, and (4) results of the individual studies.

Methods: We conducted a systematic literature search of the PubMed, Embase, and PsycInfo databases. We searched for studies that (1) included a smartphone app to collect self-monitoring data, a smartphone app to collect automatically generated smartphone-based data, or a smartphone-based system for treatment; (2) had participants who were diagnosed with psychiatric disorders or received treatment for a psychiatric disorder, which was verified by an external clinician; (3) had participants who were younger than 25 years; and (4) were published in a peer-reviewed journal. This systematic review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The risk of bias in each individual study was systematically assessed.

Results: A total of 2546 unique studies were identified through literature search; 15 of these fulfilled the criteria for inclusion. These studies covered 8 different diagnostic groups: psychosis, eating disorders, depression, autism, self-harm, anxiety, substance abuse, and suicidal behavior. Smartphone-based self-monitoring was used in all but 1 study, and 11 of them reported on the participants' adherence to self-monitoring. Most studies were feasibility/pilot studies, and all studies on feasibility reported positive attitudes toward the use of smartphones for self-monitoring. In 2 studies, automatically generated data were collected. Three studies were randomized controlled trials investigating the effectiveness of smartphone-based monitoring and treatment, with 2 of these showing a positive treatment effect. In 2 randomized controlled trials, the researchers were blinded for randomization, but the participants were not blinded in any of the studies. All studies were determined to be at high risk of bias in several areas.

Conclusions: Smartphones hold great potential as a modern, widely available technology platform to help diagnose, monitor, and treat psychiatric disorders in children and adolescents. However, a higher level of homogeneity and rigor among studies regarding their methodology and reporting of adherence would facilitate future reviews and meta-analyses.

(JMIR Ment Health 2020;7(10):e17453) doi:10.2196/17453

KEYWORDS

mHealth; child and adolescent psychiatry; eHealth; systematic review; psychiatry; mobile phone

Introduction

Background

Psychiatric disorders often have an onset of symptoms at an early age, and 3 out of 4 patients with mental disorders have an onset of symptoms before the age of 24 years [1]. According to the World Health Organization, mental health problems account for 16% of the global burden of disease in people aged 10-19 years [2]. For these patients, the early identification of symptoms and interventions may potentially lead to significant improvement in their quality of life, level of function, sense of empowerment, and prognosis [3].

Currently, markers such as blood tests, radiologic findings, or electrophysiological measurements are insufficient for supporting the diagnostic assessment of psychiatric disorders and the severity of the symptoms. Diagnoses are largely based on clinical evaluations and observations; therefore, the affected children may depend on parents/relatives/support systems and their ability to accurately report symptoms. A fine-grained, unobtrusive, and effective way to monitor symptoms and function could help distinguish severe psychiatric health problems from normal behavior and potentially lead to a more efficient use of clinical resources in today's health care system, which in turn can lead to a more equitable distribution of resources.

Ecological momentary assessment, which involves repeatedly sampling a subject's current behaviors and experiences in real-time in his/her natural environments, reduces potential recall bias and is able to give a valid momentary overview of the fluctuation of symptoms and the level of function [4]. Smartphones represent a promising platform for ecological momentary assessments, as they are readily available to many people worldwide [5]. For adolescents and young adults, interaction with a smartphone is a natural part of everyday life, and a report from the Pew Research Centre shows that 95% of the teens in the United States own a smartphone [6]. Automatically generated data collected from smartphones and wearable sensors can be combined with detailed information on the physical health, mental health, and behaviors of children and young adults to potentially aid in diagnosing, monitoring, and treating psychiatric disorders. Thus, smartphones represent a promising tool to unobtrusively obtain access to momentarily continuous data.

Smartphone apps are also widely used as a platform to deliver treatments to users with mental health disorders and may offer an alternative to patients who have difficulties participating in traditional face-to-face therapy. Furthermore, smartphone apps are able to deliver treatment between outpatient visits, thereby enabling early intervention when prodromal symptoms or signs of deterioration begin to present. However, very few apps deliver content that is in line with evidence-based theories; in a systematic review from 2019 on apps that deliver cognitive behavioral therapy and behavioral activation, only 12 out of 107 apps were consistent with evidence-based principles [7]. Even though many apps report high feasibility and user satisfaction, very few studies have investigated the clinical effects of this technology [8]. Nevertheless, over the past few years, an increasing number of studies have investigated the use of smartphone apps to monitor and treat children, adolescents, and young adults with psychiatric symptoms. However, to date, no systematic review exists on the use of smartphones for monitoring and treatment of symptoms in children, adolescents, and young adults clinically diagnosed with psychiatric disorders. In this systematic review, we wanted to restrict our inclusion to studies involving individuals diagnosed with a psychiatric disorder in order to allow the findings to be generalizable to clinical populations.

Aim of This Study

The overall aim of this systematic review was to present the overview and status of studies investigating the use of smartphones for self-monitoring, treatment, or automatically generated data (eg, smartphone usage or location tracking) in children, adolescents, and young adults with psychiatric disorders. In particular, we aimed to conduct a systematic review that identifies and evaluates all of the studies on children, adolescents, or young adults who have been clinically diagnosed with a psychiatric disorder that include the smartphone-based self-monitoring of symptoms and level of function or smartphone-based treatment intervention. Additionally, we aimed to describe the following features of the eligible studies: (1) monitoring features such as self-assessment and automatically generated data, (2) content of the treatment delivered by the app, (3) adherence of the participants to self-monitoring, and (4) results of individual studies.

Methods

Design

This systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA, Multimedia Appendix 1) [9]. The eligibility criteria and search methodology were established and documented in advance by 3 of the authors (SM, LVK, MFJ). During the review process, we decided to also include studies that only used smartphone technology to deliver treatment in addition to studies that used smartphones for monitoring, as was the original criterium.

Study Selection

The definitions of children, adolescents, and young adults may differ depending on the culture or tradition. The World Health Organization defines "young people" to be individuals between the ages of 10 and 24 years [10]. A "child" is defined as a person younger than 18 years, and the term "adolescents" is used to describe individuals between the ages of 10 and 19 years [10]. In this review, we chose to define children, adolescents, and young adults as individuals younger than 25 years. For the papers included in this review, the following inclusion criteria were applied: (1) the study utilized a smartphone app to collect

self-monitoring data or automatically generated data such as step counts, phone usage, and location data, or the study used a smartphone-based system for treatment; (2) the participants were referred by a clinician who already provided a psychiatric disorder diagnosis, or they received treatment for the disorder, or had severe symptoms requiring treatment, for example, suicidal behavior, self-harm behavior; (3) the participants were 25 years or younger or the vast majority of the participants in the study were younger than 25 years, which was reflected by a low mean age; and (4) the study was published in a peer-reviewed journal. For studies that were described by several papers, the most recent paper was chosen for inclusion in this review. During the review process, the inclusion criteria concerning the diagnostic foundation of the participants were clarified. Precisely, we added "participants were referred by a clinician who already provided a psychiatric disorder diagnosis, or they received treatment for the disorder" to criteria (2). This was done because we found several studies including participants who only self-reported that they received treatment owing to severe symptoms. Thus, we found the initial criteria to not be sufficiently precise regarding the clinical status of the participants to identify all the relevant studies for the review. The exclusion criteria were as follows: (1) the studies included people with symptoms not meeting the diagnostic criteria or who only self-reported symptoms and were not referred by a clinician; (2) the paper was an abstract, systematic review, case report, or protocol; and (3) the paper was not written in English.

Search Strategy

Studies were selected for inclusion in this review through a systematic search of the PubMed, PsycInfo, and Embase databases on May 25, 2020, for all studies published prior to this date. The following search string was designed to target studies that included children, adolescents, or young adults with psychiatric disorders and the smartphone-based registration of symptoms: (adolescents OR young adults OR young OR teenagers OR children) AND (drug OR substance OR prescription drug OR alcohol OR narcotic OR heroin OR cocaine OR amphetamine OR cocaine OR marijuana OR opioid OR morphine OR phencyclidine) AND (abuse OR dependence OR addiction) OR (feeding disorder OR feeding disorders OR eating disorders OR eating disorder OR anorexia OR bulimia OR binge eating) OR (autism OR autistic OR asperger disease OR aspergers disease) OR asperger disorder OR aspergers disorder OR adhd OR attention deficit disorder OR attention deficit hyperactivity disorder OR (personality disorder OR personality disorders OR obsessive-compulsive personality OR compulsive personality OR obsessive personality OR psychopath OR sociopathic OR antisocial OR passive-dependent personality OR dissocial OR schizoid OR schizotypal) OR (schizophrenia OR psychoses OR psychosis OR psychotic OR paranoid OR schizoaffective OR schizophreniform OR delusional) OR (major depressive disorder OR unipolar depression OR unipolar disorder OR depressive syndrome OR endogenous depression OR neurotic depression OR melancholia OR cyclothymic OR dysthymic OR mood disorder OR mood disorders OR affective disorder OR affective disorders OR bipolar OR manic-depressive OR mania OR manic) OR (anxiety OR anxieties OR panic disorder OR agoraphobia OR obsessive disorder OR compulsive disorder OR obsessive-compulsive disorder OR phobic disorder OR phobic disorders OR ptsd OR posttraumatic stress disorder OR posttraumatic stress disorder OR posttraumatic stress disorder) AND (smartphone OR cellphone).

In order to include studies published within the last 6 months, which were not yet indexed by keywords, a literature search was conducted using the Text Word field tag in PubMed. In Embase, the field tag Keywords were used, and in PsycInfo, the field tag All Text was used. There were no limits applied to the search. We did not conduct a grey literature search.

Study Selection and Data Extraction

The identified studies were imported into EndNote for further processing. After importing the studies, duplicates were removed—first automatically and then manually. Studies were then screened for eligibility by SM. For each study, the following data were extracted: (1) general description of the study: author(s), year of publication, country, sample size, study design, age of population, sex of participants, clinical profile of case group, and the follow-up period of the study; (2) description of the app: name of the app, operating system in the app, items in self-monitoring, items collected in automatically generated data, and whether the app delivered treatment; (3) treatment delivered by the app: description of the intervention; and (4) description of the control group, study procedure, and findings: description of the control group, baseline assessment, number of follow-ups, adherence to self-monitoring, and the findings.

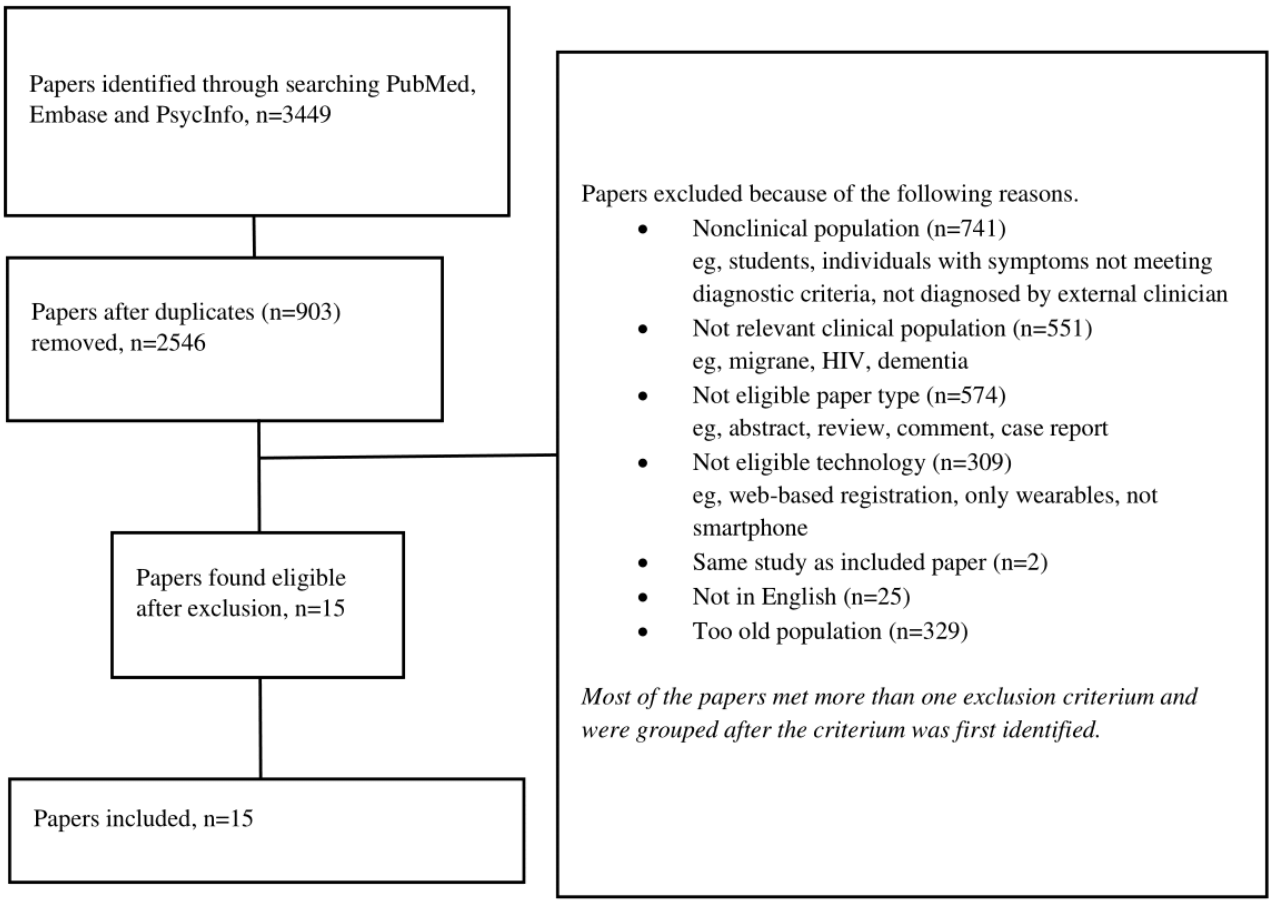
The data extraction was performed by SM and validated by MFJ. Any disagreements or uncertainties regarding eligibility or data to be extracted were resolved by discussion between 3 researchers (SM, MFJ, and LVK). The randomized controlled studies in this review were assessed for risk of bias by SM by using the Cochrane Risk of Bias tool [11]. For the remaining studies, the quality of the evidence was assessed using the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) guidelines [12].

Results

Study Selection

The search resulted in the identification of 3449 studies. After duplicates were removed, 2562 unique studies were screened either by title, abstract, or full text. The majority of the studies fell under the exclusion criteria such as nonclinical population (eg, students, individuals with subsyndromal symptoms, and individuals recruited via social media/flyers), population out of the defined age group, technology not delivered by a smartphone app (eg, web-based or use of only wearables), and publication type other than full-text paper published in a peer-reviewed journal. Finally, a total of 15 papers describing 15 unique studies were included for the review. The study selection process is presented as a PRISMA flow diagram in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) flow diagram displaying information on study flow from initial search to final inclusion.



Diagnoses and Study Origin

Of the 15 papers describing 15 unique studies (Table 1), 4 were concerning participants with psychosis [13-16], 3 were concerning participants with eating disorders [17-19], 2 were concerning participants with depression [20,21], 2 were concerning participants with autism [22,23], 1 was concerning participants with substance abuse [24], 1 was concerning participants with suicidal behavior [25], 1 was concerning participants with self-harming behavior [26], and 1 was concerning participants with anxiety [27]. In all the included studies, participants were referred by external clinicians who had established the diagnosis or the need for treatment, and in 2 studies, the diagnoses were also validated by researchers at baseline [18,27]. Three studies had some participants older than 25 years but the clear majority of the participants were children, adolescents, or young adults, as demonstrated by the low mean age [14,15,19]. Four studies included only females [17-20], 2 did not provide information about gender [22,23], while the remaining studies included both genders. Of the 15 studies, 11 were published in 2017 or later [13-16,19,20,22,25-27]. A total of 7 studies originated from the United States [14,15,20-22,24,25], 5 from Europe [13,17-19,26], 2 from Australia [16,27], and 1 from Jordan [23].

Table 1. Description of the study design and populations of studies on self-monitoring and automatically generated data collected via smartphones in children, adolescents, and young adults with psychiatric disorders (N=15).

Author, year of publication	Country	Sample size (n)	Study design	Age of population (years), range, mean (SD)/proportion[a]	Sex (women), (%)	Clinical profile of the case group	Length of project
Bucci et al, 2018 [13]	United Kingdom	24 in intervention arm, 12 in control arm	Randomized controlled trial	≥16 years, age at first symptoms: Actissist group, 20.21 (7.37) years, ClinTouch group, 18.33 (7.00) years	Actissist group: 37.5%, ClinTouch group: 75.0%, Total: 50%	Early psychosis	12 weeks
Cao et al, 2020 [21]	United States of America	13	Feasibility study	12-17 years, 14.9 (1.59) years	85%	Depression	8 weeks
Dennis et al, 2015 [24]	United States of America	29	Feasibility study	14-15 years, 28% 16-17 years, 45% 18 years, 28%	31%	Substance abuse	6 weeks
Jones et al, 2018 [22]	United States of America	20	Feasibility study	5-13 years	Not described	Autism	8 weeks
Kennard et al, 2018 [25]	United States of America	34 in intervention arm, 32 in control arm	Randomized controlled trial	12-18 years, intervention group: 14.9 (1.6) years; control group: 15.3 (1.4) years	Intervention group: 90.6%; control group: 88.2%	Suicidal ideation or recent suicide attempt	2-3 weeks
Kolar et al, 2016 [17]	Germany	20 cases, 20 healthy controls	Observational study	12-19 years, cases: 16.0 (1.55) years; controls: 15.9 (1.95) years	100%	Anorexia nervosa	2 days
Kumar et al, 2018 [14]	United States of America	61	Feasibility study	12-30 years, mean 17.4 years	48.50%	Early psychosis	Up to 5 months
Lim et al, 2020 [16]	Australia	12	Feasibility study	16-25 years, 20.50 (1.33) years	25%	Early psychosis	6 weeks
Lim et al, 2019 [27]	Australia	9 cases, 11 healthy controls	Feasibility study	18-23 years, case group: 21.00 (1.41) years; control group: 20.36 (2.16) years; total: 20.65 years	44.99%	Social anxiety disorder	6 weeks
Neumayr et al, 2019 [19]	Germany	20 in intervention arm, 20 in control arm	Randomized controlled trial	15-36 years, intervention group, 20.75 (6.4) years; control group, 18.00 (3.73) years	100%	Anorexia nervosa	8 weeks
Niendam et al, 2018 [15]	United States of America	76	Feasibility study	13-30 years, 18.8 (3.7) years	44%	Recent onset psychosis and clinical high risk	3-14 months
Seidel et al, 2016 [18]	Germany	37 cases, 33 healthy controls	Retrospective cohort	Cases: 12-20 years, 16.40 (2.33) years; control: 14-25 years, 16.51 (3.79) years	100%	Anorexia nervosa	2 weeks
Shrier and Spalding, 2017 [20]	United States of America	16	Feasibility study	15-23 years, mean 19.6 years	100%	Depression and sexual risk behavior	4 weeks
Stallard et al, 2018 [26]	United Kingdom	44	Feasibility study	12-17 years, 16.0 (1.4) years	91%	Self-harming or history of self-harm	12 weeks
Sweidan et al, 2019 [23]	Jordan	100	Feasibility study	5-13 years	Not described	Autism	1 month

[a]In some studies, only the mean age/age range/mean (SD) age/all of these were provided.

Study Characteristics

Of the 15 included studies, 3 were RCTs [13,19,25] investigating the effect of smartphone-based treatment interventions, 1 was a retrospective cohort study [18], 1 was an observational study [17], and the remaining were feasibility/pilot studies. The sample sizes of the included studies varied from 12 [16] to 100 [23] participants, with a mean (SD) sample size of 42.9 (26.5) participants.

Technical Description of the Smartphone Technology

One of the studies used an app that only administered treatment and did not use a monitoring system [23], 8 studies used a monitoring system and administered treatment

[13,16,19,20,24-27], and the remaining 6 studies included monitoring only (Table 2). In the 15 studies, there were 14 different smartphone apps, as 1 of them was used in 2 different studies [16,27]. Six of the smartphone apps were available for Android phones only [13,17,18,21,23,24], and 6 were available for both Android phones and iPhones [14-16,19,20,22,25-27]. In 1 study, only the caregiver of the diagnosed child used the app [22]. Three studies described a design wherein clinicians used the registered data in clinical sessions [14,15,19].

Table 2. Description of the app used in studies on self-monitoring, treatment, and automatically generated data collected via smartphones in children, adolescents, and young adults with psychiatric disorders (N=15).

Author, year of publication	Name of app	System	Items in self-monitored data	Items in automatically generated data	Active treatment delivered by app
Bucci et al, 2018 [13]	Actissist and ClinTouch	Android	Actissist: self-assessment focused on cognitive appraisals, belief conviction, emotions, and associated behaviors. ClinTouch: rating of 12 symptoms validated against PANSS[a]	N/A[b]	Yes
Cao et al, 2020 [21]	SOLVD	Android	Daily: mood and anxiety	Accelerometer, GPS, steps, call log, text messages, screen on/off, and ambient light intensity	No
Dennis et al, 2015 [24]	ACHESS	Android	EMA[c] 6 times/day focused on current feelings, activities, location, and company, internal and external factors that made them want to use drugs/alcohol, and their ability to resist	N/A	Yes
Jones et al, 2018 [22]	Janssen Autism Knowledge Engine	Android and iOS[d]	By caregiver: questions about the child being tense/worried, irritable, and disruptive. Once a day in weeks 1, 4, and 8, and 3 times a week in the remaining period	N/A	No
Kennard et al, 2018 [25]	BRITE	Android and iOS	Level of emotional distress	N/A	Yes
Kolar et al, 2016 [17]	Epicollect	Android	Assessment of aversive tension and possible moderator events every hour for 2 days, except predefined sleeping hours	N/A	No
Kumar et al, 2018 [14]	RealLife Exp	Android and iOS	Daily questions on mood, medication use, socialization, conflict, and medication. Weekly survey on how often in the past week they felt a range of symptoms	N/A	No
Lim et al, 2020 [16]	+Connect[e]	Android and iOS	Mood evaluation tracker	N/A	Yes
Lim et al, 2019 [27]	+Connect	Android and iOS	Mood evaluation tracker	N/A	Yes
Neumayr et al, 2019 [19]	Recovery Record	Android and iOS	Self-monitoring of meals, feelings, behavior, and thoughts.	N/A	Yes
Niendam et al, 2018 [15]	Ginger.io	Android and iOS	Daily surveys assessing mood, medication adherence, and social interactions; weekly surveys assessing symptoms, sleep, and medication adherence	Number of calls in/out, messages in/out, movement patterns based on GPS data.	No
Seidel et al, 2016 [18]	MovisensXS	Android	Rumination about food and weight; an adapted version of the MDMQ[f] assessed 3 dimensions of affect: valence, calmness, and energetic arousal	N/A	No
Shrier and Spalding, 2017 [20]	Not described	Android and iOS	EMI[g] regarding feeling, social situations, and sexual behavior 4 times/day. Questions about motivation to change risk behavior, stressful events, and use of healthy ways to manage feelings	N/A	Yes
Stallard et al, 2018 [26]	BlueIce	Android and iOS	Mood diary	N/A	Yes
Sweidan et al, 2019 [23]	AIA[h]	Android	N/A	N/A	Yes

[a]PANSS: Positive and Negative Syndrome Scale.

[b]N/A: not applicable.

[c]EMA: ecological momentary assessment.

[d]iOS: iPhone operating system.

[e]This same app was used in 2 studies.

[f]MDMQ: multidimensional mood questionnaire.

[g]EMI: ecological momentary intervention.

[h]AIA: Autistic Innovative Assistant.

Smartphone Usage

The period of use for the smartphone app varied from 2 days [17] to up to 14 months [15]. For the studies where the duration was precisely defined, the mean (SD) duration was 6.1 (3.6) weeks. In 6 of the included studies, participants received financial compensation [14-16,19,24,27]; in 2 studies, patients received gift cards as compensation for participation [13,20]; 1 study reports compensating participants but does not state how [21], and in the remaining studies, information concerning economic compensation for participation was not provided.

Only 4 studies [13,16,26,27] reported that they monitored for potential adverse effects. One of the studies listed hospital admission as a potential adverse effect [16], 1 study listed increased self-harm as an adverse effect [26], 1 listed both admission and self-harm as adverse effects [27], and the last study did not specify the adverse effects that were being monitored [13]. None of these studies identified events of adverse effects during their study periods. For the remaining 11 studies, no potential adverse effects were mentioned. There were no other reported negative consequences to using the technology in any of the studies.

Smartphone-Based Self-monitoring

All but 1 [23] of the included studies had elements of self-monitoring collected via smartphones, and self-assessment of symptoms and level of function relevant to the specific clinical population were the most frequent items included. A total of 6 studies described the self-monitoring of the participant's mood [14-16,21,26,27], 1 study requested the participants to perform self-monitoring related to recreational drug use [24], 1 requested self-monitoring on medication adherence [15], and 1 described self-monitoring of meals [19]. In studies where the frequency of self-monitoring was specified, it varied from once a day to every waking hour [27]. One of the studies reported validating smartphone-based self-monitored data on mood and anxiety by investigating the correlation between these and the validated clinical ratings on the Hamilton Depression Rating Scale [28] and the Hamilton Anxiety Rating Scale [29]. The items used for self-monitoring in each of the studies are presented in Table 2.

Automatically Generated Smartphone-Based Data

A total of 2 studies described the collection of automatically generated data via smartphones [15,21]. Both these studies described the collection of usage data, such as the number of phone calls and text messages in addition to GPS-based location data that provided data about the user's movement patterns. One of the studies also collected the information on the number of steps, the amount of time the screen was turned on time, and the registered ambient light every second minute [21]; it also investigated the correlation between the automatically generated smartphone-based data and clinical findings from rating scales and found significantly positive correlations between daily steps taken, SMS frequency, and the average call duration and scores from the clinical rating scales [21]. The other study did not describe how they used the automatically generated data [15].

Adherence to Self-monitoring

All but 4 [20,22,23,26] of the studies reported on the adherence to smartphone-based self-monitoring in some way. However, the level of adherence and acceptance was reported differently across the various studies, making it impossible to conduct meta-analyses investigating the differences in adherence measures between diagnostic categories. In 9 studies, adherence to self-monitoring was reported as a percentage—either as a percentage of the participants reaching a predefined level of satisfactory completion or as a percentage of prompts/notifications the participants responded to [13-16,18,21,24,25,27]. In all but 1 of these studies [14], the adherence to self-monitoring was above 50%. The specific rates of adherence are presented in Table 3.

Table 3. Description of the control groups, procedures, and findings in studies on self-monitoring, treatment, and automatically generated data collected via smartphones in children, adolescents, and young adults with psychiatric disorders (N=15).

Author, year of publication	Control group	Baseline assessment	Follow-up	Adherence	Findings
Bucci et al, 2018 [13]	24 participants received Actissist plus TAU[a], 12 received ClinTouch plus TAU	Demographics; PANAS[b]; PSYRATS[c]; CDSS[d]; Global Assessment of Functioning Scale; Personal and Social Performance Scale; Empowerment Rating Scale; EQ-5D-5L[e]; Timeline Follow-back, Medication Adherence Rating Scale	Clinical assessment at 12 weeks and 22 weeks	Data points completed (>33% data entries): 75% (Actissist) and 50% (ClinTouch)	Actissist was feasible, acceptable (90% recommend Actissist), and safe (0 serious adverse events), with high levels of user satisfaction. Treatment effects were large on negative symptoms, general psychotic symptoms, and mood. The addition of Actissist conferred benefit at posttreatment assessment over routine symptom-monitoring and TAU.
Cao et al, 2020 [21]	N/A[f]	Mini International Neuropsychiatric Interview to confirm diagnosis of MDD[g], PHQ-9[h], HAM-D[i], and HAM-A[j]	Biweekly clinical assessment	79.0%	Significant correlation between the self-evaluated mood averaged over a 2-week period and the biweekly psychometric scores from PHQ-9, HAM-D, and HAM-A ($0.45 \leq |r| \leq 0.63$; $P=.009$, $P=.01$, and $P=.003$, respectively). The daily steps taken, SMS frequency, and average call duration were also highly correlated with clinical scores ($0.44 \leq |r| \leq 0.72$; all $P<.05$). By combining self-evaluations and smartphone sensor data, they could predict the PHQ-9 score with an accuracy of 88%.
Dennis et al, 2015 [24]	N/A	GAIN-Q3[k]	2 visits a week to complete survey and provide urine sample	Participants completed 89% EMAs[l]; 18 participants completed over 90% of the EMAs	EMA observations were classified into 3 risk groups: “Current Use” (3%), “Unrecognized Risk” (42%), or “Recognized Risk” (55%). Unrecognized Risk (50%) and Current Use (96%) groups reported significantly higher rates of use in the next week compared with the Recognized Risk group’s use in the following week (31%). Drug use following an EMA that was accessed was lower compared to that when EMA was not accessed (32% vs 43%).
Jones et al, 2018 [22]	N/A	Caregivers completed aberrant behavior checklist, child behavior checklist, PANAS, visual analog scale	Clinic visits in weeks 1, 4, and 8.	Not described	Over 8 weeks, caregivers reported improvements in their child’s mood, irritability, and disruptive behaviors during TAU.
Kennard et al, 2018 [25]	34 patients received As Safe As Possible app+ TAU, 32 received TAU	PHQ, SIQ-JHSV[m], CSSRS[n], youth self-report scale, CRAFT[o]	At weeks 4, 12, and 24	70.6% used the app at least once. Participants rated their mood at a median of 19 times	There were no treatment effects on suicidal ideation. Participants reported high satisfaction with both the intervention and the app.
Kolar et al, 2016 [17]	Healthy controls	ChEDE[p]; Symptom Checklist 90	Not described	1030 completed the observations entered	Participants with anorexia nervosa showed higher mean and maximum levels of aversive tension. Reported food intake was associated with higher levels of aversive tension in the anorexia nervosa group, whereas reported school or sport-related events were not linked to specific states of aversive tension. After food intake, subsequent increases of aversive tension were diminished, and decreases of aversive tension were induced in adolescents with anorexia nervosa.

Author, year of publication	Control group	Baseline assessment	Follow-up	Adherence	Findings
Kumar et al, 2018 [14]	N/A	GF[q]social, GFrole; BPRS[r]; Clinical Global Impression Severity; assorted questionnaires	At the end of project with repeat of clinical assessment	Daily survey completion rate was 41% and weekly survey completion rate was 39%	27 of 41 (66%) participants with early psychosis who completed the study and 11 of 13 (85%) treatment providers who responded to satisfaction surveys reported they would continue to use the app as part of treatment services.
Lim et al, 2020 [16]	N/A	SCID-5[s], Positive and Negative Syndrome Scale, CDSS, Social Skills Performance Assessment, National Adult Reading Test, UCLA-LS[t], SIAS[u], Scales of Psychological Well-being	After treatment and 3-month follow up	Participants on average completed 95.47% of the +Connect (mean 40.10 days, SD 3.04)	Data indicate preliminary evidence that +Connect may reduce loneliness, with scores from preintervention (mean 52.58, SD 8.47) to postintervention (mean 48.10, SD 10.38) and at 3 months after the intervention (mean 42.89, SD 7.04) on UCLA-LS
Lim et al, 2019 [27]	11 lonely students without mental health conditions	SCID-5-Research version, UCLA-LS, SIAS, Centre for Epidemiological Studies-Depression	Posttreatment and 3-months follow up	Social anxiety group: 84.66%; control group: 90.26%	The UCLA-LS and straightforwardly worded SIAS scores decreased in a linear trend from baseline to months after the intervention for the case group. There were higher acceptability ratings across different ratings in a nonclinical lonely student group compared with those with social anxiety disorder.
Neumayr et al, 2019 [19]	50% were randomized to receive intervention	EDE-Q[v], BMI, BDI-II[w]	8 weeks and 6 months	Mean of 231 logs during the 8-week intervention.	There were postintervention nonsignificant small to moderate between‐group effect sizes favoring the intervention group regarding BMI (d=–0.24 [–0.90, 0.41]) and eating disorder symptoms. At 6‐month follow‐up, there were no differences between the intervention group and control group
Niendam et al, 2018 [15]	N/A	BPRS	Not described	Weekly survey completion: mean 77.3%; Daily survey completion: mean 69.0%.	Weekly survey positive symptoms were significantly associated with BPRS-positive symptoms (β=.56, SE=0.10; P<.001).
Seidel et al, 2016 [18]	Healthy controls, normal weight, no history of eating disorders	Structured Interview for Anorexic and Bulimic Syndromes for Experts; Eating Disorder Inventory; BDI; Perseverative Thinking Questionnaire; State-Trait Anxiety Inventory; body weight	Not described	Participants answered 84.19% of their prompts compared to 75.73% in the control group	Momentary negative affect is positively associated with a higher amount of disorder-related rumination in participants (P<.001).
Shrier and Spalding, 2017 [20]	N/A	BDI-II	Not described	Not described	Participants expressed positive opinions about the ecological momentary intervention. They desired a high degree of personalization of the message quality, style, and voice.
Stallard et al, 2018 [26]	N/A	MFQ[x]; Revised Children's Anxiety and Depression Scale; Strengths and Difficulties Questionnaire; Safety-assessment; Self-Harming information	After 2 weeks (post-familiarization) and 12 weeks (after use)	Not described	73% of those who had recently self-harmed reported reductions in self-harm after using BlueIce for 12 weeks. There was a statistically significant mean difference of 4.91 (P=.04) on postuse symptoms of depression (MFQ) and 13.53 (P=.001) on symptoms of anxiety (Revised Child Anxiety and Depression Scale), which was evident across all anxiety subscales.

Author, year of publication	Control group	Baseline assessment	Follow-up	Adherence	Findings
Sweidan et al, 2019 [23]	N/A	Not described	Not described	Not described	A detailed survey filled out by 100 parents and teachers after testing showed encouraging results

[a]TAU: treatment as usual.
[b]PANAS: Positive Affective and Negative Affective Scale.
[c]PSYRATS: Psychotic Symptom Rating Scale.
[d]CDSS: Calgary Depression Scale for Schizophrenia.
[e]EQ-5D-5L: 5-level health status and health-related quality of life.
[f]N/A: not applicable.
[g]MDD: major depressive disorder.
[h]PHQ-9: patient health questionnaire-9.
[i]HAM-D: Hamilton Depression Rating scale.
[j]HAM-A: Hamilton Anxiety Rating scale.
[k]GAIN-Q3: Global Appraisal of Individual Needs-Quick 3.
[l]EMA: ecological momentary assessment.
[m]SIQ-JHSV: Suicidal Ideation Questionnaire-Junior High School Version.
[n]CSSRS: Columbia Suicide Severity Rating Scale.
[o]CRAFT: Car, Relax, Alone, Forget, Friends, and Trouble questionnaire.
[p]ChEDE: child eating disorder examination.
[q]GF: global functioning.
[r]BPRS: Brief Psychiatric Rating Scale.
[s]SCID-5: Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders.
[t]UCLA-LS: University of California, Los Angeles Loneliness Scale score.
[u]SIAS: Social Interaction Anxiety Scale.
[v]EDE-Q: Eating Disorder Examination-Questionnaire.
[w]BDI-II: Beck Depression Inventory-II.
[x]MFQ: mood and feeling questionnaire.

Treatment Delivered by the Apps

Eight of the studies included delivered treatment content in addition to and often in response to self-monitoring [13,16,19,20,24-27]. One of the studies used an app delivering educational content designed for children with autism and did not include any monitoring of symptoms or level of function [23]. The specific findings are presented in Table 4.

Table 4. Description of the treatments delivered by the apps in studies on self-monitoring and automatically generated data collected via smartphones in children, adolescents, and young adults with psychiatric disorders (n=9).

Author, year of publication	Intervention
Bucci et al, 2018 [13]	Actissist: Messages and cognitive or behavioral strategies aimed at ways of coping with distress; use of video, fact sheets, and external links. ClinTouch: only symptom monitoring.
Dennis et al, 2015 [24]	Participants had access to ecological momentary intervention content.
Kennard et al, 2018 [25]	Psychoeducation, behavioral activation and pleasant event scheduling, affect regulation strategies: savoring, switching, and distress tolerance, consolidation and review, distress tolerance strategies, emotion regulation skills, and safety plan.
Lim et al, 2020 [16] and Lim et al, 2019 [27][a]	The app delivers positive psychology content daily.
Neumayr et al, 2019 [19]	Positive reinforcement, coping skills suggestions, motivational slogans, positive affirmations, guided meditations, and therapist feedback.
Shrier and Spalding, 2017 [20]	Messages of general support and messages to avoid sexual risk.
Stallard et al, 2018 [26]	Personalized mood-lifting activities and safety check to prevent self-harm.
Sweidan et al, 2019 [23]	The app delivers educational content in the following categories: numbers, vocabularies, letters, social skills, relaxation, and anger management

[a]This app was used in 2 different studies.

Findings of the Studies

The majority of the included studies were feasibility or pilot studies. A total of 9 studies reported on acceptability and satisfaction specifically [13-16,19,24-27], with all studies reporting 70% or more of the participants stating they would recommend others to use the app or rating the app as helpful/useful or better. None of the included studies reported findings that would suggest the technology is not feasible. Specific findings are presented in Table 3.

Findings of the Retrospective Cohort Study

One study described an app for self-monitoring of rumination about food and weight, as well as the self-assessment of valence, calmness, and energetic arousal [17]. The correlation between affect and negative rumination was investigated in a retrospective cohort study that compared the registrations from participants with anorexia nervosa and registrations from healthy controls. Analyses showed that for participants with anorexia nervosa, negative affect registered on the app was positively correlated with the amount of disorder-related rumination.

Methodology and Findings of the RCTs

One RCT investigated the effectiveness of a self-monitoring system on participants with psychosis, thereby focusing on cognitive appraisals, belief convictions, emotions, and associated behaviors on a smartphone app [13]. The app used videos and fact sheets in combination with messages and cognitive or behavioral strategies aimed at coping with distress. The effect of this system was tested over a 12-week period on participants with early psychosis in an RCT that included 46 participants randomized in 2:1 to use the Actissist app for both self-monitoring and intervention, while the control group used an app with only self-monitoring. The primary outcome was feasibility and acceptability, and participants with early psychosis found the Actissist app to be both feasible and acceptable. The RCT also found a large treatment effect in relation to the secondary outcome, specified as an improvement of negative symptoms, general psychotic symptoms, and mood, as assessed by the Positive and Negative Syndrome Scale and Calgary Depression Scale for Schizophrenia.

The second RCT investigated the effectiveness of a self-monitoring system focusing on emotional distress, and the app responded with distress tolerance strategies, emotion regulation skills, and a safety plan [25]. The effect of this system was tested in an RCT on participants hospitalized for suicidal ideation or a recent suicide attempt. This included 66 participants randomly organized into treatment and control groups in a 1:1 ratio, with the treatment group receiving the intervention app, while the control group received treatment as usual over the course of 2-3 weeks. Analyses based on their primary outcomes showed that the treatment had no effect on suicidal ideation.

The third RCT investigated the effectiveness of a self-monitoring system focusing on meals, feelings, thoughts, and behavior, where the app responded with positive reinforcement, coping skills suggestions, motivational slogans, positive affirmations, guided meditations, and therapist feedback [19]. The effect of this system was tested in an RCT on participants with anorexia nervosa, including 40 participants randomly organized into treatment and control groups in a 1:1 ratio, with the treatment group receiving the intervention app while the control group received treatment as usual over the course of 8 weeks. Analyses on the primary outcome concerning feasibility suggested that the intervention was both feasible and acceptable, at least in the short term in combination with feedback from therapists. Analyses based on secondary outcomes showed nonsignificant differences favoring the intervention group in the normalizing of the participant's body mass index.

Risk of Bias and Quality of Evidence Assessment

Of the 3 RCTs, only 1 conducted an intention-to-treat analysis [25]; the remaining 2 [13,19] had dropouts but did not describe how these were handled in the analyses. Two studies described being conducted in accordance with a predefined protocol; the protocol is included in the reference list [13,25], and the remaining 1 did not mention following a specific protocol. In 2 studies, the researchers were blinded for the randomization [13,25] but the participants were not blinded for any of the studies. All the studies described randomization processes with a low risk of bias; however, all studies were evaluated to have an unclear risk of bias due to other sources. One of the studies mentioned their design's lack of ability to determine which components of the intervention or app were effective as a limitation [25]. All the nonrandomized studies were evaluated to have low quality of evidence, mainly due to the lack of controls. Results from the Cochrane Risk of Bias assessment and the GRADE assessment of quality of evidence are presented in Figure 2 and Figure 3, respectively.

Figure 2. Cochrane risk of bias assessment chart for the included randomized controlled trial studies.

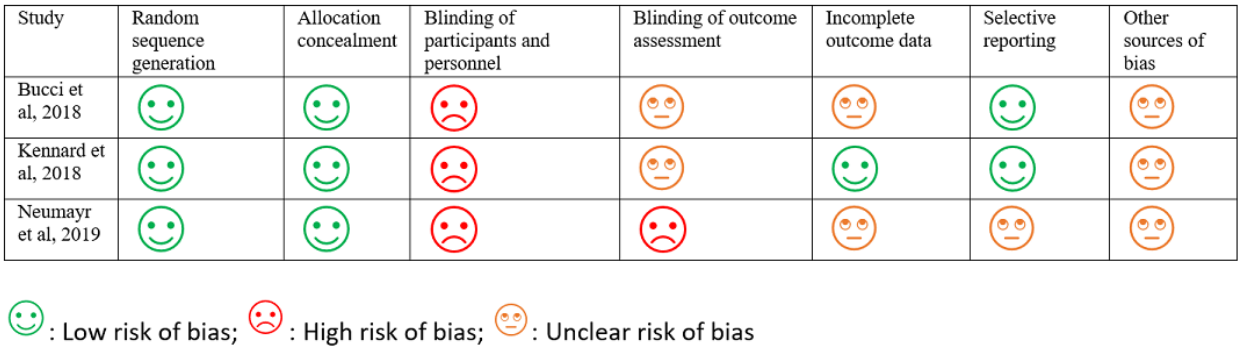


Figure 3. Grading of Recommendations, Assessment, Development and Evaluations (GRADE) quality of evidence chart for nonrandomized studies.

Study, year of publication	*Failure to develop and apply appropriate eligibility criteria*	*Flawed measurement of both exposure and outcome*	*Failure to adequately control confounding*	*Incomplete follow-up*
Cao et al, 2020 [20]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕⊕⊕◯ Moderate
Dennis et al, 2015 [23]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Jones et al, 2018 [21]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Kolar et al, 2016 [16]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕⊕⊕◯ Moderate
Kumar et al, 2018 [13]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Lim et al, 2019a [15]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Lim et al, 2019b [26]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Niendam et al, 2018 [14]	⊕◯◯◯ Very low	⊕⊕⊕◯ Moderate	⊕⊕◯◯ Low	⊕⊕⊕◯ Moderate
Seidel et al, 2016 [17]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕⊕⊕◯ Moderate	⊕◯◯◯ Very low
Shrier and Spalding, 2017 [19]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Stallard et al, 2018 [25]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Sweidan et al, 2019 [22]	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low	⊕◯◯◯ Very low
Quality of evidence	⊕◯◯◯ Very low	⊕⊕◯◯ Low	⊕⊕⊕◯ Moderate	⊕⊕⊕⊕ High

Declarations

In 9 of the included studies, conflicts of interest were disclosed [14,16,18-21,23,26,27]. Six of these studies disclosed no relevant conflicts of interest, and in 3 studies [19,21,26], 1 of the authors of the study was also the designer of the app used in the study.

Discussion

Principal Findings

Despite the fact that 95% of the teens in the United States own and use a smartphone, we were able to identify only 15 unique studies using smartphone-based self-monitoring and treatment for 8 different diagnostic groups in children, adolescents, and young adults with psychiatric disorders. The included studies were highly heterogeneous in terms of the aims of the study, the included participants, the methodology used, and the reporting of the findings. The fact that 11 out of the 15 included studies were published during the last 3 years demonstrates that the use of smartphone-based health technology for children, adolescents, and young adults with mental health problems is still in an early stage. Although all the studies used smartphones for self-monitoring or treatment, only 3 RCTs with relatively small sample sizes that investigated the effectiveness of smartphone-based intervention treatments have been published. Of these, 2 found a positive treatment effect and the third showed no effect. However, 2 of these studies had feasibility and acceptability as the primary outcome measure, and all the RCTs had several issues concerning a high or unclear risk of

bias. In general, the effectiveness of smartphone-based treatment for children, adolescents, and young adults with various psychiatric disorders has been sparingly investigated and is yet undetermined. Despite the great potential of smartphone-based monitoring and treatment, more RCTs investigating the potential positive and negative effects of using smartphones to deliver health interventions in this population are required.

The majority of the studies identified in this systematic review were feasibility or pilot studies, with the main findings describing different aspects of the acceptance, usability, and feasibility of smartphone-based self-monitoring during generally quite short study periods or different lengths. The vast majority of these studies reported positive attitudes among participants regarding the acceptance and feasibility of self-monitoring information. Notably, only 1 of the included studies reported on the validity of the various self-monitored data as compared with the validated rating scales such as the Hamilton Depression Rating Scale [28]. Therefore, the validity of the self-monitored data collected in the included studies is yet undetermined. In 2 studies, automatically generated data were collected. Both collected data on location and usage. One of them collected data on step count and ambient light and investigated the correlation between automatically generated data and clinical rating scores. It may be that some of the studies collected automatically generated data but did not include or mention it in the respective studies.

Limitations of the Individual Studies

Only 1 RCT described strictly monitoring, reviewing, and documenting any serious adverse effects of the intervention [13]. None of the other RCTs conducted a systematic assessment of the potential adverse effects of the intervention. The generalizability of the results is questionable as none of the included studies investigated the large-scale use of smartphone-based treatment in daily clinical practices, and all but 1 of the studies were conducted in developed countries. Only 9 of the 15 studies disclosed a potential conflict of interest. In 6 of these studies, there were no relevant conflicts of interest, and in the remaining 3, one of the authors of the study designed the app used in the study. However, they did not receive any financial gain from its development. The findings of the studies were reported in a number of different ways, especially with regard to reporting the participant adherence to self-monitoring. In all of the studies that reported the adherence to self-reporting, each study had its own definition of completion of a task and how to report this as adherence; it would be greatly beneficial if this could be done in a more homogenous and standardized way in order to facilitate comparisons and meta-analyses. The participants' clinical diagnoses were validated by the researchers in only 2 of these studies. Only 1 of the 3 RCTs used an intention-to-treat analysis, and in the remaining 2, it was not reported how dropouts were handled. Only 2 were single-blinded, and none were double-blinded.

Limitations and Strengths of This Review

The studies included in this systematic review were heterogeneous both in the clinical profiles of the participants and in the methodologies, making it difficult to compare the results and draw legitimate conclusions. Because we were interested in describing studies performed on clinical populations, we chose to only perform the literature search in databases dedicated to medical and psychological publications. Therefore, we may have missed some eligible studies that were only published in technology-oriented journals or conference proceedings or literature that may have been identified by a grey literature search. Because the included studies presented with a number of different ways of securing or assessing the diagnosis in their clinical populations, we were not able to create strict inclusion criteria regarding diagnostic assessments according to standardized diagnostic interviews. However, we chose to include only studies where participants were referred by an external clinician who had established the diagnosis or need for treatment. Thus, we only included populations with a psychiatric diagnosis. Further, it is important to mention that the inclusion criteria for the diagnostic foundation of the participants were clarified during the review process to also include studies with participants with severe symptoms requiring treatment, for example, suicidal behavior and self-harm behavior. This specification regarding the clinical status of the participants was made to ensure identification of all relevant studies for the review. Similarly, the exclusion criteria were slightly specified during the review process adding that studies including "people with symptoms not meeting diagnostic criteria" to criterion 1. We do find that the inclusion and exclusion criteria were predefined as good as possible and further clarified during the review process, and the review therefore has been conducted in accordance with the principles of the Cochrane Handbook for Systematic Reviews of Interventions. Further, it would be interesting for future reviews to include studies investigating the use of smartphone-based self-assessment, treatment, and automatically generated data in populations at risk of developing psychiatric disorders or in populations with subclinical symptoms. During the review process, we decided to include studies investigating smartphone-based treatment, in addition to only studies involving monitoring, which was the original criterium; this was done because we saw many of the monitoring apps also provided treatment, and thus, it was meaningful to describe both monitoring and treatment in the same review. This review was performed with a systematic approach and we conducted a thorough investigation of more than 2000 potential studies. Even though this review has 4 authors, only SM performed the eligibility screening and the risk of bias assessment. The literature search was updated throughout the process, and the results reflect an updated review of the existing literature. This review was not preregistered in any prospective review databases (eg, PROSPERO). The authors of this systematic review are experts within the field on both the research and clinical sides. All of the authors are involved in a Horizon 2020 project named Technology Enabled Mental Health-Innovation Training Network, which focuses on technology-based solutions to improve the assessment, prevention, and treatment of mental health disorders in children, adolescents, and young adults [30]. The studies included in this review covered a broad range of diagnostic groups and thus provided a good overview of the current research published within this rapidly expanding field.

Conclusions and Implications

This systematic review identified 15 individual studies examining the use of smartphone-based monitoring and treatment of children, adolescents, and young adults with psychiatric disorders, who were referred by external clinicians, thereby covering 8 different diagnostic categories. This review identified a large diversity in the research conducted in the field of smartphone-based self-monitoring and treatment of children, adolescents, and young adults with psychiatric disorders. Most of the included studies were feasibility or pilot studies, and only 3 RCTs investigating the effect of smartphone-based treatment were identified. This review demonstrates that for children, adolescents, and young adults with psychiatric disorders, adherence to smartphone-based symptom registration was generally high, as was the satisfaction with such a system, as reported by participants, clinicians, and caregivers. Among the 3 RCTs, 2 found a positive treatment effect, which is promising for the future of technological interventions in the mental health of children, adolescents, and young adults with psychiatric disorders. However, all the 15 studies were short-term studies and generally had small sample sizes, with an average of 43 participants.

In conclusion, the findings from this review strongly emphasize the need for a larger number of studies as well as studies with a larger number of participants, including RCTs investigating the potential positive and negative effects of fine-grained smartphone-based self-monitoring and treatment over prolonged periods of time. Such RCTs should provide details on the methodology, reporting, and interpretation of findings, as recently described by our group [31], thereby making it easier to compare studies and to facilitate future meta-analyses.

Smartphones represent a fine-grained, unobtrusive, and effective way to monitor symptoms and level of function that could help distinguish severe psychiatric health problems from normal behavior. This could potentially lead to more efficient use of clinical resources within today's health care system, which in turn can lead to the more equitable distribution of resources. One of the studies in this review used a model where the caregiver of the child reported the symptoms, which might help parents/caregivers observe their child in a more systematic manner. Children, adolescents, and young adults often have well-established behaviors regarding smartphone usage, which suggests that in order to help them engage with mental health apps, the apps need to be designed to fit their habits and be customizable to their needs [32]. In this way, smartphones hold great potential as a modern and widely available technology platform for psychiatric care, especially as children, adolescents, and young adults can be reluctant to seek professional help due to the stigma and negative attitudes toward mental health problems [33].

Acknowledgments

SM is an early stage researcher of Technology Enabled Mental Health (TEAM) for young people. This project has received funding from the European Union's Horizon 2020 research and innovation program under the Marie Sklodowska-Curie grant agreement No. 722561.

Conflicts of Interest

SM and MFJ have no conflicts to declare. LVK has, within the preceding 3 years, been a consultant for Lundbeck. JEB is a cofounder, board member, and shareholder in Monsenso ApS, a supplier of smartphone-based technology for mental health.

Multimedia Appendix 1
PRISMA 2009 checklist.
[DOC File , 66 KB - mental_v7i10e17453_app1.doc]

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Abbreviations

GRADE: Grading of Recommendations, Assessment, Development and Evaluations
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 13.12.19; peer-reviewed by D Leightley, B Teachman, A Wickersham, M Semwal; comments to author 20.01.20; revised version received 27.02.20; accepted 09.09.20; published 29.10.20.

Please cite as:
Melbye S, Kessing LV, Bardram JE, Faurholt-Jepsen M
Smartphone-Based Self-Monitoring, Treatment, and Automatically Generated Data in Children, Adolescents, and Young Adults With Psychiatric Disorders: Systematic Review
JMIR Ment Health 2020;7(10):e17453
URL: http://mental.jmir.org/2020/10/e17453/
doi:10.2196/17453
PMID:33118950

Original Paper

A Patient-Centered Framework for Measuring the Economic Value of the Clinical Benefits of Digital Health Apps: Theoretical Modeling

Adam Powell[1], PhD; John Torous[2], MD

[1]Payer+Provider Syndicate, Boston, MA, United States

[2]Division of Digital Psychiatry, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, United States

Corresponding Author:
John Torous, MD
Division of Digital Psychiatry
Beth Israel Deaconess Medical Center
Harvard Medical School
330 Brookline Avenue
Boston, MA
United States
Phone: 1 617 667 6700
Email: jtorous@bidmc.harvard.edu

Abstract

Background: As digital health tools such as smartphone apps evolve and enter clinical use, questions regarding their value must be addressed. Although there are scarce generalizable data on the value of health apps given their nascency and diverse use cases, it is possible to estimate the economic value of the clinical improvement they bring to patients using a quality-adjusted life-year (QALY)-based approach and generalized values from existing literature.

Objective: This paper aims to provide a patient-centered framework for assessing the economic value of the clinical benefits delivered by digital health apps.

Methods: We proposed a model based upon 5 levers: country-specific monetary value of a QALY, QALYs lost due to the condition, engagement rate of app users, average effect size of the app's health impact, and duration of the app's impact before remission.

Results: Using 2 digital health apps from the United States and United Kingdom as examples, we explored how this model could generate country-specific estimates of the economic value of the clinical benefits of health apps.

Conclusions: This new framework can help drive research priorities for digital health by elucidating the factors that influence the economic value.

(JMIR Ment Health 2020;7(10):e18812) doi:10.2196/18812

KEYWORDS

value; digital health; apps; payment models

Introduction

As smartphone apps for health become more prevalent and their evidence base continues to expand, questions around the reimbursement and value of health apps are gaining importance. Today, insurers, health care organizations, and employers are signing contracts with app developers, even though the data and published literature on the economic value of health apps remain nascent. The existing data are either from small studies of single apps funded by the developers themselves, and thus introducing bias due to conflicts of interest, or from larger reviews [1]. Given the lack of economic evidence, there is a need for pragmatic models to guide informed decision making around pricing and determine the clinical value delivered by health apps.

The issue of measuring the value of digital health apps is of further importance, as digital health formularies are developed [2,3], and governments allocate taxpayer funds to cover costs associated with digital health tools [4,5]. Costs associated with apps are currently reimbursed using a variety of channels, including Current Procedural Terminology codes, device codes, and laboratory codes [6]. App users are also paying for the costs associated with apps directly, through a combination of one-time payments, in-app payments, subscription models, and participation in advertising [7]. However, some apps are not

readily reimbursable within the existing frameworks, and thus app-specific reimbursement channels may need to be developed [8].

All economic activity, including the reimbursement of health apps, is about trade-offs; and higher-value interventions are typically preferred to lower-value interventions when resources are scarce. Generally, apps have a higher price point if they offer some form of human support, such as coaching, reflecting the additional costs associated with delivering that service. Given that human guidance within apps has been shown to be significantly associated with larger effect sizes, an analysis is needed to ensure that the cost of such guidance is outweighed by its benefits [9].

Value has been defined in the context of health care as outcomes relative to costs; when outcomes improve or costs decline, it suggests an improvement in value [10]. The items that are included in a value analysis depend upon the intended user of the analysis and thus will vary between patients, providers, health care systems, and payers. For example, if the intended user is a health care provider organization, which has based its decision to adopt a technology upon its own welfare, then the costs included in the analysis will only be those relevant to that organization. A framework for measuring the value delivered to a radiology department by a software, which helps the department detect anomalies more efficiently, listed the following elements: one-time direct costs, one-time costs of operational changes, ongoing change in direct costs, ongoing cost of operational changes, and ongoing change in downstream costs [11]. None of these costs are relevant in an analysis that takes a patient-centered perspective.

This paper aims to provide readers with a patient-centered framework for assessing the economic value of the clinical benefits delivered by digital health apps. Although patients also potentially receive value from nonclinical benefits, such as improved productivity at work, this paper strictly focuses on the valuation of the improvement in health outcomes. Value that accrues to other stakeholders, such as health care providers and payers, is outside the scope of this analysis. This approach has been chosen, as self-pay is the primary model of payment for many mental health apps. The approach is also appropriate for app evaluations made by a paternalistic payer whose primary objective is to maximize health benefits that patients achieve for a given level of spending (eg, a large government payer who does not consider increases in productivity or cost substitution benefits).

Although specific data on individual apps are often not available, there are now enough data from meta-analyses on the effect sizes of apps' impacts on health and research on engagement to inform general models around value. Health care providers and payers are also impacted by the use of apps, but evaluating the financial impact caused by apps on these users is outside of the scope of this paper. These other stakeholders experience changes in one-time, ongoing, and downstream costs. The degree to which these changes are borne by health care providers or payers is determined by the nature of their contracts and the extent to which each is exposed to the cost of utilization.

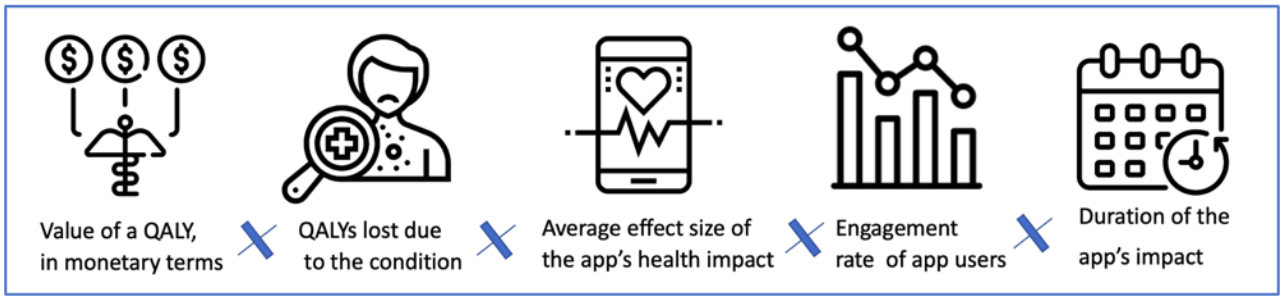
Methods

There are 2 main components in the outcome component of the value equation: (1) change in clinical outcomes and (2) change in financial outcomes. Although clinical outcomes are experienced as health, and not as money, they can be translated into financial terms. Many societies have in various ways indicated their willingness to pay for improvements in health as measured in quality-adjusted life-years (QALYs). A QALY is "a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life," where a year of perfect health is equal to 1 QALY [12]. In the United States, willingness to pay for a single QALY appears to be somewhere between US $50,000 to US $500,000, with a cutoff value of US $175,000 beyond which the Institute for Clinical and Economic Review no longer classifies an intervention as "low value" [13,14]. By mapping clinical outcomes to money, it is possible to measure values solely in monetary terms.

As shown in Figure 1, the economic value of the clinical benefits delivered by an app is determined by the following 5 levers:

1. Country-specific monetary value of a QALY
2. QALYs lost due to the condition
3. Engagement rate of app users
4. Average effect size of the app's health impact
5. Duration of the app's impact before remission

Figure 1. Methodology for estimating the economic value of the clinical benefits of digital health apps. Economic value of an app's clinical benefits = country-specific monetary value of a QALY * QALYs lost due to the condition * engagement rate of app users * average effect size of the app's health impact * duration of the app's impact before remission.



Results

As an example, we can estimate the value delivered by an app used in the United States for reducing depression. The data used below are derived from recent evidence, although assumptions must be made where the data are currently limited, not publicly available, or unclear. Estimates for the 5 levers of the model were derived as follows:

1. As previously mentioned, willingness to pay for QALYs in the United States appears to be somewhere between US $50,000 and US $500,000, per year, with US $175,000 per year serving as a potential cut-off for a low-value intervention [13,14].
2. The literature suggests that patients on average lose 0.159 QALYs per year from depression, based upon depression's impact on EuroQOL 5 dimensions (EQ-5D) questionnaire scores [15]. Although a single number cannot capture the diversity of ways in which people are impacted by depression, this number offers an evidence-based estimate useful for modeling.
3. Health apps are often downloaded but are rarely used more than a few times. A recent study examined real-world data on app use to conclude that only 4% of users actually engage with apps meaningfully after 15 days [16], suggesting that few people receive an adequate "dose" of apps. The degree of engagement can be impacted through the use of human coaching or peer support or through app design [17,18].
4. Many app studies define a response as 50% reduction in symptoms. Studies on remission often also feature a 50% reduction in symptoms, which brings patients into a lower range of depression scores, indicating that patients may now experience lack of functional impairment related to the illness. Thus, as an estimate, it is reasonable to assume based on the current evidence that the effect size of apps for depression may offer up to a 50% reduction in symptoms [19].
5. There is little evidence on the long-term effects of mental health apps in sustaining benefits among users. Most studies feature no follow-up data, although some suggest mixed results, such as no impact at 3 months [20], while others suggest maintained benefit [19]. Assuming that these apps can yield a benefit at 3 months, we can use this number in our models.

When these 5 levers are considered together, we can form an estimate of the economic value of the clinical benefits delivered by an app for depression. Although the numbers used in the above 5 stages are estimates, they provide reasonable guidance and can be adjusted by the user for any particular app and health condition under consideration. Using these numbers, the following estimate of economic value can be generated:

US $175,000 per QALY × 0.159 QALYs lost per year of depression × 4% receiving effective dose × 50% reduction in symptoms × 0.25 years of improvement = US $139.13

The above example suggests that the economic value of the clinical benefit is US $139.13 per patient treated, US $11.59 per month if all users subscribe to the app for a year. Note that the outcomes delivered may achieve a higher valuation if nonclinical outcomes, such as enhanced wages at work due to greater productivity or savings within the health care system, are considered while developing an estimate. Nonetheless, on purely clinical grounds, the value delivered by an app addressing depression leads to a pricing that seems within the bounds of what is observed in the marketplace today.

Each of the numbers used in our example for a depression app will vary based upon the unique context at hand. For example, in a country with developing economy or a country more frugal with its health care resources is likely to place a lower value on a QALY than the one placed by the United States. For a second example, consider an app deployed in the United Kingdom, which has a user engagement rate that has been enhanced through the use of peer support. To further examine how these levers can change outcomes, the second example will explore an app for anxiety management, rather than depression support. Lever values are as follows:

1. In the United Kingdom, the government's threshold for cost-effectiveness has been reported within the range of £20,000 to £30,000 per QALY (roughly US $25,000 to US $40,000 per QALY) [18].
2. The literature suggests that patients lose an average of 0.070 QALYs due to anxiety based on recent evidence from the EQ-5D questionnaire [15].
3. The engagement rate of app users can be increased to as high as 17% with the addition of peer support, and the rate will vary by app and health condition [16]. Although adding coaches or peers to encourage uptake can benefit the clinical outcomes of the value equation, these additions come with a trade-off of added ongoing costs.
4. The duration and durability of the health impacts of the app likely vary. For simplicity, we assume that the app has the same duration of impact as that of the previously examined depression support app (a 50% reduction in symptoms).
5. Similarly, we assume that the duration of the impact is the same as it was for the depression support app (3 months).

By altering 3 of the levers in the equation (reducing the value of a QALY to US $25,000, reducing the QALYs lost from the condition to 0.070, and increasing the engagement rate to 17%), we can estimate that the clinical value delivered by the anxiety management app with peer support in United Kingdom is as follows:

US $25,000 per QALY × 0.070 QALYs lost per year of anxiety × 17% receiving effective dose × 50% reduction in symptoms × 0.25 years of improvement = US $37.19

If we amortized the US $37.19 clinical benefit over a year, the value per month would be US $3.10.

Discussion

As digital health apps mature, evidence-based pricing models have not kept pace with the market demands. Our model offers a simple, interpretable, and context-specific means to estimate cost and understand factors that may change the economic value of a digital health app. As the evidence for these apps continues to evolve, the results of this model will become more accurate.

Given that many subscription-based depression support apps are currently priced at around US $12 a month, our model offers face validity.

The estimates provided by the model are imprecise and subject to some limitations. As illustrated by the examples, estimates will vary across countries due to national differences in parameter values (eg, the valuation of a QALY), even if the apps themselves remain unchanged. It is also possible that the parameters are not fully independent, and many do not have linear relationships. For instance, apps with higher effect sizes may have higher engagement rates, as people sense the effectiveness of those apps and remain more engaged. Furthermore, some apps may be outliers and have parameter values that deviate so substantially from other similar apps that the estimates of the proposed model are not representative. The effect size of a depression support app may differ between people or populations. These situations can be rectified if app-specific parameter estimates are used, rather than generalizations. As with all models, modelers must weigh the effort of obtaining more precise parameter values against the benefit of a more precise estimate.

When considering app evaluations in other contexts, it may be necessary to alter evaluation models in order to better address the context in which deployment is planned [21]. With the advent of personalized medicine in digital health, it may be possible to use digital biomarkers and other factors to identify the patients most likely to respond to specific digital treatment [22,23]. Personalized digital medicine will potentially boost the engagement, effect size, and effect duration levers of the clinical value equation, enabling higher price-points for apps to be justifiable based upon their higher clinical value. Although the existing literature may be used to estimate the clinical value delivered when apps are deployed in an untargeted fashion, estimates derived from the general literature should be seen as a lower bound to the potential that apps may deliver.

Monetary estimates of the economic value of the clinical benefits delivered by digital health apps to patients can be generated using a QALY-based approach involving values reported in the literature. Valuations are context-dependent and may change over time as apps are better targeted to specific populations of patients. Nonetheless, it is possible to produce estimates of the economic value of the clinical benefits that patients derive from apps using a universal framework.

Acknowledgments

JT reports support from a grant from the NIMH (1K23MH116130-01), which does not directly relate to this research.

Conflicts of Interest

AP reports employment by Payer+Provider Syndicate and stock ownership of Berkshire Hathaway, Community Health Systems, HCA Healthcare, Payer+Provider Syndicate, and Tenet Healthcare Corp. AP is a paid member of the Scientific Advisory Board of PsyberGuide. JT reports research support from Otsuka Pharmaceuticals.

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Abbreviations

EQ-5D: EuroQOL 5 dimensions
QALY: quality-adjusted life-year

Edited by G Eysenbach; submitted 19.03.20; peer-reviewed by S Li, B Rudd, E Stratton; comments to author 16.08.20; revised version received 07.09.20; accepted 15.09.20; published 30.10.20.

Please cite as:
Powell A, Torous J
A Patient-Centered Framework for Measuring the Economic Value of the Clinical Benefits of Digital Health Apps: Theoretical Modeling
JMIR Ment Health 2020;7(10):e18812
URL: https://mental.jmir.org/2020/10/e18812
doi:10.2196/18812
PMID:33124995

Original Paper

Smartphone App to Address Loneliness Among College Students: Pilot Randomized Controlled Trial

Emma Bruehlman-Senecal[1], PhD; Cayce J Hook[1], PhD; Jennifer H Pfeifer[2], PhD; Caroline FitzGerald[1], MSc; Brittany Davis[2]; Kevin L Delucchi[3], PhD; Jana Haritatos[1], PhD; Danielle E Ramo[1], PhD

[1]Hopelab, San Francisco, CA, United States

[2]Department of Psychology, University of Oregon, Eugene, OR, United States

[3]Department of Psychiatry and Weill Institute for Neurosciences, University of California, San Francisco, San Francisco, CA, United States

Corresponding Author:
Danielle E Ramo, PhD
Hopelab
100 California Street #1150
San Francisco, CA, 94111
United States
Phone: 1 415 728 8387
Email: dramo@hopelab.org

Abstract

Background: Loneliness is a widespread and significant problem on college campuses. Prolonged loneliness in young adulthood is a risk factor for concurrent and future mental health problems and attrition, making college a critical time for support. Cognitive and behavioral interventions show promise for decreasing loneliness and can be widely disseminated through technology.

Objective: This pilot randomized controlled trial was conducted to examine the initial efficacy, feasibility, and desirability of a smartphone app, Nod, designed to deliver cognitive and behavioral skill-building exercises to reduce loneliness during the transition to college.

Methods: First-year college students (N=221, mean age 18.7 years, 59% female) were recruited online during incoming student orientation, and randomized to either receive immediate access to Nod (experimental group, n=100) or access after 4 weeks (control group, n=121). The app delivered skills via fully automated (1) "social challenges," suggested activities designed to build social connections; (2) reflections, brief cognitive reframing exercises; and (3) student testimonials that encouraged a growth mindset toward social connection building. Main intention-to-treat analyses were used to compare the conditions on self-assessed loneliness, depressive symptoms, and other mental health and college adjustment outcomes at week 4, controlling for baseline values on those variables. Analyses were also performed to test the hypothesis that the treatment benefits would be particularly pronounced for participants with heightened psychological vulnerability at baseline (ie, higher baseline depressive symptoms and loneliness).

Results: Retention was 97% at week 4, and participants viewed an average 36.7 pages of app content. There were no significant condition differences in loneliness at week 4 ($F_{1,211}$=0.05, P=.82; η_p^2 <.001). However, there was a significant condition-by-baseline depression interaction to predict week-4 loneliness ($F_{1,209}$=9.65, P=.002; η_p^2 =.04). Simple slope analyses indicated that baseline depression positively predicted week-4 loneliness among control participants (r=0.30, t_{209}=3.81, P<.001), but not among experimental participants (r=–0.09, t_{209}=–0.84, P=.40), suggesting that Nod buffered participants with high baseline depression scores from experiencing heightened midquarter loneliness. Similarly, there were no significant condition differences in other week-4 outcomes. However, moderation by baseline vulnerability was found for week-4 depressive symptoms, sleep quality, and indices of college adjustment (eg, perceived social support and campus belonging).

Conclusions: Although Nod exposure did not impact outcomes for the full sample, these results provide initial evidence of its benefit for vulnerable students. The results of this trial suggest that cognitive and behavioral skills delivered via a mobile app can buffer psychologically vulnerable college students against heightened loneliness and depressive symptoms, as well as other negative college adjustment outcomes. Future work will aim to improve upon app engagement, and to address loneliness among other key populations.

Trial Registration: ClinicalTrials.gov NCT04164654; https://clinicaltrials.gov/ct2/show/NCT04164654

(JMIR Ment Health 2020;7(10):e21496) doi:10.2196/21496

KEYWORDS

loneliness; mental health; smartphone app; college; app; student; young adult; randomized controlled trial; efficacy; feasibility; desirability

Introduction

Loneliness is a painful feeling that arises when there is a discrepancy between one's desired and achieved patterns of social interactions [1]. Lonely feelings function as an "alarm bell," signaling that one's fundamental need for connection and belonging is not being adequately met [2]. Although most of the literature on loneliness focuses on older adults, multiple studies indicate that loneliness is especially prevalent among younger generations [3-5]. For example, in recent national surveys, Generation Z (aged 18-22 years) reported higher loneliness than any other generation surveyed in the United States [6], and 26% of teens and young adults reported they can "never" or "rarely" find companionship when they need it [7]. Loneliness is not just an unpleasant feeling. Prolonged feelings of loneliness in young adulthood are concurrently and prospectively associated with a variety of negative mental health outcomes, including depression, anxiety, social anxiety, and suicidality [8-12]. Compounding these relationships, loneliness is associated with poorer sleep quality [13-15], which can contribute to poorer emotion regulation [16,17] along with further social withdrawal and loneliness in a self-reinforcing cycle [18].

Loneliness in the college context is pervasive and of particular concern: in a 2019 survey, 30% of US undergraduates reported feeling "very lonely" in the last 2 weeks and 67% reported feeling "very lonely" in the last year [19]. Loneliness among college students is associated with lower social adjustment to college [20,21], lower perceived social support [22], and lower campus belonging [23]. In addition to poorer mental health and poorer sleep, college students experiencing heightened loneliness report a greater likelihood of leaving before degree completion [24], as well as lower confidence in their employment prospects and ability to succeed in life [11].

Incoming college students face a major social transition and may be particularly vulnerable to loneliness. Developmental and social psychological evidence indicates that interventions delivered at key moments of transition (such as the transition to college) can substantially impact young adults' social, academic, and health trajectories [25,26]. As students enter college, they begin to form new routines, new habits, and new relationships that can have powerful recursive effects over time [27]. The college transition thus represents a unique opportunity for intervening to reduce loneliness and improve students' mental health and academic outcomes.

Loneliness is associated with cognitive biases, including vigilance to social threat and perceptions that others are judging and rejecting [28,29]. Meta-analytic research indicates that the most effective loneliness interventions are those grounded in cognitive behavioral therapy, which target maladaptive cognitions and behaviors [30]. However, most of these interventions have been aimed at older adults, and those designed for college students tend to be resource-intensive. For example, McWhorter and Horan [31] developed an intervention focused on modifying attributional styles with modeling, role playing, and assignments for developing communication skills. The intervention, consisting of six 2-hour structured group experiences led by trained facilitators, significantly decreased participants' loneliness. Although group-based interventions can effectively reduce loneliness, such interventions may have relatively limited reach in university contexts, where counseling centers are often stretched beyond capacity [32-34]. There is thus a need to develop and test interventions to address youth loneliness at scale.

Mobile apps offer the ability to deliver mental health resources and interventions in a standardized, scalable, and cost-effective manner [35-37]. Smartphone ownership is nearly ubiquitous among young adults [38], and surveys suggest that nearly 1 in 4 smartphone owners aged 18-29 use apps to track or manage health [39]. Further, college counseling centers are increasingly interested in using mobile health apps to disseminate information and interventions to students [40]. Apps provide support on-demand, lowering barriers to much-needed support, such as limited availability of in-person counseling and stigma that can hold back students from seeking help [40]. Prior research has validated the feasibility and acceptability of smartphone app–based loneliness interventions for young people [41,42]. Moreover, systematic reviews of prior psychosocial interventions for youth suggest that technology-based interventions are an appropriate and effective delivery modality for reducing loneliness [43]. However, research is needed to evaluate the efficacy of digital interventions targeting loneliness in undergraduate populations.

We here present the results of a pilot randomized controlled trial of the Nod digital intervention for loneliness among first-year college students (N=221) delivered via a smartphone app. Nod was selected as the intervention in this study because, to our knowledge, it is the only existing mobile intervention specifically designed to address the psychological and behavioral underpinnings of loneliness during the transition to college. Outcomes were compared across two randomly assigned conditions: an experimental group who received 4 weeks of Nod exposure and a waitlist control group given access to Nod after 4 weeks. Our primary hypothesis was that students in the experimental group would report lower loneliness by the end of treatment (week 4) as compared to students in the control group. Secondary hypotheses were that the experimental group would report better outcomes on key mental health indicators associated with loneliness: depression symptoms, anxiety symptoms, social anxiety symptoms, and sleep quality. Exploratory analyses were used to examine effects related to friendship and belonging at the university, namely perceived social support, campus belonging, social adjustment to college,

and intention to remain enrolled. Finally, we tested the hypothesis that the treatment benefits would be particularly pronounced for students with heightened psychological vulnerability at baseline, given prior research indicating that targeted interventions have greater effect sizes than universal interventions [44]. Since this was a pilot trial, we also examined app engagement and user experience.

Methods

Study Design

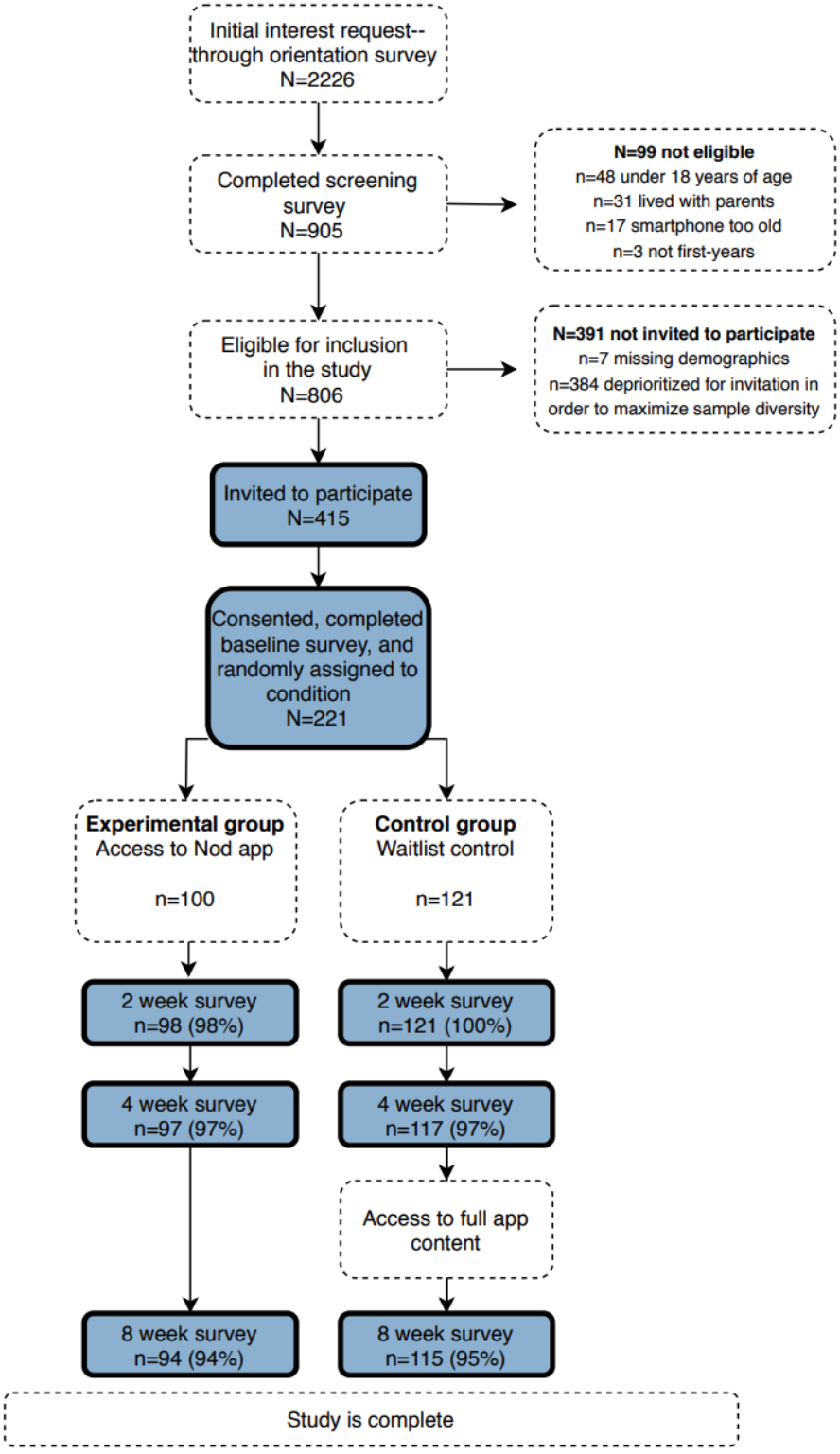
This 4-week pilot randomized controlled trial evaluated the initial efficacy, feasibility, and desirability of Nod. At 4 weeks, control participants were given full app access. An 8-week follow-up survey allowed for validation of the main outcome analyses in the control group and an exploration of whether uptake of Nod was similar when delivered later in the school year.

Participants and Recruitment

Participants were incoming first-year students at a large public university in the northwestern United States, and all recruitment and study procedures were approved by the university Institutional Review Board. Students were eligible for inclusion if they were: (a) entering their first year of undergraduate education, (b) aged 18 to 25 years, (c) English-literate, and (d) not residing with parents/guardians. Students also needed to have a smartphone with an operating system capable of supporting Nod (ie, Mac iOS 9-12 or Android OS 8-10), which 97.9% (806/823) of students who met the four eligibility criteria had.

Participants were recruited from July to September of 2019, in collaboration with the university's first-year orientation program. All incoming students indicated whether they would like to receive information about a study examining the college transition via a question embedded within a longer orientation survey. Interested participants (N=2226) were sent additional information, and linked to a brief online screening survey containing questions to assess eligibility as well as an 8-item version of the UCLA loneliness questionnaire (UCLA-8) [45]. Of the 905 students who completed the screening survey, 806 met all inclusion criteria (Figure 1). Among these 806 students, we excluded 7 students who did not complete all of the demographic screening questions. The remaining 799 students were divided into those experiencing high loneliness (ie, scoring ≥1 SD above the sample mean on the UCLA-8 loneliness scale, n=176) and those not experiencing high loneliness (n=623). Students in the former group were overrecruited such that they comprised approximately 50% of the sample. Ethnic and racial minority students were also invited to participate at higher rates to achieve a diverse participant pool. Within each loneliness category (high/not high), interested participants were grouped into gender and ethnicity categories, and groups of potential participants were invited to maximize diversity across the sample. In the high-loneliness group, male gender was prioritized due to underrepresentation in the interest pool; in both groups, racial/ethnic and gender minority status were prioritized for similar reasons.

Figure 1. Participant recruitment and flow through the Nod pilot trial.



A total of 415 students were invited to participate. This number was selected to ensure that the target enrollment of 220 would be reached with the expectation that not all participants who initially expressed interest in participating would respond to further outreach. Spots in the study were filled on a first-come, first-served rolling basis until the target enrollment was achieved. The enrollment process took 6 days over the second week of classes, and was completed before the third week of classes began. The target sample size of 220 was selected to allow for the detection of condition differences in week-4 outcomes that were medium or larger in size after accounting for potential loss of up to a third of participants due to attrition or noncompliance [46]. In total, 221 participants completed a baseline assessment and were randomized to a study condition. The target enrollment number of 220 was exceeded by 1 participant because 2 control participants accessed the baseline survey at the same time, and thus both were permitted to complete the assessment before automatic survey closure.

Study Procedure

Informed consent was obtained online, with assessment of understanding used in previous online research [47], immediately prior to completion of the baseline assessment (Multimedia Appendix 1). Following the baseline assessment, participants were randomized 1:1.2 via Qualtrics to either (1) immediate access to Nod (experimental group) or (2) access to Nod following a 4-week waiting period (control). Randomization was stratified after dividing students into two groups: higher loneliness (ie, mean score≥21 on the UCLA-8 screening survey, translating to a loneliness score≥1 SD above the mean of all eligible participants) and lower loneliness (mean score<21 on UCLA-8). Twenty more students were recruited into the control group to account for the possibility that control participants could access Nod prematurely. In-app data confirmed that no control participants did so; therefore, all participants were included in reported analyses. Authors were not blind to participants' condition during data collection or analysis; however, because randomization was carried out via Qualtrics and all outcome measures were self-assessed by participants, there was no interaction between study staff and participants that could have led to response biases on the part of participants due to demand characteristics.

Within 72 hours of completing the baseline survey, participants in the experimental group were emailed an invitation to download Nod. Those in the control group were notified via email that they would receive access to the app after 4 weeks and advised to await a download invitation. Participants accessed Nod through their university single sign-on, thus preventing an individual from making multiple accounts.

Online assessments through Qualtrics Software (Salt Lake City, UT, USA) were administered at baseline, and at weeks 2, 4, and 8. Participants received US $20 gift cards for (a) creating a Nod account within 1 week of receiving the email invitation, (b) completing each of 4 surveys ($20/survey), and (c) completing all 4 surveys (a $20 bonus), for a possible total of US $120 for their participation. Participants were not incentivized for app usage beyond account registration, and were instructed to use Nod as much or as little as they desired.

Intervention Conditions

Experimental

Nod is a mobile app that was co-developed by Grit Digital Health and Hopelab. Nod incorporates positive psychology, mindfulness-based self-compassion, and cognitive behavioral skill-building exercises to address loneliness among first-year college students. The app delivers skills via three key features: (1) social challenges, suggested ideas for reaching out to others and taking action to build social connections; (2) reflections, short in-app exercises that help students process social experiences and reduce self-criticism; and (3) written student testimonials that encourage a growth mindset toward social connection building. These features were based on exercises and interventions demonstrated to build social connectedness and address negative self and social cognitions in prior empirical research, as described below.

Social challenge content focused on 6 core social skills and behaviors known to strengthen social connections: (1) performing acts of kindness [48,49], (2) expressing gratitude [50,51], (3) active listening [52,53], (4) initiating social outreach/invitations [54,55], (5) being receptive to others' invitations, and (6) engaging in appropriate self-disclosure [56,57]. Social challenges were designed to encourage in-person socialization within the campus community. Some examples include "Get someone a snack from the dining hall," and "When you get the urge to bail on a conversation, ask a couple more questions than you normally would, and really listen to the answer." App content was written to be broadly applicable across campuses (ie, no references were made to university-specific locations or events within the app).

Reflections were short in-app exercises designed to scaffold cognitive restructuring of negative social experiences and savoring of positive social experiences. After completing app-based social challenges, participants were directed to use an interactive mood-rating tool to indicate how they felt about their social experience. Positive mood ratings directed participants to exercises designed to amplify and prolong positive emotions, such as savoring [58] and gratitude [50]. Negative ratings directed participants to cognitive reframing exercises such as self-compassion meditations [59,60] and reappraisal [61,62].

To reinforce a growth mindset toward college friendship [63-65], challenges were accompanied by brief written testimonials (ie, short recommendations of specific in-app social challenges written by college students), which were selected to bolster the belief that forming satisfying social connections takes time and effort.

Users were able to opt to receive intermittent push notification messages that encouraged participants to try new challenges and reflections, to set deadlines for completing challenges, and reminders to come back to the app to mark challenges as completed.

Before launching the pilot trial, Hopelab conducted formative work through interviews, focus groups, and surveys of first-year college students. The app content and visual elements were tailored based on student feedback. Screenshots containing example challenge, reflection, and student testimonial content are presented in Multimedia Appendix 2, and a video describing Nod is provided in Multimedia Appendix 3.

Control

Control participants completed the baseline, 2- and 4-week surveys, and received full access to Nod at week 4.

Measures

Engagement

Over 4 weeks, analyses examined (1) the cumulative number of app pages the user accessed, a common measure of app engagement that serves to index the extent of accessed content [66]; (2) the total number of social challenges the user marked as completed; and (3) the total number of reflections clicked through. The latter two measures indexed completion of specific cognitive and behavioral skill-building modules.

Loneliness

Loneliness was measured using the UCLA-8 scale. This measure is highly correlated with the longer 20-item version, and its reliability and validity have been established within a college student sample [45]. Participants indicated how frequently they experienced lonely feelings (eg, "I feel left out") on a 4-point (1=never; 4=often) scale, and items were summed to yield a total score; Cronbach α across all surveys was >.84, indicating high reliability. To increase this measure's sensitivity to pick up intervention-induced changes, participants indicated their feelings over the past 2 weeks rather than "in general."

Mental Health Indicators

Anxiety and Depression Symptoms

Symptoms of anxiety and depression were respectively measured using the 7-item Generalized Anxiety Disorder Scale (GAD-7) [67] and the 9-item Patient Health Questionnaire (PHQ-9) [68]. These brief clinical measures have been widely used to screen for generalized anxiety and depression within a diverse range of settings, including among college students [69-71]. Participants rated the frequency of their symptoms over the prior 2 weeks on a 4-point scale (0=not at all; 3=nearly every day). Items were summed to compute total scores for each construct; Cronbach α across all surveys was >.84 for the PHQ-9 and was >.87 for the GAD-7 (see Multimedia Appendix 4 for the risk assessment protocol associated with this measure.)

Social Anxiety Symptoms

The 3-item Mini Social Phobia Inventory, a validated provisional screening tool for social anxiety disorder [72,73], was used to measure social anxiety symptoms over the past week (eg, "Fear of embarrassment causes me to avoid doing things or speaking to people"; 0=not at all, 4= extremely). Items were summed to yield a total score; Cronbach α across all surveys was >.78.

Sleep Quality

Subjective sleep quality was measured using one item from the Pittsburgh Sleep Quality Index [74]: "During the past 2 weeks, how would you rate your overall sleep quality?" (0=very good; 3=very bad). Participants indicated how they felt over the past 2 weeks rather than the past month to increase this measure's sensitivity to intervention-induced changes.

College Adjustment Indicators

Perceived Social Support

A modified version of the 3-item support subscale of the Comprehensive Inventory for Thriving was used to measure perceived social support [72]. Items were modified to refer to support from people at one's university (eg, "There are people at [university name] who give me support and encouragement"; 1=strongly disagree, 5=strongly agree), and averaged to yield a total score. Cronbach α across all surveys was >.88.

Campus Belonging

Campus belonging was measured using two items adapted from the Student Experiences in the Research University Questionnaire [75], a multi-institutional survey focused on undergraduates' experiences. Participants rated their agreement with two statements: "I feel like I belong at [university name]" and "I'm happy that I chose to enroll at [university name]" (1=strongly disagree; 6=strongly agree). Items were averaged to yield a total score. Cronbach α across all surveys was >.81.

Social Adjustment to College

The 20-item Social Adjustment subscale of the Student Adaptation to College Questionnaire was used to measure adjustment to college social life. Prior research demonstrates the validity of this subscale for predicting college retention [76]. Participants responded to items such as "I'm meeting as many people, and making as many friends as I would like to at [university name]" (1=applies very closely to me; 9=does not apply to me at all). Items were averaged to yield a total score, with higher scores indicating better adjustment; Cronbach α across all surveys was >.89.

Intention to Return

Participants' intention to remain enrolled was measured with a single item adapted from the National Survey for Student Engagement [77]: "Do you intend to return to [university name] in the next year?" (1=definitely yes; 5=definitely not). Responses were skewed, with 69.7% (154/221) of participants at baseline and 64.5% (138/214) at week 4 reporting they would "definitely" return, and were therefore dichotomized (1=definitely yes; 0=all other responses).

Demographic Measures

We assessed participants' age, gender, race/ethnicity, parent/guardian education, subjective socioeconomic status, financial stress, sexual orientation, romantic relationship status, employment status, campus living situation, transfer student status, student athlete status, and autism spectrum status at baseline. All demographic variables were measured via participant self-report.

User Experience

A 5-item measure was administered to the experimental group at week 4 and to the control group at week 8 to assess the perceived helpfulness and desirability of Nod (eg, "The Nod app gave me sound advice"; 1=strongly disagree, 7=strongly agree). We computed the proportion of participants endorsing each item (ie, responding "somewhat agree" to "strongly agree").

Additionally, participants in the experimental group were prompted to give open-ended feedback about the Nod app at weeks 2 and 4 (eg, "What do you find most useful about Nod?" "How could Nod be more helpful to you?").

Data Analytic Strategy

Engagement

We descriptively compared the engagement of the experimental group (weeks 0-4) to that of the control (weeks 4-8) across each group's first 4 respective weeks of app exposure. As the distributions of the three engagement variables were highly positively skewed, we report median engagement metrics with their IQRs.

Loneliness, Mental Health, and College Adjustment Indices

Analyses of all outcome variables were performed using an intention-to-treat approach, which included all available data from participants randomly assigned to the experimental and control groups. We took a two-step approach to these analyses, reflecting our two main lines of inquiry. In step 1, we tested the primary and secondary hypotheses that the experimental group would report lower loneliness, and other indicators of better mental health and college adjustment at the end of treatment (week 4) as compared to the control group. In step 2, we tested the hypothesis that treatment benefits would be more pronounced for participants with heightened psychological vulnerability at baseline.

Step 1 evaluated condition differences in outcomes at the end of treatment (week 4). Because missing data at week 4 was minimal (213/221, 96.4% of the sample provided full data on all outcome variables), we opted for a straightforward analytic approach that compared the means of the experimental and control groups on each outcome at week 4, adjusting for each outcome's respective baseline value. A separate analysis of covariance was conducted for each outcome, and each model was evaluated on the basis of the statistical significance (P<.05) of the condition term (1=experimental; 0=control). Two outcomes, social adjustment to college and perceived social support, were not measured at baseline, because participants had not yet had enough social experiences on campus to meaningfully answer survey questions. Thus, models for these two outcomes omit baseline scores as a covariate.

Step 2 added an interaction term between baseline vulnerability and condition, allowing us to evaluate whether the benefits of Nod were more pronounced for more vulnerable students. The model of loneliness at week 4 included four predictors: condition, baseline loneliness, baseline depression, and a condition-by-baseline depression interaction term to capture baseline vulnerability. In modeling all other outcomes, models included four predictors: condition, baseline loneliness, baseline score on the outcome variable, and a condition-by-baseline loneliness interaction term. We selected depression as the baseline moderator of week-4 loneliness, and loneliness as the baseline moderator of week-4 depression and all other outcomes, given previous research demonstrating a strong bivariate and reciprocal relationship between loneliness and depression [8,12,78], including in first-year college students [78], and a strong relationship at baseline in this study (r=0.52). To determine whether Nod differentially benefitted vulnerable participants, each model was evaluated on the basis of the statistical significance (P<.05) of the interaction term.

To validate the results, we separately modeled comparisons between outcomes in the control group at week 8 to outcomes in the experimental group at week 4 (Multimedia Appendix 5).

Engagement and Improvement in Outcomes

To explore whether greater engagement with Nod was associated with greater improvement in outcomes, we report correlations between our three measures of engagement and within-participant change in each outcome variable from week 0 to 4 within the experimental group. Due to the skewed distribution of the engagement variables, we report nonparametric (ie, Spearman ρ) correlations. Social support and social adjustment to college, which were not measured at baseline, are excluded from these analyses.

User Experience

Within the experimental group, the percentage of users endorsing each desirability statement was reported. Open-ended feedback was analyzed by a single coder using a general inductive approach [79]. Core questions guiding the coding included, "What do students like about Nod?" "What do they wish would change?" and "Based on participant feedback, what factors might improve user experience and engagement with the app?" Quotes were selected to exemplify prominent themes. To validate results, we report quantitative comparisons between user experience of the control group at week 8 to the experimental group at week 4 (Multimedia Appendix 5).

Results

Retention

A total of 221 participants completed a baseline assessment and were randomized to study condition ($n_{experimental}$=100; $n_{control}$=121). The rate of follow-up survey completion was high at all time points, and did not differ significantly by condition at any time point (all P values >.45; Figure 1).

Participant Characteristics

Demographic information for the final sample is presented in Table 1. The sample was racially, ethnically, and socioeconomically diverse, with an average age of 18.68 years (SD 0.35, range 18.10-19.77).

Table 1. Demographic data of participants.

Characteristic	Total sample (N=221)	Experimental (n=100)	Control (n=121)
Age (years), mean (SD)	18.68 (0.35)	18.66 (0.33)	18.69 (0.36)
Gender, n (%)			
Male	81 (36.7)	43 (43.0)	38 (31.4)
Female	131 (59.3)	51 (51.0)	80 (66.1)
Nonbinary	9 (4.1)	6 (6.0)	3 (2.5)
Race, n (%)			
White	117 (52.9)	48 (48.0)	69 (57.0)
Latino	30 (13.6)	13 (13.0)	17 (14.0)
Asian/Asian American	21 (9.5)	15 (15.0)	6 (5.0)
Black	8 (3.6)	2 (2.0)	6 (5.0)
Native American	2 (0.9)	0 (0.0)	2 (1.7)
Hawaiian or Pacific Islander	2 (0.9)	2 (2.0)	0 (0.0)
Two or more races/ethnicities	41 (18.6)	20 (20.0)	21 (17.4)
Parent/guardian education, n (%)			
High school or less	27 (12.2)	12 (12.0)	15 (12.4)
Some college (not 4-year)	50 (22.6)	25 (25.0)	25 (20.7)
One has a 4-year degree	30 (13.6)	13 (13.0)	17 (14.0)
Both have 4-year degrees	51 (23.1)	24 (24.0)	27 (22.3)
One has a graduate degree	34 (15.4)	13 (13.0)	21 (17.4)
Both have graduate degrees	29 (13.1)	13 (13.0)	16 (13.2)
Subjective SES[a], n (%)			
Low income	15 (6.8)	7 (7.0)	8 (6.7)
Working class	48 (21.8)	27 (27.0)	21 (17.5)
Middle class	93 (42.3)	41 (41.0)	52 (43.3)
Upper middle class	61 (27.7)	24 (24.0)	37 (30.7)
Wealthy	3 (1.4)	1 (1.0)	2 (1.7)
Financial stress, n (%)			
Never stressful	8 (3.6)	2 (2.0)	6 (5.0)
Rarely stressful	43 (19.5)	20 (20.0)	23 (19.0)
Sometimes stressful	90 (40.7)	46 (46.0)	44 (36.4)
Often stressful	61 (27.6)	25 (25.0)	36 (29.8)
Always stressful	19 (8.6)	7 (7.0)	12 (9.9)
Sexual orientation, n (%)			
Heterosexual	146 (66.1)	69 (69.0)	77 (63.6)
Gay or lesbian	10 (4.5)	3 (3.0)	7 (5.8)
Bisexual	36 (16.3)	12 (12.0)	24 (19.8)
Queer	13 (5.9)	5 (5.0)	8 (6.6)
Questioning	8 (3.6)	6 (6.0)	2 (1.7)
Other	5 (2.3)	2 (2.0)	3 (2.5)
Prefer not to respond or missing	3 (1.4)	3 (3.0)	0 (0.0)
Relationship status			
Single	174 (78.7)	80 (80.0)	94 (77.7)

Characteristic	Total sample (N=221)	Experimental (n=100)	Control (n=121)
Dating	7 (3.2)	4 (4.0)	3 (2.5)
In a relationship	38 (17.2)	16 (16.0)	22 (18.2)
Married	1 (0.5)	0 (0.0)	1 (0.8)
Other	1 (0.5)	0 (0.0)	1 (0.8)
Number of hours of weekly paid employment, mean (SD)	4.98 (7.91)	4.30 (7.47)	5.55 (8.24)
Transfer student, n (%)	1 (0.5)	1 (1.0)	0 (0.0)
Residence, n (%)			
Campus residence	215 (97.3)	97 (97.0)	118 (97.5)
Off campus apt	5 (2.3)	3 (3.0)	2 (1.7)
Other	1 (0.5)	0 (0.0)	1 (0.8)
Living situation, n (%)			
Dorm (alone)	1 (0.5)	0 (0.0)	1 (0.8)
Dorm (roommate)	172 (77.8)	80 (80.0)	92 (76.0)
Dorm suite (roommates)	37 (16.7)	16 (16.0)	21 (17.4)
Apartment (with students)	4 (1.8)	3 (3.0)	1 (0.8)
Apartment (with nonstudents)	1 (0.5)	0 (0.0)	1 (0.8)
Family	1 (0.5)	0 (0.0)	1 (0.8)
Other	5 (2.3)	1 (1.0)	4 (3.3)
Student athlete, n (%)	7 (3.2)	2 (2.0)	5 (4.1)
Autism spectrum, n (%)	3 (1.4)	1 (1.0)	2 (1.7)

[a]SES: socioeconomic status.

Engagement

Ninety-six of the 100 participants (96.0%) in the experimental group and 111 of the 121 participants (91.7%) in the control group created a Nod account within 4 weeks of being granted access to the app. As compared to the control, the experimental group demonstrated descriptively higher engagement with Nod during their first 4 weeks of access, although average engagement was low across both groups (Table 2). Participants in the experimental group viewed a mean of 36.69 pages in the app, while those in the control group viewed a mean of 20.85 pages. We note that although there were 102 pages of total content, users were not expected to progress through all pages in the app sequentially but rather to browse challenges and reflections, and engage as they desired.

Table 2. Descriptive statistics for engagement with Nod among first-year college students in the 4 weeks following first access to the Nod app (weeks 0-4 for the experimental group and weeks 4-8 for the control group).

Engagement measures	Experimental: weeks 0-4 (n=96)[a]		Control, weeks 4-8 (n=111)[a]	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Cumulative pages of app content accessed	36.69 (38.50)	23.0 (12.0-43.0)	20.85 (12.71)	17 (10.0-27.0)
Total number of challenges marked as completed by the user	0.89 (1.61)	0.0 (0.0-1.0)	0.31 (0.78)	0.0 (0.0-0.0)
Total number of reflections clicked through	1.13 (1.79)	0.0 (0.0-2.0)	0.37 (0.82)	0.0 (0.0-0.0)

[a]Excludes participants who were randomized to a condition but never created a Nod account ($n_{experimental}$=4 and $n_{control}$=10).

Loneliness

Descriptive examination of means revealed that both groups' loneliness scores declined slightly from baseline to week 4 (Table 3). Step 1 of the analyses, which examined condition differences in loneliness at week 4 controlling for baseline scores, showed no evidence for an overall effect of treatment on loneliness ($F_{1,211}$=0.05, P=.82; η_p^2=<.001).

Table 3. Loneliness, mental health, and college adjustment outcomes at baseline and week 4 among first-year college students (N=214) receiving the Nod intervention (experimental) versus waitlist (control).

Outcome	Baseline[a], mean (SD)		Week 4, mean (SD)	
	Experimental	Control	Experimental	Control
Loneliness (UCLA-8[b])	18.87 (4.32)	18.91 (4.40)	16.71 (4.73)	16.87 (5.32)
Depression (PHQ-9[c])	5.31 (4.18)	6.65 (5.52)	5.71 (4.14)	7.12 (5.90)
Anxiety symptoms (GAD-7[d])	5.90 (4.31)	6.85 (5.10)	5.22 (4.24)	6.50 (5.39)
Social anxiety symptoms (Mini-SPIN[e])	5.21 (2.89)	5.25 (3.23)	4.19 (3.20)	4.54 (3.45)
Sleep quality (PSQI[f])	1.20 (0.62)	1.33 (0.78)	1.21 (0.64)	1.38 (0.77)
Perceived social support (CIT[g] subscale)	not measured	not measured	4.20 (0.67)	4.08 (0.77)
Campus belonging (SERU[h])	5.00 (0.89)	4.96 (0.89)	4.94 (1.00)	4.86 (0.99)
Social adjustment to college (SACQ[i] subscale)	not measured	not measured	6.07 (1.26)	5.92 (1.50)
Intention to return (NSSE[j])	0.68 (0.47)	0.71 (0.46)	0.69 (0.46)	0.61 (0.49)

[a]Baseline scores exclude data from 7 participants who were missing data at week 4.

[b]UCLA-8: UCLA Loneliness Scale, 8-item.

[c]PHQ-9: Patient Health Questionnaire, 9-item.

[d]GAD-7: Generalized Anxiety Disorder, 7-item scale.

[e]Mini-SPIN: Mini Social Phobia Inventory.

[f]PSQI: Pittsburgh Sleep Quality Index (higher scores reflect lower quality sleep).

[g]CIT: Comprehensive Inventory of Thriving.

[h]SERU: Student Experiences in the Research University Questionnaire.

[i]SACQ: Student Adaptation to College Questionnaire.

[j]NSSE: National Survey for Student Engagement.

Step 2 of the analyses revealed a significant condition-by-baseline depression interaction ($F_{1,209}$=9.65, P=.002; η_p^2=.04). To interpret this interaction, we conducted follow-up analyses of the simple slopes of baseline depression on week-4 loneliness for each condition separately. Within the control group, there was a significant positive relationship between baseline depression and week-4 loneliness. In contrast, there was no significant relationship between baseline depression and week-4 loneliness within the experimental group (Table 4), suggesting that Nod buffered participants high in baseline depression from experiencing heightened midquarter loneliness (Figure 2).

Table 4. Simple slopes for loneliness, mental health, and college adjustment outcomes at week 4 among first-year college students receiving the Nod intervention (experimental) versus waitlist (control).

Outcome	*r* of simple slope[a]	*t* value	df	*P* value
Loneliness (UCLA-8[b])				
Experimental	–0.09	–0.84	209	.40
Control	0.30	3.81	209	<.001
Depression (PHQ-9[c])				
Experimental	–0.04	–0.44	209	.66
Control	0.23	2.60	209	.01
Sleep quality (PSQI[d])				
Experimental	–0.02	–1.24	208	.22
Control	0.04	2.89	208	.004
Social support (CIT[e] subscale)				
Experimental	–0.02	–1.41	209	.16
Control	–0.07	–4.60	209	<.001
Campus belonging (from SERU[f])				
Experimental	0.03	1.54	209	.13
Control	–0.05	–2.70	209	.007
Social Adjustment to College (SACQ[g] subscale)				
Experimental	–0.11	–3.73	209	<.001
Control	–0.18	–7.05	209	<.001
Intention to return to college (NSSE[h])				
Experimental	1.15 (1.01-1.32)	2.16	209	.03
Control	0.89 (0.80-1.00)	–2.01	209	.05

[a]Except for intention to return to college, which was assessed based on odds ratio (95% CI).

[b]UCLA-8: UCLA Loneliness Scale, 8-item.

[c]PHQ-9: Patient Health Questionnaire 9-item.

[d]PSQI: Pittsburgh Sleep Quality Index (higher values indicate poorer quality sleep).

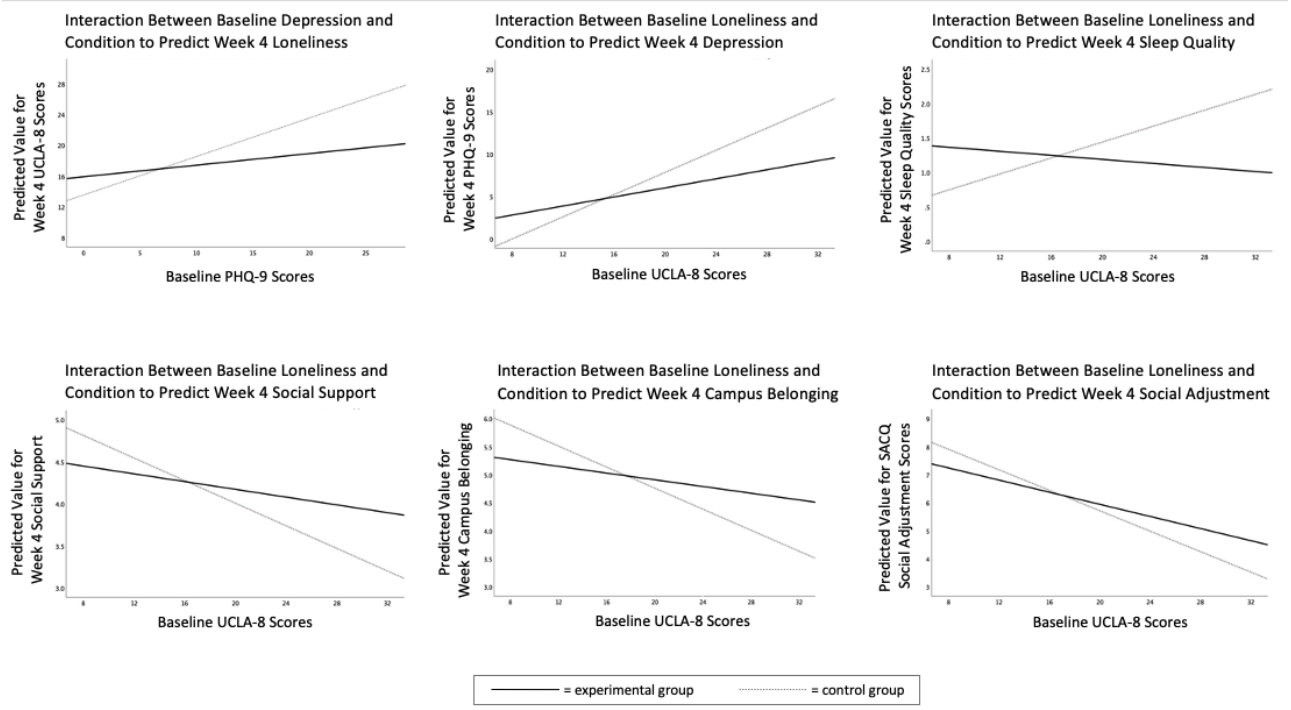
[e]CIT: Comprehensive Inventory of Thriving.

[f]SERU: Student Experiences in the Research University Questionnaire.

[g]SACQ: Student Adaptation to College Questionnaire.

[h]NSSE: National Survey for Student Engagement (1=will definitely return; 0=all other responses).

Figure 2. Simple slopes of baseline vulnerability on select week-4 mental health and college adjustment outcomes in the experimental vs control groups. All graphs represent complete case analyses. Higher sleep quality scores indicate lower quality sleep. UCLA-8: UCLA Loneliness Scale, 8-item; PHQ-9: Patient Health Questionnaire 9-item; SACQ: Student Adaptation to College Questionnaire.



Mental Health Indicators

Analyses in step 1 showed no evidence for an overall effect of treatment on any of the four indices of mental health (ie, week-4 depression, anxiety, social anxiety, or sleep quality): all *F* values were <1.60 and all *P* values were >.20. Step 2 of the analyses revealed a significant condition-by-baseline loneliness interaction to predict week-4 depression ($F_{1,209}$=5.17, *P*=.02, η_p^2=.02) and week-4 sleep quality ($F_{1,208}$=8.26, *P*=.004, η_p^2=.04). Similar to the pattern observed for week-4 loneliness, simple slope analyses indicated that Nod buffered participants with higher baseline loneliness against heightened midquarter depression and poor sleep quality (Table 4; Figure 2). Baseline loneliness did not significantly moderate the effect of condition on week-4 anxiety or social anxiety (both *F* values<1.80, *P*>.18).

College Adjustment Indicators

There was no evidence for an overall effect of treatment on any of the three indices of college adjustment (ie, week-4 social support, campus belonging, or social adjustment to college); all *F* values were <1.40 and all *P* values were >.23. However, the experimental group was more likely to report that they definitely intended to return to campus in the upcoming school year compared with the control (odds ratio=2.11, 95% CI 1.00-4.49, *z*=1.95, *P*=.05).

Step 2 of the analyses revealed a significant condition-by-baseline loneliness interaction to predict week-4 social support ($F_{1,210}$=4.05, *P*=.045; η_p^2=.02) and campus belonging ($F_{1,209}$=9.44, *P*=.002; η_p^2=.04). The condition-by-baseline loneliness interaction to predict week-4 social adjustment to college approached but did not reach statistical significance ($F_{1,210}$=3.66, *P*=.06; η_p^2=.02). Simple slope analyses suggested that Nod buffered participants with higher baseline loneliness against reduced social support, campus belonging, and social adjustment at week 4 (Table 4 and Figure 2).

Additionally, the significant main effect of condition on intention to return was moderated by a condition-by-baseline loneliness interaction (odds ratio=1.29, 95% CI 1.09-1.54, *z*=2.90, *P*=.004). Probing of this interaction revealed that within the control group, the odds of "definitely" intending to return to campus significantly decreased as baseline loneliness increased. In contrast, in the experimental group, the odds of intending to return significantly *increased* as baseline loneliness increased (Table 4).

Engagement and Outcome Improvement

Within the experimental group, the three indicators of engagement with Nod from week 0 to 4 were weakly positively associated with outcome improvement across a broad array of mental health and college adjustment indices, including loneliness, although many of these associations failed to reach statistical significance (Table 5).

Table 5. Spearman correlation coefficients (ρ) between engagement with Nod and change in outcomes from baseline to week 4 within the experimental group (N=94).[a]

Outcome	Total number of app pages clicked through		Total number of challenges marked as completed		Total number of reflections completed	
	ρ	*P* value	ρ	*P* value	ρ	*P* value
Loneliness (UCLA-8[b])	–0.20	.06	–0.23	.03	–0.17	.11
Depressive symptoms (PHQ-9[c])	–0.16	.13	–0.20	.05	–0.02	.88
Anxiety symptoms (GAD-7[d])	–0.24	.02	–0.26	.01	–0.17	.10
Social anxiety symptoms (Mini-SPIN[e])	–0.02	.82	–0.02	.85	0.01	.90
Sleep quality (PSQI[f])	0.07	.51	–0.002	.99	0.06	.59
Campus belonging (from SERU[g])	0.08	.43	0.07	.52	0.16	.13
Intention to return (from NSSE[h])	0.13	.21	0.08	.46	0.18	.08

[a]Only participants in the experimental group who created an account within Nod during the first 4 weeks in the study were included in these analyses.

[b]UCLA-8=UCLA Loneliness Scale, 8-item.

[c]PHQ-9=Patient Health Questionnaire 9-item.

[d]GAD-7=Generalized Anxiety Disorder, 7-item scale.

[e]Mini-SPIN=Mini Social Phobia Inventory.

[f]PSQI Sleep Quality=Sleep Quality item from the Pittsburgh Sleep Quality Index (higher values indicate lower quality sleep).

[g]SERU=Student Experiences in the Research University Questionnaire.

[h]NSSE=National Survey for Student Engagement.

User Experience

The majority of participants in the experimental group rated the app as easy to understand, and agreed that Nod gave them sound advice and something new to think about. However, fewer participants indicated that they would like to continue to use Nod, or had used what they learned in daily life (Table 6).

When asked what they found most useful about Nod, the majority of participants noted that Nod gave them new ideas for socializing or new ways of reflecting on social experiences: "Nod allows me to think of ways to interact with people that I probably wouldn't have thought of on my own. It opens more opportunities for me."

Additional benefits related to increased confidence to push outside of one's social comfort zone, social goal setting, and accountability, and the simple user experience design.

> *I've been more outgoing. The challenges I set up for myself really help me push my comfort zone to socialize more than I usually do.*
>
> *It's nice that the app has actual goals for you to do. I try to set social goals for myself, but this app makes me more accountable and really encourages me to be creative in social interaction. It's actually really fun!*
>
> *I think the simplicity of the app makes it effective...*

When asked what they would change about Nod and how it could be more helpful, a majority of participants expressed a desire for greater personalization. For example, one participant stated: "I would maybe add in the ability to make your own interaction goals and give more of an ability to track your progress."

Other notable themes included wanting more and different types of push notifications, requesting the addition of social networking features, and suggesting improvements to app gamification.

> *I would like to be able to establish more connections with people through the app—it can be difficult for me to introduce myself to people face-to-face so having that option might be of use to someone like me.*
>
> *Give students points or rewards or something that makes students feel like they should take the tips.*
>
> *Send daily reminders, facts, recommendations, encouragement.*

Table 6. Proportion of participants in the experimental group who responded "somewhat agree," "agree," or "strongly agree" to the respective statements (N=97).

Statement	Respondents in agreement, n (%)
The content of the Nod app was easy to understand.	81 (84)
The Nod app gave me sound advice.	74 (76)
The Nod app gave me something new to think about.	72 (74)
I'd like to continue to use the Nod app.	45 (46)
I've used what I've learned from Nod in my daily life.	40 (41)

Discussion

Principal Results

Intention-to-treat analyses indicated that there were no significant overall effects of the Nod app on loneliness, mental health, or college adjustment outcomes. However, Nod did have significant benefits for students who entered college with elevated risk (ie, heightened loneliness and depression) relative to their peers. Exposure to Nod buffered vulnerable first-year college students from experiencing heightened mid-semester loneliness and depressive symptoms, and protected against poor sleep quality, reduced social support, and reduced campus belonging. Notably, the experimental group was more likely to report that they would definitely return to campus in the upcoming school year, a benefit that was particularly pronounced for vulnerable students who are at heightened risk of early attrition [24]. These results support using app-based interventions to facilitate social connection, especially among first-year students experiencing elevated loneliness or depressive symptoms during key moments of social transition.

Less vulnerable students (ie, those with average to low levels of baseline loneliness and depression) did not derive significant benefits from Nod. These students may have had less need for the provided skills, and thus may have used Nod less frequently and benefited from it less. This possibility is supported by exploratory analyses demonstrating that baseline loneliness was positively associated with all measures of app engagement in the experimental group (all $r>.27$, all $P<.05$), indicating that more vulnerable participants used Nod more frequently than less vulnerable participants. This pattern is consistent with the broader study findings that students higher in baseline vulnerability derived greater benefit from being assigned to use Nod.

However, on average, even vulnerable students did not engage with Nod extensively, raising questions regarding what elements of Nod usage account for its benefits. Prior research has demonstrated that very brief (eg, 1 hour) growth mindset and social belonging interventions, when delivered at key points of social transition, can have prolonged positive effects on student well-being and achievement [27,65,80]. One possibility is that the social growth mindset messaging woven into Nod might have set in motion recursive psychosocial processes that accumulated over time. For example, reading student testimonials that normalize feelings of nervousness or awkwardness, and receiving prompts to try out new social activities, may have encouraged vulnerable students to take small social risks early in college (eg, to strike up new conversations or to go out to an event rather than staying home), which may have in turn set the stage for future patterns of positive interaction without requiring extensive engagement with the app. It is also possible that Nod's benefits might accrue from the additional socializing that Nod encourages students to engage in "in real life," regardless of whether students return to the app to mark challenges as complete. The goal of Nod, and indeed many app-based behavior-change interventions, is not engagement with the app per se, but engagement in behaviors that are the target of the intervention—in Nod's case, supportive social interactions. Future research might seek to measure these real-world engagements to better explore the mechanisms by which Nod supports the well-being of vulnerable students.

Participants' engagement data and qualitative feedback indicated several strengths of Nod as well as areas for improvement. The majority of participants agreed that the content was easy to understand and that Nod gave them new ideas. However, less than half of the participants indicated that they would like to continue to use Nod after the trial ended, and the majority did not mark any challenges as completed within the app. Several factors may have impeded continued engagement. The majority of participants expressed that Nod would benefit from greater personalization such as challenges that adapt to the user's comfort level. Participants also indicated that they would benefit from more and different types of push notifications, and suggested providing more in-app incentives. Future work will aim to boost motivation and reminders to engage through increased notifications, gamification, and clearer description of the potential benefits of app usage to students.

Limitations

Several limitations motivate further investigation. First, on average, participants did not engage extensively with Nod, raising questions regarding what elements of Nod usage account for its benefits to vulnerable students. Future research should incorporate finer-grained measures of in-app feature use, including details on how many and which specific challenge titles, tips, and testimonials students view, as well as out-of-app social behavior, to explore in greater depth the question of how Nod has beneficial effects. Future research should examine additional measures of engagement, including daily session duration, number of sessions per week, trends in use over time, and cumulative time spent in the app, as well as the proportion of students accepting push notifications, and examine possible differences in outcomes across these engagement metrics. Doing so may facilitate a clearer understanding of how Nod supports

mental health, as well as the minimum effective exposure needed to achieve positive effects. To improve engagement, developers could also investigate whether additional features such as video testimonials, the ability to connect with and message other users, or the inclusion of a module with links to campus-specific resources such as information on mental health resources, local hangouts, and interest groups might draw more students to return to the app.

A second limitation was the relatively small sample size of this initial pilot trial and its inclusion of a single university. Future larger trials should be conducted on a diverse range of college campuses, including commuter campuses and those with diverse student populations. In this trial, more women than men expressed interest in participating. Future user research aimed at increasing the appeal of study recruitment materials among college-aged men could help to ameliorate this gender imbalance.

Although there is precedent for loneliness interventions significantly reducing loneliness by 4 weeks [81-83], future studies would also benefit from longer follow-up periods to understand the magnitude and longevity of effects over time. Additionally, similar to many other pilot studies of tech-based behavioral interventions, it was not feasible to blind participants to condition. Future studies could deliver a "dummy" (ie, "sham") app to blind control participants and strengthen evidence for the efficacy of Nod.

Finally, participants were motivated to participate in a trial and were incentivized to download Nod, potentially weakening the generalizability of the findings. A naturalistic study of engagement outside of a clinical trial could provide more generalizable insights regarding Nod's benefits.

Comparison With Prior Work

Despite recent research demonstrating that 18-22 year olds report higher loneliness than any other generation, most loneliness interventions have been designed for older adults [84]. Systematic reviews of prior loneliness interventions identified a need for theoretically driven and rigorously evaluated interventions for loneliness in younger populations [43,84]. Our randomized controlled design and use of theory-driven strategies to reduce loneliness in college students helps to fill a significant gap in the research literature. To our knowledge, this study represents the first randomized controlled trial of a scalable, universal mobile intervention to address loneliness during the transition to college—a time of particular vulnerability.

Our finding that the beneficial effects of Nod exposure were most pronounced among vulnerable students accords with prior research. First, previous interventions for loneliness in undergraduate populations specifically recruited students experiencing heightened loneliness or depressive symptoms, as these populations were deemed most in need of resources [31,81]. Second, meta-analytic research suggests that mental health interventions have larger effects when targeting vulnerable populations [44]. Nevertheless, Nod's intentional design to be appropriate for a universal audience offers several benefits. By avoiding identifying students as "in need" of targeted support, Nod avoids stigmatizing users. Nod can also be delivered before students present with problems at counseling centers, allowing upstream prevention without requiring screening of at-risk students.

Conclusions

This study demonstrated that a smartphone app can provide scalable, self-paced, and confidential support for students to prevent and cope with loneliness. Exposure to Nod buffered against heightened loneliness and depression, and resulted in enhanced sleep quality, campus belonging, social support, and intention to return to college among vulnerable first-year students. Given its simple user interface and a format that supports iteration on content, the app is likely to appeal to a broad range of students. The randomized design of this trial extends the promising findings of similar interventions for college students [41], and bolsters confidence that loneliness can be addressed digitally. Future work will aim to improve upon app engagement, and to address loneliness during other key social transitions and among other young populations who may benefit from digital interventions to support social connectedness.

Acknowledgments

We are grateful to all of our partners who participated in the co-design of Nod and the study reported herein. In particular, we would like to thank Denise Ho, Janise Chan, Lionel Ramazzini, Julie Tinker, Lauren Girardin, Monique Nguyen, Christopher Lloyd Chang, Lena Bertozzi, Kristen Chu, Juliyen Davis, Kelly Stuckey Jr, Manali Kulkarni, Ashlyn Gary, Ankur Shah, Arian Mobasser, and Danielle Cosme who were instrumental in the design and development of Nod. We would also like to thank our scientific advisors, Melissa Gilliam, Julianne Holt-Lundstad, Sonja Lyubomirsky, Kali Trzesniewski, Leah Weiss, Lea Seigen Shinraku, Nick Allen, and Ahna Suleiman, for their thoughtful input and feedback.

Conflicts of Interest

Nod is a mobile app co-developed by Grit Digital Health and Hopelab. While both organizations own rights to the Nod product, Grit Digital Health is solely responsible for the commercial operation and distribution of Nod. As co-owner, Hopelab receives a limited portion of Nod sale net proceeds. The research reported here as well as the development of Nod were supported by the nonprofit Hopelab Foundation. Hopelab develops behavioral interventions to improve the health and well-being of young people. The design, conduct, analysis, and reporting of this study represent a scientific collaboration between Hopelab, JP, and BD at the University of Oregon, and KD at the University of California, San Francisco and Weill Institute for Neurosciences. EB-S, CJH,

CF, JH, and DER are employed by Hopelab Foundation. The study sponsor was involved in the study design, collection, analysis, and interpretation of data; writing of the article; and decision to submit it for publication.

Multimedia Appendix 1
Consent form.
[PDF File (Adobe PDF File), 272 KB - mental_v7i10e21496_app1.pdf]

Multimedia Appendix 2
Nod challenge, testimonial, and reflection screenshots.
[PNG File , 414 KB - mental_v7i10e21496_app2.png]

Multimedia Appendix 3
Nod informational video.
[MP4 File (MP4 Video), 9941 KB - mental_v7i10e21496_app3.mp4]

Multimedia Appendix 4
Nod risk assessment protocol.
[PDF File (Adobe PDF File), 383 KB - mental_v7i10e21496_app4.pdf]

Multimedia Appendix 5
Comparisons between outcomes and engagement in the control group at week 8 to the experimental group at week 4.
[PDF File (Adobe PDF File), 608 KB - mental_v7i10e21496_app5.pdf]

Multimedia Appendix 6
CONSORT-eHEALTH checklist (v1.6.1).
[PDF File (Adobe PDF File), 1343 KB - mental_v7i10e21496_app6.pdf]

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Abbreviations

GAD-7: 7-item Generalized Anxiety Disorder Scale
PHQ-9: 9-item Patient Health Questionnaire
UCLA-8: 8-item version of the UCLA loneliness questionnaire

Edited by G Eysenbach; submitted 17.06.20; peer-reviewed by E Achtyes, K Reynolds; comments to author 09.07.20; revised version received 12.08.20; accepted 19.09.20; published 20.10.20.

Please cite as:
Bruehlman-Senecal E, Hook CJ, Pfeifer JH, FitzGerald C, Davis B, Delucchi KL, Haritatos J, Ramo DE
Smartphone App to Address Loneliness Among College Students: Pilot Randomized Controlled Trial
JMIR Ment Health 2020;7(10):e21496
URL: http://mental.jmir.org/2020/10/e21496/
doi:10.2196/21496
PMID:33079071

Original Paper

Intent to Adopt Video-Based Integrated Mental Health Care and the Characteristics of its Supporters: Mixed Methods Study Among General Practitioners Applying Diffusion of Innovations Theory

Markus W Haun[1], BSc, MSc, MD; Isabella Stephan[1]; Michel Wensing[2], Prof Dr; Mechthild Hartmann[1], Dipl Psych; Mariell Hoffmann[1*], BA, MA; Hans-Christoph Friederich[1*], Prof Dr

[1]Department of General Medicine and Psychosomatics, Heidelberg University, Heidelberg, Germany

[2]Department of General Practice and Health Services Research, Heidelberg University, Heidelberg, Germany

[*]these authors contributed equally

Corresponding Author:
Markus W Haun, BSc, MSc, MD
Department of General Medicine and Psychosomatics
Heidelberg University
Im Neuenheimer Feld 410
Heidelberg, D-69120
Germany
Phone: 49 622156 ext 8774
Email: markus.haun@med.uni-heidelberg.de

Abstract

Background: Most people with common mental disorders, including those with severe mental illness, are treated in general practice. Video-based integrated care models featuring mental health specialist video consultations (MHSVC) facilitate the involvement of specialist mental health care. However, the potential uptake by general practitioners (GPs) is unclear.

Objective: This mixed method preimplementation study aims to assess GPs' intent to adopt MHSVC in their practice, identify predictors for early intent to adopt (quantitative strand), and characterize GPs with early intent to adopt based on the Diffusion of Innovations Theory (DOI) theory (qualitative strand).

Methods: Applying a convergent parallel design, we conducted a survey of 177 GPs and followed it up with focus groups and individual interviews for a sample of 5 early adopters and 1 nonadopter. We identified predictors for intent to adopt through a cumulative logit model for ordinal multicategory responses for data with a proportional odds structure. A total of 2 coders independently analyzed the qualitative data, deriving common characteristics across the 5 early adopters. We interpreted the qualitative findings accounting for the generalized adopter categories of DOI.

Results: This study found that about one in two GPs (87/176, 49.4%) assumed that patients would benefit from an MHSVC service model, about one in three GPs (62/176, 35.2%) intended to adopt such a model, the availability of a designated room was the only significant predictor of intent to adopt in GPs (β=2.03, SE 0.345, $P<.001$), supporting GPs expected to save time and took a solution-focused perspective on the practical implementation of MHSVC, and characteristics of supporting and nonsupporting GPs in the context of MHSVC corresponded well with the generalized adopter categories conceptualized in the DOI.

Conclusions: A significant proportion of GPs may function as early adopters and key stakeholders to facilitate the spread of MHSVC. Indeed, our findings correspond well with increasing utilization rates of telehealth in primary care and specialist health care services (eg, mental health facilities and community-based, federally qualified health centers in the United States). Future work should focus on specific measures to foster the intention to adopt among hesitant GPs.

(JMIR Ment Health 2020;7(10):e23660) doi:10.2196/23660

KEYWORDS

video consultations; videoconferencing; telehealth; integrated care; mental health; preimplementation; diffusion of innovations; early adopters; mixed methods; cumulative logit model; content analysis

Introduction

Telehealth in General Practice Mental Health

Most people with common mental disorders and many of those with severe and enduring mental illness are treated within general practice [1-3]. For example, according to German health insurance claims data, one in every 2 patients with two or more mental health conditions is treated by general practitioner (GP) only [4]. By increasing the access to specialist care, integrated care models are effective in ensuring seamless care trajectories [5-8]. However, in many remote and rural areas, mental health specialists (MHS), who play a pivotal role in these models, are not readily available [9]. Moreover, patients, particularly those with long-term conditions, struggle with long travel distances [10-12]. Hence, video-based integrated care models have been introduced to overcome the limitations of face-to-face models and have proven to be safe and equally effective [13-18]. Although telemedicine in mental health is relatively common compared with other specialties, only 12.7% of all GPs use video consultations in their practice [19,20]. GPs are concerned with increased workload and the lack of reimbursement and training [21,22].

GPs as Early Adopters of Telehealth

In the Diffusion of Innovations (DOI) theory, innovativeness is defined as the degree to which an individual is relatively early in adopting new practices compared with other members of a social system [23,24]. To this end, GPs can be characterized by the extent to which they are open to the implementation of new technologies [25,26]. Specifically, GPs can be placed on a spectrum running from early adopters to the so-called laggards (nonadopters) [27]. Putting aside the uncertainty, early adopters show a more favorable attitude toward change and science, less dogmatism, and a greater knowledge of innovations. Currently, little is known about the innovativeness of GPs with respect to telehealth applications such as video consultations. Specifically, the characteristics of GPs with early intent to adopt are unknown. In this regard, we conducted a systematic search in MEDLINE (Medical Literature Analysis and Retrieval System Online) and Web of Science from inception to August 19, 2020 (Multimedia Appendix 1 [28]). Among the 3944 records, we found 5 records concerning the early adoption of telehealth interventions in general practice. We identified 1 conceptual article [29], 1 study protocol [30], 1 case study of an early adopter site [31], and 2 qualitative studies [32,33]. The case study describes the impact of a web-based consultation system on working practices in an inner-city general practice. Overall, evidence on anticipated efficiency gains was scarce [29]. One qualitative interview study investigated the perceptions of 9 Norwegian GPs toward the use of 4 digital health services for patients (electronic booking to schedule visits, electronic prescriptions, text-based nonclinical inquiries, and text-based electronic consultation). Besides skepticism about the clinical utility of e-consultations, GPs entertained concerns that elderly patients, people unfamiliar with technology, and some patients receiving psychiatric care required traditional face-to-face alternatives. None of the studies determined the proportion of GPs intending to adopt mental health specialist video consultations (MHSVC). Predictors of early adoption and characteristics of GPs with early intent to adopt also remain unclear. However, evidence on both the early adopter proportion and predictors, along with the characteristics of GPs with early intent to adopt, is needed to efficiently promote and implement telehealth applications in general practice [34].

Rationale of the Study

This mixed method study aims to (1) assess GPs' intent to adopt MHSVC in their practice, (2) identify predictors for early intent to adopt (quantitative strand), and (3) characterize GPs with early intent to adopt based on the DOI (qualitative strand) theory by Everett Rogers. Specifically, we conducted a survey followed by focus groups and interviews with GPs as part of the preimplementation phase of the PROVIDE (ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations) project [35,36]. PROVIDE features a service model in which GPs refer patients with depression and/or anxiety to video consultations conducted in their practice with a remotely located MHS. The model comprises up to 5 MHSVC sessions that focus on specialized clinical evaluation (systematic assessment and diagnostics), brief therapy (general support, brief psychotherapy, and psychopharmacology), and, if required, triage to specialist mental health service.

Methods

Mixed Methods Study Design

We applied a convergent parallel design to gain an understanding of GPs' attitudes toward adopting MHSVC. This design allows for the collection and analysis quantitative and qualitative data followed by an integration of both. Specifically, we started with the collection and analysis of cross-sectional survey data and followed it up with the collection and analysis of the qualitative focus group and interview data [37]. The quantitative strand comprised (1) the estimation of the anticipated benefit, acceptability, and intent to adopt MHSVC among GPs, (2) the exploration of predictors for the intent to adopt, and (3) the identification of supporters in this population of interest. The subsequent qualitative strand included the in-depth characterization of these supporters, whose sampling was informed by the quantitative results. Specifically, the composition of the qualitative sample resulted from a direct interaction between the two strands (point of interface) [38].

This study received ethical approval from the Ethics Committee of the Medical Faculty at the University of Heidelberg (Reference: S-197/2017) and was preregistered with the German Clinical Trials Register (DRKS00012487). We applied the COnsolidated criteria for reporting qualitative research (COREQ; Multimedia Appendix 2).

Setting

The PROVIDE research group at Heidelberg University in Heidelberg, Germany coordinated and conducted the survey, the focus groups and the telephone interviews. Recruitment and data collection lasted from May 2017 to June 2017 for the survey and from July 2017 to August 2017 for the focus groups and interviews, respectively.

Participants

We invited all GPs registered with the Association of Statutory Health Insurance Physicians in 1 urban and 4 rural districts (from a total of 35 districts in Baden-Wuerttemberg, one of 16 German federal states) to participate in the study. Apart from registration, there were no other eligibility criteria for GPs. All the GPs received a personalized cover letter, a 4-page leaflet containing information about the study, including the MHSVC care model, and a questionnaire on the intent to adopt (Multimedia Appendix 3), which the GPs were asked to send back by fax. We reminded all nonresponders with up to 3 follow-up phone calls. We did not offer any incentive for answer the questionnaire. A total of 41 GPs declared interest in participating in the focus groups. We conducted 4 focus groups (range: 2-6 participants, 90-120 min) involving 16 GPs at Heidelberg University Hospital. One GP, who had been invited by another GP, participated without a formal invitation. Whenever possible, we opted for focus groups that facilitated less constrained discussions for capturing a broad range of perceptions [39,40]. We conducted individual telephone interviews with 3 GPs (40-55 min) who were eventually unable to attend focus groups. We offered a nonadvertised individual monetary compensation of €50 (US $58) to each participant. A total of 16 GPs refused to participate, mostly because of holiday leave (n=4) and lack of interest (n=4). A total of 7 GPs were not contacted because of the earlier-than-expected data saturation. The initial analysis based on the data of all 19 participants focused on the overall potential for integrating MHSVC in general practice. The findings were published elsewhere [35]. For this study, we limited our analysis to 6 focus group and interview participants who had (1) also participated in the initial survey and (2) were identified as supporters and nonsupporters.

Data Sources and Measurement

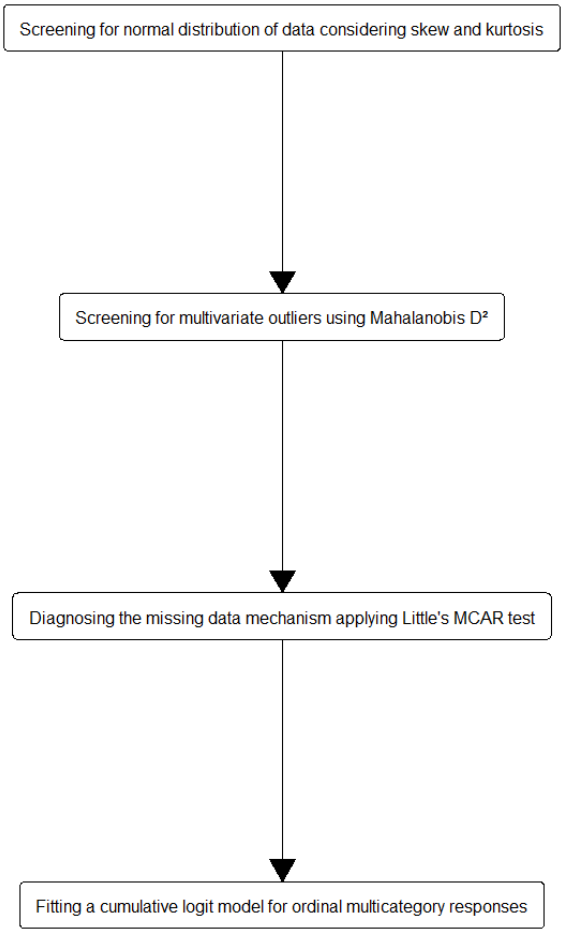
We developed a brief 12-item self-completion, written questionnaire (Multimedia Appendix 3). It contained 3 domains: (1) demographic data of the GP, (2) characteristics of the practice, and (3) intent to adopt MHSVC (anticipated benefit for patients, acceptance of MHSVC, and intent to adopt). We only used closed questions with precoded response options. To ensure content validity, we piloted the questionnaire to an experienced GP and a senior health services researcher to check for the unambiguous meaning of instructions and questions, along with sufficiency of the response categories available. The degree of urbanization of the area practices was stratified according to the current standard established by the European Commission [41].

To prompt group discussions and interviews, we developed a semistructured question guide (Multimedia Appendix 4). The questions focused on how GPs perceived current health care for patients with mental disorders, the potential for integrating MHSVC into office-based routine general practice, and the determinants of the implementation of MHSVC. We piloted the guide to one GP and one senior health services researcher, and it was also reviewed after the first focus group. After obtaining written informed consent from all participants, M Haun (internal medicine specialist, senior researcher, and content expert for mental health services) and M Hoffmann (sociologist, PhD student, and expert in qualitative research) moderated the focus groups. To stimulate the discussion, the moderators presented a 7-min video clip illustrating the MHSVC model. We also compiled field notes during all focus groups and interviews. Qualitative data were audio-recorded and uploaded to a secure server of Heidelberg University Hospital, which was accessible only to the research team. We stopped data collection when no new insights emerged from the data, suggesting that we had achieved saturation of content and a rich description through a variety of codes and associated meanings [42].

Statistical Analysis (Quantitative Strand)

An overview of the statistical analysis is provided in Figure 1. The data preparation for the multivariate analysis included screening for normality and outliers. First, we inspected univariate distributions assuming multivariate normality if skewness and kurtosis item and score values fell within the normal range (2 to 2 and 7 to 7, respectively). In addition, we computed Mahalanobis D^2; outliers were deleted before subsequent analyses. Second, Little's test of missing completely at random (R package *BaylorEdPsych*) indicated a missing-completely-at-random pattern (χ^2_2=1.3; N=176; *P*=.53) and a maximum fraction of missing information of 2.8% (5/177) at the item level. Hence, we refrained from imputing missing data, assuming comparable efficiency for *the available case analysis. Finally, we fitted a cumulative logit model for ordinal multicategory responses with proportional odds structure (R package VGAM*) to the data using the intent-to-adopt item 11 as the dependent variable and 6 GP and practice-related predictors (age of the GP, additional mental health care qualification of the GP, degree of urbanization of the area that the practice was in, practice type (single or group or shared), average number of treated cases, and availability of a room designated for video consultations). We tested the proportional odds assumption, that is, the effect of an independent variable would be uniform for all levels of the intent-to-adopt item 11 as the dependent variable, using the likelihood ratio test from the ordinal package [43]. Concerning the qualitative analysis, we considered all GPs to be supporters who fully agreed on the intent-to-adopt item 11 (*In principle, can you personally imagine providing video consultations conducted by MHS to patients with mental disorders in your practice?*). Similarly, we identified all GPs as nonsupporters (1) who fully disagreed on item 11 and (2) rather or fully disagreed on item 10 (*Would you support the idea of treating patients with mental health disorders through video consultations conducted by MHS in primary care practices?*). The statistical analysis was conducted independently by 2 analysts (M Haun and Justus Tönnies, MSc) using R, version 4.0.2 [44]. For all analyses, statistical significance was evaluated at a type 1 error of 5% (two-tailed).

Figure 1. Overview of the statistical analysis. MCAR: missing completely at random.



Content Analysis (Qualitative Strand)

Before anonymizing the data, a professional transcription service conducted verbatim audio transcriptions of the recordings. The aim of the qualitative analysis was to find common characteristics across the 5 supporters and to interpret these findings using DOI [24]. Thus, we accounted for differences and similarities between the supporters and nonsupporters of the MHSVC and the generalized categories of early adopters and nonadopters (so-called laggards), as proposed in DOI. Therefore, we conducted an inductive content analysis with inductive or bottom-up development of the coding system in MAXQDA, version 18 [45]. For data collection, analysis, and interpretation, we followed the principle of investigator triangulation (Table 1) to limit potentially prevailing researcher biases by leveraging multidisciplinary expertise [46]. First, to gain an initial understanding of the data, two coders (IS and M Hoffmann) independently read one transcript, highlighting the most important passages. Second, to facilitate the comparison of the major topics, each researcher defined codes that represented the highlighted key aspects (IS and M Hoffmann). Third, both coders compared their analyses, discussed disagreements, and resolved them (IS and M Hoffmann). Fourth, both researchers independently applied the new coding system to another transcript and reviewed their findings (IS and M Hoffmann). To ensure that all key aspects were represented in the coding system, codes were continuously modified when new aspects emerged. Finally, IS analyzed the remaining transcripts and met with M Hoffmann and M Haun to check the coding system for inter-coder consistency and discuss its validity (Multimedia Appendix 5; IS, M Hoffmann, and M Haun). All researchers involved in the investigator triangulation checked the final interpretation of the data for completeness and cohesiveness.

Table 1. Details for investigator triangulation.

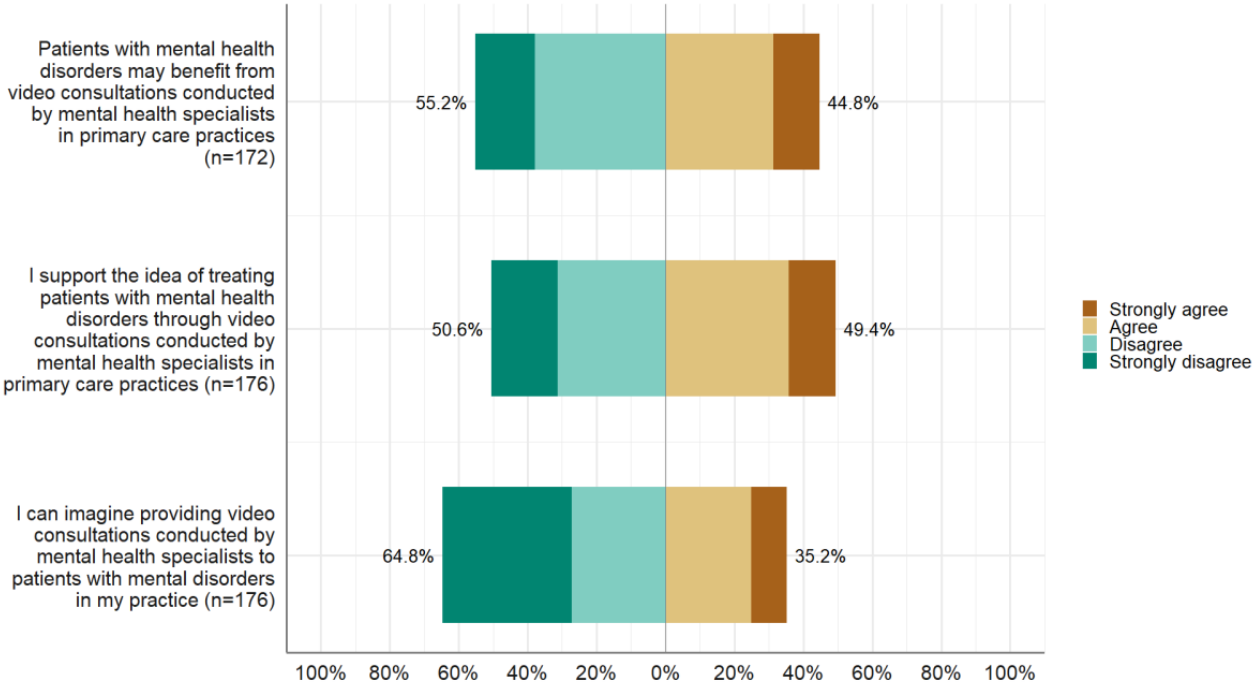
Characteristics	M Hoffmann	IS	M Haun
Disciplinary background	Sociologist	Medical student, final year elective	MD, psychologist, internal medicine specialist, attending physician in psychosomatic medicine
Training and expertise	Early career researcher, >6 years of experience with qualitative methods	Early career researcher	Senior researcher, >10 years of experience with quantitative and qualitative methods
Epistemological stance	Critical realist	Critical realist	Critical realist
Role	PhD student in the PROVIDE[a] project	MD student in the PROVIDE project	Principal investigator of the PROVIDE project
Stages involved or points of collaboration (Degree of investigator independence)	Collection of quantitative and qualitative data (moderate), cleaning of qualitative data (high), inductive content analysis (high), development of a joint coding system (moderate to high)	Cleaning of qualitative data (high), inductive content analysis (moderate), development of joint coding system (moderate)	Collection of quantitative and qualitative data, quantitative data analysis (high), content analysis: review of initial coding systems (high), content analysis: arbiter for developing a joint coding system (moderate to high)
Statement of investigator triangulation impact	Overall, investigator triangulation contributed to (1) consensus reaching on divergent views or interpretations and (2) confirmation of codes and themes which covered the data quite completely and cohesively.	Overall, investigator triangulation contributed to (1) consensus reaching on divergent views or interpretations and (2) confirmation of codes and themes which covered the data quite completely and cohesively.	Overall, investigator triangulation contributed to (1) consensus reaching on divergent views or interpretations and (2) confirmation of codes and themes which covered the data quite completely and cohesively.

[a]PROVIDE: ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations.

Results

We present the quantitative results followed by the qualitative characterization of the supporters and the nonsupporter of the MHSVC model. Finally, we interpret these findings with respect to their fit with the generalized categories of early adopters and nonadopters conceptualized in DOI (Figure 2).

Figure 2. General practitioners' agreement on benefit for patients, acceptance, and intent-to-adopt concerning mental health specialist video consultations.



Main Results of the Quantitative Strand: Intent to Adopt Among GPs

Survey Participants

We invited 788 eligible GPs to participate in the initial survey (Multimedia Appendix 6 for the study flow chart). Eventually, 22.5% (177/788) GPs responded. Common reasons for nonparticipation were unknown (373/611, 61.3%), lack of interest (146/611, 23.6%), and time constraints (66/611, 10.8%). There were no statistically significant differences between nonresponders and responders concerning gender (χ^2_1=0.0; N=788; *P*=.96) and the degree of urbanization of the areas of practice were as follows: (χ^2_2=4.6; N=788; *P*=.10; Multimedia Appendix 7 for mosaic plots). There was no major difference in the average age (M=55.9 years, SD 8.8) of our sample compared with the average age of GPs at the country level (M=55.3 years), although no statistical comparison was possible owing to the missing SD for age at the country level. Table 2 shows the sociodemographic characteristics of the sample. After removing the 4 outliers, we included 173 cases in the multivariate analysis.

Table 2. Sample description for the quantitative strand.

Variable	Values
Female gender, n (%)	85 (48.0)
Age (years), mean (SD)	55.9 (8.8)
Additional qualification in addiction medicine and/or psychotherapy, n (%)[a]	19 (10.9)
Years in office-based practice, mean (SD)	18.2 (9.8)
Type of practice, n (%)	
Solo practice	103 (58.5)
Shared practice	63 (35.8)
Group practice	10 (5.7)
Number of physicians in the practice, mean (SD)	
Overall	2.1 (2.2)
Full time	1.4 (0.9)
Part time	0.7 (2.1)
Degree of urbanization of the area the practice was located in, n (%)	
Cities (densely populated areas)	27 (15.3)
Towns and suburbs (intermediate density areas)	111 (62.7)
Rural areas (thinly populated areas)	39 (22.0)
Average number of patients per quarter, n (%)	
<500	4 (2.3)
501-1000	47 (27.3)
1001-1500	54 (31.4)
>1500	67 (38.9)
Patients with mental health conditions per week, n (%)	
1-5	13 (7.4)
5-10	32 (18.2)
10-15	53 (30.1)
>15	78 (44.3)
Designated room available for video consultations, n (%)	86 (49.1)

[a]Includes addiction medicine and/or psychotherapy. Multiple responses possible.

Anticipated Benefits for Patients, Acceptability, and Intent to Adopt

We assessed GPs' attitudes concerning the anticipated benefit for patients from MHSVC, their acceptance of MHSVC, and their intent to adopt to MHSVC on ordinal agreement scales with 4 response categories, ranging from *strongly agree* to *strongly disagree* (Figure 2). Notably, while one in every 2 GPs stated having a designated room available for video consultations in their practice, only one in every 10 GPs indicated that they would be willing to offer video consultations.

Predictors for Intent to Adopt MHSVC (Proportional Odds Model)

To identify predictors for the intent to adopt MHSVC among GPs, we fitted a cumulative logit model for ordinal responses (Table 3). Applying the likelihood ratio test, we identified the availability of a designated room for video consultations in general practice as the only significant predictor. The deviance test statistic indicated that the model fitted adequately (χ^2_{467}=371.5; N=788; *P*=.99). The likelihood ratio test of the proportional odds assumption did not yield any evidence that this assumption was violated for any predictor variable.

Table 3. Proportional odds model for intent-to-adopt video consultations[a].

Predictor variables	Coefficient[b]	SE[c]	z value	*P* value
Age of general practitioner	−0.014	0.017	0.830	.41
Additional qualification in addiction medicine and/or psychotherapy (ref: no)	−1.002	0.545	1.837	.07
Type of practice (ref[d] : Solo practice)				
Shared practice	−0.386	0.389	0.990	.32
Group practice	−0.545	0.738	0.738	.46
Degree of urbanization of the area the practice was located in (ref: Cities [densely populated areas])				
Towns and suburbs (intermediate density areas)	−0.659	0.392	1.682	.09
Rural areas (thinly populated areas)	−0.243	0.268	0.906	.37
Average number of patients per quarter (ref: <500)				
<500	0.493	0.848	−0.581	.56
501-1000	−0.115	0.625	0.185	.85
1001-1500	−0.195	0.378	0.518	.61
Designated room available for video consultations (ref: no)	2.025	0.345	5.876	<.001

[a]Number of observations: 788. R^2: 0.33 (Cox & Snell); 0.35 (Nagelkerke); and 0.15 (McFadden). Residual deviance: 371.52 on 467 degrees of freedom. Log-likelihood: 185.76 on 467 degrees of freedom. Akaike information criterion (AIC): 397.52. Bayesian information criterion (BIC): 437.49. Intercepts not displayed.

[b]Negative values indicate a lower likelihood of intent to adopt, positive values indicate a higher likelihood of intent to adopt.

[c]SE: standard error.

[d]ref: reference category.

Main Results of the Qualitative Strand: Characterization of Supporters and Nonsupporters

Focus Group Participants

We identified 18 supporters and 56 nonsupporters among the 177 responding GPs. A total of 5 supporters (out of 10 who initially declared interest) and 1 nonsupporter (out of 4 who initially declared interest) eventually participated in the focus groups. Each of these 6 GPs joined a different focus group or participated in an individual interview and provided the data on which the following qualitative analysis was based (Table 4).

Table 4. Sample description for the qualitative strand.

Type of innovativeness	Gender	Age (years)	Additional qualification in addiction medicine and/or psychotherapy	Type of practice	Degree of urbanization of the area the practice was located in	Designated room available for video consultations	Focus group and interview
Supporter #1	Male	57	No	Solo	Towns and suburbs	Yes	# F1
Supporter #2	Male	60	Yes	Group	Rural area	Yes	# F3
Supporter #3	Male	53	No	Solo	Towns and suburbs	Yes	# F4
Supporter #4	Male	62	No	Solo	Towns and suburbs	Yes	# I2
Supporter #5	Female	60	No	Solo	Towns and suburbs	Yes	# I3
Nonsupporter	Female	56	Yes	Group	Towns and suburbs	No	# F2

In the following, we present shared characteristics among the 5 supporters and 1 nonsupporter. We then elaborate the specific characteristics of the supporters and the nonsupporter, highlighting major distinctions between the 2 groups.

Shared Characteristics of Supporters and Nonsupporters

Both, the 5 supporters and the 1 nonsupporter, strongly identified with the key role attributed to GPs in most health care systems and were highly committed to fostering the doctor-patient relationship unique to general practice:

> *The structure of a specialist's practice is completely different from that of a GP. We are practically the last resort. We take everyone, unselected. This makes up the quality and uniqueness of our work.* [Supporter #2]

> *Who else in the medical field actually dares to proceed to this intimate level with patients? This is my advantage.* [Supporter #1]

Considering themselves as the principal health care providers for patients, GPs felt responsible for the early identification of mental health conditions. However, they perceived the referral of patients to specialist mental health care as very challenging. Specifically, they observed a high number of burdened patients faced long waiting times owing to the very limited availability of MHS:

> *There is a huge problem in routine care: When you have patients with an acute condition, referring them is always very difficult in my view.* [Supporter #1]

> *We still have the problem of getting patients referred. I have two psychotherapists, who I really like, but they work to capacity.* [Nonsupporter]

Continuously struggling with this ubiquitous supply-demand dilemma in their daily routine, all 6 GPs called for measures to increase the accessibility of specialist mental health services, for example, by scaling up cross-sectoral care models. Table 5 presents a joint display of the quantitative and qualitative results of the identified supporters and the nonsupporter.

Table 5. Joint display organized by the supporter and nonsupporter categories.

Group	Anticipated benefits for patients, mean (SD)	Acceptability[a], mean (SD)	Intent-to-adopt criterion[a]	Participants' statements (exemplary quotes from focus group or interview)
Supporter	1.28 (0.67)	1.28 (0.57)	1	• Supporter #1: "Yes, if I have the possibility, to provide short-term video consultations for the patient at least for an initial therapy so that the patient does not have to wait endlessly until I can make an appointment with a suitable psychotherapist." • Supporter #3: "You have to see it like this: I would also benefit from it [the model], because it would help my patients." • Supporter #5: "I deal with hundreds of different diseases, which take up a lot of my time. But here I can get help that would also give me some relief."
Nonsupporter	3.46 (0.57)	3.61 (0.49)	4	• Nonsupporter: "It also depends a bit on the overall attitude. I am a more reserved type with these things, as you've already noticed. Others, who might start from the scratch, will be more interested." • Nonsupporter: "Let's put it this way: I think it's legitimate to try to use resources in a way that it is beneficial to most people. But I just don't think it's reasonable to shift patients in need from one provider to another." • Nonsupporter: "With patients being in an acute crisis, I am not sure if the video consultation works if they haven't had experience with this setting before."

[a]Lower values indicate higher anticipated benefits, higher acceptability, and higher intent to adopt, respectively.

Characteristics of Supporters

The supporters identified difficulties inherent in the organization of modern general. Specifically, they reported time constraints and a lack of qualification in mental health care. Supporters postulated that the MHSVC model would be effective at enabling low-threshold access to specialist care, primarily for patients presenting in general practice but also for themselves as GPs (eg, for brief case discussions):

> *I mean, we would lower the threshold significantly by offering the patient to only come to the familiar GP's practice [to receive the video consultation] and nothing more. I think at some point during the treatment course, a moderate threshold is acceptable for the patient.* [Supporter #3]

Supporters were also open to new technology-based interventions and expected them to yield outcomes comparable with face-to-face treatments. They appreciated the possibility of immediately linking patients with MHS and, at the same time, saving the resources of the general practice:

> *I would be happy if I had such an instrument [the video consultations]. I could tell the patients who I consider to be in urgent need of treatment: 'Listen, there's something, that you can do here for a few hours, at least temporarily. You may give it some thought'.* [Supporter #4]

> *If I know that I have someone in the background, I tell the patient, 'Okay, I see your difficulties, but I can make some effort to get you a rapid appointment with a specialist' knowing that the patient will be cared for.* [Supporter #5]

Supporters were genuinely interested in the practical implementation of the MHSVC, which reflected in detailed questions about which components the model would include and how it would be compatible with existing workflows in their practices:

> *My assistant could, so to speak, take the patient friendly by the hand and explain the technical details to him, where to press. They would also clarify whom the patient would turn to if there was a problem [during the video consultation].* [Supporter #2]

Although the supporting GPs demanded high usability from the video consultation platform and readily available technical support, they also took a solution-focused perspective on potential problems. Notably, the supporters expressed high confidence about being able to rapidly tackle unexpected difficulties during both the setup and the maintenance of the service:

> *As I said, so you just must seat the people in front of it [the screen] and see what happens. I would also be interested in experiencing that.* [Supporter #4]

Eventually, supporters reflected on the target population for video consultations and estimated the acceptability to be high with a few exceptions in certain patient groups. Specifically, supporters argued that older people would be less affinitive to the technology and struggle with it more often compared with younger patients:

> *Therefore, I think, the barrier to admitting that you have a psychological problem, this barrier is certainly very high for many. [...] This is certainly higher with the elderly than with younger ones.* [Supporter #4]

Overall, supporters (1) regarded video consultation as a mode of delivery equal to face-to-face settings, (2) anticipated specific advantages both for patients and themselves as GPs, and (3) tried to gain a comprehensive understanding of the practical ramifications of MHSVC.

Specific Characteristics of the Nonsupporter

The nonsupporter did not assume that video consultations could be effective for treating patients with mental health conditions. Specifically, she argued that not meeting in-person would entail the risk of specialists missing nonverbal cues and preclude physical contact, for example, through common gestures, the recognition of which, in her opinion, was essential for health care to be effective:

> *There are so many small things that you can notice, and they would, of course, be missed during the video consultation.* [Nonsupporter]

The nonsupporter advocated firmly that a trusting therapeutic relationship could only be developed in the traditional face-to-face setting and saw no room for new, technology-facilitated service delivery models. Arguing from a problem-oriented perspective, the nonsupporter displayed a fundamental disapproval for video consultations:

> *As I said, I think that it might work for some, but generally it is very different from sitting across from someone. Then, you get information that you do not get over the screen.* [Nonsupporter]

At the health care system level, the nonsupporter considered the MHSVC model to be ineffective in increasing access to specialist mental health care. Specifically, she expected a shift of MHS/personnel resources away from specialist in-person care to virtual care models. From her perspective, there would be less workforce available in specialist mental health care than today:

> *I am going to be very heretical now: If the need was better met, this project would not even have come up, would it?* [Nonsupporter]

At some point, the nonsupporter referred to her self-concept, characterizing herself as being reluctant to support and adopt new health care technologies. She clearly wanted to preserve her reserved stance toward change:

> *I am a rather more reserved type with these things. [...] I personally feel that I would really like to keep myself as I am. And maybe I do not have this readiness for change in me; I am rather reserved.* [Nonsupporter]

Like the supporters, the nonsupporter emphasized that older people would be less familiar with the technology, and therefore, inevitably display a negative attitude toward video consultations:

> *I imagined my mother sitting there at the age of 87. [...] And I cannot imagine that the elderly really feel comfortable in this setting, but rather the younger and middle-aged perhaps.* [Nonsupporter]

Beyond that, the nonsupporter expected that the acceptability of MHSVC in patients would *generally* be rather low. However, she also expected a small proportion of younger patients with mild disorders to be likely to benefit from the model. Overall, the nonsupporter regarded integrated video-based mental health care as ineffective because she expected (1) a rather low acceptability by patients and (2) that MHSVC would be ineffective owing to the lack of nonverbal cues and face-to-face interaction, the latter being essential for mental health care in her consideration.

Integration of Results and Comparison With Rogers' Diffusion of Innovations Theory

We found some evidence supporting the generalized adopter categories in the DOI. Supporters in our sample showed both a general openness toward technology and a great ability to deal with uncertainty related to the relatively new concept of MHSVC. Specifically, supporters tried to develop forward-looking strategies for potential problems (eg, technical failures) potentially impeding working routines in general practice. Such a solution-focused stance is typical of early adopters, as conceptualized in the DOI. Moreover, supporters in our study were less dogmatic and expressed a more favorable attitude toward change compared with the nonsupporter, an

observation that is also in line with the generalized DOI categories of early adopters and nonadopters, respectively. In contrast, the nonsupporter in our sample anticipated several problems (eg, the elderly being less open-minded) but was not concerned with potential solutions. Rather, she explicitly highlighted her preference for preserving the status quo and revealed an attitude based on values tied to the established in-person standard. Although supporters were very interested in the success of the MHSVC model as they expected future benefits for patients and themselves, the nonsupporter's point of reference was the past (what has been done ever since). When exploring links between innovativeness and sociodemographic characteristics, we found no support for the hypothesis of the DOI that early adopters have larger units (absorbing the loss from occasional innovation failures) compared with late adopters. Rather, the nonsupporter in our sample ran a large practice (>1500 patients on average per quarter). However, in line with the DOI, we found no differences in age between the various categories of adopters. We did not explicitly address other characteristics related to innovativeness according to the DOI and could therefore not evaluate evidence for early adopters being opinion leaders, adopting new ideals as a result of information exchange with interpersonal networks or exhibiting greater empathy.

Discussion

Principal Findings

This study found that (1) about one in every 2 GPs assumed that patients would benefit from the MHSVC service model, (2) about one in every 3 GPs intended to adopt such a model, (3) the availability of a designated room was the only significant predictor of intent to adopt in GPs, and (4) supporting GPs also expected to save time in their practice and took a solution-focused perspective on the practical implementation of MHSVC. Furthermore, the GP who did not support the MHSVC model assumed that no effective therapeutic relationship could be established with patients using video consultations. Finally, we found preliminary evidence that the characteristics of supporting and nonsupporting GPs in the context of MHSVC corresponded well with the generalized adopter categories conceptualized in the DOI.

Limitations

Our findings must be interpreted considering some shortcomings. First, concerning the quantitative results, this was a cross-sectional study that did not allow inferring any temporal or even causal associations between attitudes toward video consultations and actual behavior. To illuminate the direction of the observed associations, longitudinal studies (randomized controlled trials or prospective cohort studies) are needed. Second, nonresponse bias undermining the generalizability of the findings is a ubiquitous challenge, particularly in general practice research [47]. Nevertheless, our response rate was somewhat higher than the usual 20% expected in postal questionnaires [48]. Although we were only able to include 2 variables in the nonresponder analysis, we did not find any statistically significant differences between nonresponders and responders. Moreover, the mean age of our sample was comparable with the mean age of GPs in Germany. These findings indicate that the sampling error was rather low and that we obtained a composite profile of the larger population.

With respect to the qualitative findings and given the limited number of 6 individuals, our findings are preliminary. However, recruitment of nonadopters for studies of interventions that do not support is usually particularly challenging. At any rate, the integration of quantitative and qualitative data in our study contributes to the credibility of our findings. As is characteristic of preimplementation studies, none of the participants had practically conducted MHSVC before participating in the focus group. Instead, our study collected pretrial observations focusing on the behavior of intended users and their perspectives. Therefore, some GPs may revise their attitude toward the intervention model after the actual implementation. However, by describing the model in detail accompanied by a video clip, we encouraged the participants to gain a comprehensive understanding of the model. Finally, the classification of adopters is a simplification that inevitably neglects information on individuals. In the true sense, innovativeness is a continuous variable with no sharp cut points. Moreover, recent work has called some generalizations of the DOI into question, elucidating that nonadopters often very consciously refute evidence-based practices that they do not find to be relevant for their everyday psychosocial practice [49]. Nevertheless, generalizations proposed in the DOI are of tremendous heuristic value for understanding human behavior change and tailoring audience segmentation strategies [24,50]. Future studies should investigate larger sample sizes and collect performance data on overt behavioral changes, which may reveal additional characteristics of supporting and nonsupporting GPs in the context of MHSVC.

Comparison With Previous Work

From a macro-level perspective, the frequency of adoption of consequential innovations begins slowly before accelerating through spread in the professional community, following an S-shaped pattern for the cumulative number of adopters over time [24,51,52]. Indeed, considering our response rate and the frequency of respondents who indicated that they would adopt MHSVC, the rate of adoption in our sample amounts to 7.9%, which is similar to previous findings [53]. Notwithstanding, the proportion of GPs intending to adopt MHSVC in their own practice corresponds well with increasing utilization rates of telehealth in primary care and specialist health care services (eg, mental health facilities and community-based federally qualified health centers in the United States) [19,54-56]. At a microlevel, the importance of preimplementation assessments of barriers to change, as anticipated by clinicians, has been emphasized frequently [57]. Specifically, by assessing the current provider environment and characterizing early adopters based on the generalizations of the DOI, our study will facilitate the selection of GPs for feasibility and effectiveness trials evaluating MHSVC as a cornerstone of primary care mental health [58-60]. Following an audience segmentation strategy [50], the early and late majority should be targeted only in the next step. In this regard, the characteristics of GPs exhibiting high innovativeness or a high tendency to adopt MHSVC,

correspond well in our study not only with the generalized type of the DOI [24] but also with the description of early adopting GPs in other areas of primary care mental health [33]: GPs in our study regarded MHSVC as a sound opportunity for addressing common mental health care problems (eg, by increasing treatment initiation and engagement) and expected the MHSVC to fit logistically with the workflows in their practices and, in some instances, even produce some workload relief. This finding is somewhat in contrast to observations from a study on web-based consultations to foster communication between GPs and specialists for seamless care coordination [29]. These consultations, similar to web-based consultations provided by GPs themselves [31], not only proved to be difficult to integrate into existing workflows but also lacked reimbursement strategies. However, in our study, MHSVC was conceptualized to take place between patients and MHS and to focus on the communication between MHS and GPs using written short reports. This format may be more feasible in a busy general practice environment where reimbursement opportunities for collaborative work are still limited and less disruptive digital services are welcomed more readily [32]. In accordance with Rogers' DOI, the early adopters in our study appeared to be somewhat less dogmatic with respect to in-person visits and have a more favorable attitude toward change compared with late adopters [24]. Our finding that GPs not supporting MHSVC in general practice place much value on face-to-face encounters and entertain concerns about loss of nonverbal and social presence cues has been reported previously [61-64]. Indeed, a strong preference for in-person communication is the main reason why clinicians do not use mental health services via videoconferencing [65,66]. In contrast, current evidence demonstrates that patients using clinical videoconferencing visits are comfortable and satisfied with this mode of care delivery [67]. They experience the sessions to be as beneficial as in-person visits [68,69]. Moreover, there is some evidence that clinicians have more concerns about alliance than patients do [70]. Concerning socioeconomic characteristics, early adopters in our study, in contrast to the DOI hypothesis, did not maintain larger units compared with late adopters. As GPs in our study were only questioned on attitudinal change, it seems plausible that early adopters did not account for the potential need to absorb financial losses in case MHSVC could not be implemented successfully. However, prices for videoconferencing systems have decreased significantly in recent years.

Conclusions

GPs' readiness for implementing the anticipated MHSVC delivery model in general practice is considerable, as this model may be suitable for addressing the most pressing needs of both patients and clinicians. Currently, there is a significant proportion of GPs who may function as (1) early adopters with solid buy-in in future feasibility and effectiveness trials and (2) key stakeholders facilitating the spread of MHSVC through information exchange in interpersonal networks. Indeed, we have just completed a feasibility trial (Trial registration: DRKS00015812), which has yielded promising results and initiated a full-scale trial (NCT04316572). Beyond that, future work should focus on educational measures to facilitate the implementation of the model for the large number of GPs who are hesitant to this day (early and late majority). Interventions targeting acceptance and implementation should account for the clinicians' competencies (eg, technology commitment) and information needs (eg, how MHSVC works and how to manage emergencies, benefits, and limitations) to increase their comfort with videoconferencing as a treatment modality [71]. Although the number of patients in need in remote and rural areas may be high [54,72], the demand for MHSVC is dependent on the willingness of GPs caring for those patients to refer them.

Acknowledgments

The authors would like to thank Justus Tönnies, MSc, for rerunning and checking the statistical analysis. This work was supported by the German Federal Ministry of Education and Research (BMBF; grant no. 01GY16129). The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strings for the systematic review.
[DOCX File , 16 KB - mental_v7i10e23660_app1.docx]

Multimedia Appendix 2
Consolidated Criteria for Reporting Qualitative Research checklist.
[DOCX File , 21 KB - mental_v7i10e23660_app2.docx]

Multimedia Appendix 3
Questionnaire for general practitioners.
[DOCX File , 20 KB - mental_v7i10e23660_app3.docx]

Multimedia Appendix 4
Semistructured question guide for focus groups and telephone interviews.
[DOCX File , 16 KB - mental_v7i10e23660_app4.docx]

Multimedia Appendix 5
Description of the coding system.
[DOCX File , 19 KB - mental_v7i10e23660_app5.docx]

Multimedia Appendix 6
Study flowchart.
[DOCX File , 123 KB - mental_v7i10e23660_app6.docx]

Multimedia Appendix 7
Mosaic plots for the nonresponder analysis.
[DOCX File , 182 KB - mental_v7i10e23660_app7.docx]

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Abbreviations

DOI: Diffusion of Innovations Theory
GP: general practitioner
MHS: mental health specialists
MHSVC: mental health specialist video consultations
PROVIDE: ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations

Edited by J Torous; submitted 19.08.20; peer-reviewed by J Li, D McMaughan; comments to author 09.09.20; accepted 11.09.20; published 15.10.20.

Please cite as:
Haun MW, Stephan I, Wensing M, Hartmann M, Hoffmann M, Friederich HC
Intent to Adopt Video-Based Integrated Mental Health Care and the Characteristics of its Supporters: Mixed Methods Study Among General Practitioners Applying Diffusion of Innovations Theory
JMIR Ment Health 2020;7(10):e23660
URL: http://mental.jmir.org/2020/10/e23660/
doi:10.2196/23660
PMID:33055058

Original Paper

Mental Health Practitioners' Immediate Practical Response During the COVID-19 Pandemic: Observational Questionnaire Study

Shannon E Reilly[1], PhD; Katherine L Zane[1], PhD; William T McCuddy[1], PhD; Zachary A Soulliard[1], PhD; David M Scarisbrick[1,2,3], PhD; Liv E Miller[1,2,3], PsyD; James J Mahoney III[1,2,3], PhD

[1]Department of Behavioral Medicine and Psychiatry, West Virginia University, Morgantown, WV, United States

[2]Department of Neuroscience, West Virginia University, Morgantown, WV, United States

[3]Rockefeller Neuroscience Institute, West Virginia University, Morgantown, WV, United States

Corresponding Author:
Shannon E Reilly, PhD
Department of Behavioral Medicine and Psychiatry
West Virginia University
930 Chestnut Ridge Road
Morgantown, WV, 26508
United States
Phone: 1 9737384736
Email: shannon.reilly596@gmail.com

Abstract

Background: The COVID-19 pandemic has been associated with increased psychological distress, signaling the need for increased mental health services in the context of stay-at-home policies.

Objective: This study aims to characterize how mental health practitioners have changed their practices during the pandemic. The authors hypothesize that mental health practitioners would increase tele–mental health services and that certain provider types would be better able to adapt to tele–mental health than others.

Methods: The study surveyed 903 practitioners, primarily psychologists/doctoral-level (Psych/DL) providers, social workers/master's-level (SW/ML) providers, and neuropsychologists employed in academic medical centers or private practices. Differences among providers were examined using Bonferroni-adjusted chi-square tests and one-way Bonferroni-adjusted analyses of covariance.

Results: The majority of the 903 mental health practitioners surveyed rapidly adjusted their practices, predominantly by shifting to tele–mental health appointments (n=729, 80.82%). Whereas 80.44% (n=625) were not using tele–mental health in December 2019, only 22.07% (n=188) were not by late March or early April 2020. Only 2.11% (n=19) reported no COVID-19–related practice adjustments. Two-thirds (596/888, 67.10%) reported providing additional therapeutic services specifically to treat COVID-19–related concerns. Neuropsychologists were less likely and Psych/DL providers and SW/ML providers were more likely than expected to transition to tele–mental health (P<.001). Trainees saw fewer patients (P=.01) and worked remotely more than licensed practitioners (P=.03). Despite lower rates of information technology service access (P<.001), private practice providers reported less difficulty implementing tele–mental health than providers in other settings (P<.001). Overall, the majority (530/889, 59.62%) were interested in continuing to provide tele–mental health services in the future.

Conclusions: The vast majority of mental health providers in this study made practice adjustments in response to COVID-19, predominantly by rapidly transitioning to tele–mental health services. Although the majority reported providing additional therapeutic services specifically to treat COVID-19–related concerns, only a small subset endorsed offering such services to medical providers. This has implications for future practical directions, as frontline workers may begin to seek mental health treatment related to the pandemic. Despite differences in tele–mental health uptake based on provider characteristics, the majority were interested in continuing to provide such services in the future. This may help to expand clinical services to those in need via tele–mental health beyond the COVID-19 pandemic.

(JMIR Ment Health 2020;7(9):e21237) doi:10.2196/21237

KEYWORDS

COVID-19; clinical practice; tele–mental health; mental health; survey

Introduction

In December 2019, SARS-CoV-2—more commonly referred to as COVID-19 [1]—was identified in Wuhan, China. The World Health Organization formally declared COVID-19 a global pandemic on March 11, 2020, with approximately 6.8 million cases and over 192,000 virus-related deaths in the United States as of September 23, 2020 [2,3]. Unsurprisingly, there have been calls to understand COVID-19's psychological impact and how providers are responding [4,5].

In a recent large-scale study conducted in China, the majority of respondents endorsed moderate or severe psychological impact (eg, increased depressive symptoms, anxiety, and stress) related to COVID-19 [6]. In the United States, nearly half of respondents in a nationally representative survey endorsed anxiety about contracting COVID-19, and 40% worried about serious illness or death [7]. These findings are consistent with the psychiatric and emotional sequelae of prior pandemics, including severe acute respiratory syndrome in 2002-2003 [8,9], H1N1 influenza in 2009-2010 [10,11], and Ebola in 2013-2016 [12,13]. Evidence from these and other pandemics has indicated that longer quarantine duration is associated with higher levels of psychological distress, including depression, irritability, and posttraumatic stress symptoms [14]. Notably, adverse mental health symptoms long surpassed physical symptoms during prior pandemics [15-17]. Consistent with recommendations from prior pandemics [18,19], guidelines in countries such as China and Singapore have emphasized using tele-based platforms to understand psychological impacts, disseminate accurate health information, and provide counseling services to treat COVID-19–related distress, particularly to at-risk populations such as health care workers [20-22].

Tele–mental health services (eg, via video or phone) have become more common in recent years (2% in a 2007 review [23] to around 20% recently [24,25]), offering a potential avenue for US practitioners to continue providing mental health services remotely during quarantine. Although practitioners largely agree that tele–mental health is promising [26] and effective, there remains apprehension that it is not as effective as in-person services [24,27], despite research indicating comparable effectiveness [28,29] and patient satisfaction [30,31]. Another perceived barrier is the perception of inadequate tele–mental health education and training [23,27,32,33]. Despite concerns, it is likely that more mental health practitioners may turn to tele–mental health to provide clinical services during the COVID-19 pandemic, particularly given expanded reimbursement for such services [34].

It is likely that adoption and implementation of tele–mental health may be easier for some mental health practitioners than others based on characteristics such as provider career stage, services and treatments offered, or provider setting. For example, prior studies have found that trainees and early career psychologists were less confident about implementing tele–mental health than experienced providers [32], that mental health practitioners providing testing and evaluation services used tele–mental health at a lower rate than those providing other services [25], and that providers working in Veterans Affairs (VA) and private practices were more likely to use tele–mental health than those in other settings [25].

As of yet, there is limited information about how US mental health practitioners are adjusting their practices to respond to COVID-19. This study seeks to characterize practitioners' immediate practical response, as well as how practice adjustments may differ across various types of providers and settings. The authors hypothesized that mental health providers overall would increase services provided via tele–mental health and that certain providers would be better able to adapt to tele–mental health services than others. The analyses were exploratory, with the intention that these findings may provide a foundation for future research examining professionals' response to increased psychological needs during pandemics.

Methods

Recruitment

This study was determined to be exempt from research ethics review by the Institutional Review Board affiliated with the coauthors' university. Eligible participants included adults (ie, 18 years or older) fluent in reading English who were currently working in a behavioral or mental health field. Participants were recruited via a Qualtrics survey link disseminated to relevant professional listservs (eg, American Psychological Association, National Academy of Neuropsychology, state psychology boards), departmental listservs, mental health practitioner colleagues, and social media platforms such as Facebook. The recruitment email included a request for participants to forward the email to colleagues if willing (ie, snowball sampling). All questions were optional, and participants were informed that they could discontinue participation at any time. Eligible individuals consented to participate by submitting their responses.

Data Collection

Online survey data were collected from March 30, 2020, to April 10, 2020. In the Qualtrics survey (see Multimedia Appendix 1), participants were asked to provide information about their demographics, patient populations, practice adjustments in response to COVID-19, perceptions of their employer's response, and their emotional response to and perceptions about the COVID-19 pandemic. For some questions, participants were asked about their practices months before the pandemic (ie, December 2019), directly before the pandemic (ie, late February 2020), and "currently" during the pandemic (ie, whenever they completed their survey between late March and early April 2020). Of the 1220 individuals who initiated the survey, the final sample consisted of 903 participants. Data were excluded based on the following criteria: completion of less than 66% of the survey (ie, did not provide information on variables of interest in this study; n=306); younger than 18 years (n=1); not currently working in the behavioral or mental health field (eg, gym owner, retired; n=4); and responding from outside the United States (n=6), given the extremely small number and the aim to examine practices within the specific US sociopolitical context. Compared to those who completed less than 66% of the survey, those in the final sample were on

average younger (t_{1129}=3.53, *P*<.001); more likely to be a neuropsychologist (n=991, χ^2_1=9.98, *P*=.002); and less likely to be unemployed (n=991, χ^2_1=12.42, *P*<.001), a bachelor's-level provider (n=991, χ^2_1=16.46, *P*<.001), support staff (n=991, χ^2_1=14.11, *P*<.001), a different type of provider (n=991, χ^2_1=14.20, *P*<.001), and to be employed at a law firm (n=989, χ^2_1=10.38, *P*=.001).

Data Preparation

Fewer than 5% of data were missing for each variable of interest, with a few exceptions: number of patients seen remotely in December 2019 (126/903, 13.95%) and February 2020 (133/903, 14.73%), number of patients seen currently in person (75/903, 8.31%) and remotely (51/903, 5.65%), and percent of the week spent working remotely (105/903, 11.63%). Missing data were addressed using pairwise deletion. There were 12 respondents who identified as marriage and family therapists that were recoded as therapists or counselors due to the small number (master's-level therapist or counselor: n=10, doctoral-level therapist or counselor: n=2). A medical provider category was created to encompass nonpsychiatrist physicians, psychiatric nurse practitioners or physician assistants, and registered nurses. When there was a discrepancy between respondents' reported highest education level and reported provider type (eg, individuals with a master's degree who self-identified as a psychologist or doctoral-level therapist or counselor, or individuals with a bachelor's degree who self-identified as a master's-level therapist or counselor), provider type was recoded to reflect education level (n=7) so that, for instance, individuals with a master's degree would be described as a master's-level provider and not a doctoral-level provider.

Data Analysis

Analyses were conducted in SPSS Version 26 (IBM Corp) and Stata Version 14.2 (StataCorp). Outcome variables were compared across three sets of predictors: provider level (trainee vs licensed practitioner [LP]), provider type (social worker or master's-level provider vs psychologist or doctoral-level provider vs neuropsychologist), and setting (academic medical center [AMC] vs private practice vs VA vs community mental health [CMH] setting). The trainee category comprised graduate-level practicum students, predoctoral interns, and postdoctoral fellows. Board-certified practitioners were combined with LPs (including resident physicians) because the authors did not have specific hypotheses associated with this distinction. Social workers/master's-level (SW/ML) providers, psychologists/doctoral-level (Psych/DL) providers, and neuropsychologists were compared because these three groups comprised the majority of the sample. The same justification was employed for comparing the four previously mentioned settings.

Chi-square tests with Bonferroni corrections (for 11 comparisons, *P*<.001) were used to compare across groups on binary variables (yes=1), including whether participants worked in a setting with easy access to information technology (IT) staff and services; whether they were *not* implementing tele–mental health in December 2019, late February 2020, and currently; and whether they endorsed making various practice adjustments. Practice adjustments were as follows: not applicable (N/A), no change in practice; cancelling patient appointments; rescheduling or postponing patient appointments; using tele–mental health or virtual appointments instead of in-person appointments; restricting the types of patients scheduled for appointments (eg, by age, medical comorbidities); or other adjustment to practice. Over 5% of the sample specified using precautionary measures (eg, personal protective equipment, social distancing) as an "other" practice adjustment; as such, this was added as a category. Selecting "N/A, no change in practice" was mutually exclusive with other practice adjustments. Otherwise, practice adjustments were not mutually exclusive. Standardized residuals were examined to assess which groups significantly contributed (z>|1.96|) to overall chi-square differences.

One-way analyses of covariance (ANCOVAs) with Bonferroni-corrected post-hoc tests were used to compare continuous variables across groups. Continuous variables included the number of in-person, remote, and total weekly patient visits during late February 2020 and currently (ie, late March or early April 2020); the percent of time per week currently working remotely; difficulty of tele–mental health implementation (1=*easy or not at all difficult* to 5=*very difficult*); the extent to which respondents thought that their institution, employer, or practice offered adequate information and training about providing tele–mental health (1=*strongly disagree* to 5=*strongly agree*); and the likelihood of continuing to provide tele–mental health in the future (1=*very unlikely* to 5=*very likely*). Percent of time working remotely was only calculated for those who reported >0% (n=785). Respondent age was included in ANCOVA analyses as a covariate because it was significantly correlated with all continuous outcome variables except for percent of time working remotely. For each predictor variable, there were significant differences among groups in the number of patients seen in December 2019. These were considered baseline differences, so the relevant number of December 2019 patients (total, in-person, or remote) was included as a covariate when outcomes involved the number of patients seen weekly in late February 2020 or currently. As such, group differences in these analyses can be understood as differences related to COVID-19. Square root transformations were conducted on continuous variables to address concerns with normality and homogeneity of variance, as well as to reduce outliers. *F* statistics and *P* values were derived using analyses with square root transformed variables. The original, untransformed data were reported descriptively (ie, estimated marginal means [EMMs], SEs) for ease of interpretation. EMMs represent means adjusted for covariates included in the models; as such, EMMs may differ from raw means.

Results

Overall Sample

The 903 participants were recruited from listservs (n=362, 40.13%), personal emails (n=291, 32.26%), social media (n=239, 26.50%), or a combination thereof (n=10, 1.11%). The majority of the sample identified as heterosexual, White, non-Hispanic,

and/or cisgender women (see Table 1). Respondents were predominantly LPs, with a smaller subset of trainees (see Table 2). Of nontrainees, most were SW/ML providers, Psych/DL providers, or neuropsychologists.

Table 1. Demographic characteristics of the full sample (N=903).[a]

Characteristic	Participants
Age (years), mean (SD)	39.50 (11.50)
Gender, n (%)	
Man	149 (16.50)
Woman	749 (82.95)
Transgender man	2 (0.22)
Genderqueer/nonconforming	3 (0.33)
Race, n (%)	
American Indian/Alaska Native	1 (0.11)
Asian/Asian American	29 (3.22)
Black/African American	29 (3.22)
Hispanic/Latinx	33 (3.67)
White	781 (86.78)
Multiracial	25 (2.78)
Different racial identity (ie, Arab, Jewish, Mestiza)	2 (0.22)
Sexual orientation, n (%)	
Bisexual	57 (6.34)
Gay	24 (2.67)
Heterosexual	762 (84.39)
Lesbian	23 (2.56)
Queer	20 (2.22)
Different sexual orientation (ie, asexual, fluid, pansexual, questioning)	13 (1.44)
Region, n (%)	
Midwest	175 (19.44)
Northeast	129 (14.33)
South	425 (47.22)
West	171 (19.00)
Work status, n (%)	
Full-time	671 (74.31)
Part-time	71 (7.86)
Trainee	155 (17.17)
Not currently employed (N/A[b])	1 (0.11)
Other (ie, as needed, independent contractor, self-employed)	5 (0.55)

[a]The number of respondents who did not provide information about demographic characteristics were as follows: gender (n=1), race (n=3), sexual orientation (n=4), and region (n=3).

[b]N/A: not applicable.

Table 2. Professional characteristics of the full sample (N=903).[a]

Characteristic	Participants, n (%)
Provider type	
Bachelor's-level therapist/counselor	10 (1.11)
Social worker/master's-level therapist/counselor	153 (16.94)
Psychologist/doctoral-level therapist/counselor	367 (40.64)
Neuropsychologist	144 (15.95)
Trainee (ie, graduate-level practicum student, predoctoral intern, postdoctoral fellow)	155 (17.17)
Psychiatrist	23 (2.55)
Other medical provider (eg, other physician, psychiatric nurse practitioner/physician assistant)	12 (1.33)
Support staff (eg, case manager, medical assistant, psychometrist)	34 (3.77)
Other (eg, mental health specialist, peer recovery, research project manager)	5 (0.55)
Provider level	
Graduate-level practicum student	58 (6.42)
Predoctoral intern	38 (4.25)
Postdoctoral fellow	59 (6.59)
Unlicensed practitioner	38 (4.25)
Licensed practitioner	551 (61.56)
Licensed practitioner and board-certified in specialty area	117 (13.07)
Not applicable (eg, support staff)	34 (3.80)
Current practice setting	
Private practice	196 (21.73)
Academic medical center	172 (19.07)
Veterans hospital or military hospital/clinic (VA[b])	90 (9.97)
Community mental health setting	70 (7.76)
Psychiatric hospital or facility	50 (5.54)
General hospital	46 (5.10)
Rehabilitation hospital or setting	35 (3.88)
University counseling center	23 (2.55)
Department/graduate training clinic	20 (2.22)
Outpatient clinic	15 (1.66)
School	9 (1.00)
Primary care	7 (0.78)
Prison	5 (0.55)
Other (eg, cancer center, employee assistance program, nonprofit organization, intensive outpatient/partial hospitalization program)	16 (1.77)
Multiple practice settings	148 (16.41)
Age specialty	
Pediatric only (ie, younger than 18 years)	85 (9.42)
Adults only (ie, 18 years and older)	472 (52.33)
Lifespan (ie, pediatrics and adults)	345 (38.25)

[a]The number of respondents who did not provide information about professional characteristics were as follows: provider level (n=8), practice setting (n=1), and age specialty (n=1).

[b]VA: Veterans Affairs.

The majority of the sample reported at least one practice adjustment (see Table 3), most commonly using tele–mental health rather than in-person appointments. Of the 903 respondents, only 2.11% (n=19) reported not changing their practice. Respondents saw similar numbers of patients weekly in December 2019 (mean 18.00, SD 13.25) and February 2020 (mean 17.68, SD 13.26), then saw fewer patients weekly in late March or early April 2020 (mean 14.39, SD 14.41) compared to the two prior time points (t_{876}=10.41, P<.001 and t_{876}=10.30, P<.001, respectively). In December 2019 (t_{775}=36.99, P<.001) and February 2020 (t_{763}=32.31, P<.001), respondents saw more patients in-person (December: mean 17.05, SD 12.00; February: mean 16.38, SD 12.02) than remotely (December: mean 1.11, SD 4.66; February: mean 1.62, SD 5.51). In contrast, the opposite was true currently (in-person: mean 4.92 SD 9.01; remote: mean 10.09, SD 10.75; t_{799}=11.86, P<.001). More respondents reported using tele–mental health currently than in December 2019 or February 2020. Respondents working remotely did so for 79.05% of the week, on average. The majority reported working in a setting with easy access to IT staff and services. Over half (474/859, 55.18%) *somewhat* or *strongly agreed* that their employer offered adequate tele–mental health information and training. Almost half (329/684, 48.10%) of those implementing tele–mental health rated it as *somewhat* or *very difficult*. Over half (530/889, 59.62%) were *somewhat* or *very likely* to continue providing tele–mental health services in the future.

Of the 888 respondents, approximately two-thirds (n=596, 67.10%) reported providing additional therapeutic services specifically to treat COVID-19–related concerns (results not shown but available upon request). The most common additional services included providing individual therapy to support new and current patients (n=420, 47.30%), resources (eg, pamphlets; n=256, 28.83%), crisis care (n=158, 17.79%), and nonclinical support groups (eg, social media page; n=157, 17.68%). Smaller percentages reported providing individual (n=127, 14.30%), family (n=13, 1.46%), or group (n=59, 6.64%) therapy specifically to medical providers to support them during COVID-19.

Table 3. Descriptive statistics of practice adjustments, patients seen, and tele–mental health factors during COVID-19 for the full sample (N=903).

Variables	Participants
Practice adjustments, n (%)	
Tele–mental health/virtual appts[a] (vs in-person)	729 (80.82)
Rescheduling/postponing appts	435 (48.23)
Cancelling appts	240 (26.61)
Restrictions on appts (eg, by patient age, medical comorbidity, recent travel)	155 (17.18)
Precautionary measures (eg, personal protective equipment, social distancing)	53 (5.88)
Other adjustment (eg, expanding therapeutic services, education/training-related restrictions)	38 (4.21)
N/A[b] (no change in practice)	19 (2.11)
Patients seen weekly (Dec 2019)	
In-person	
Mean (SD)	17.05 (12.00)
Range	0-50
Remote/tele–mental health	
Mean (SD)	1.11 (4.66)
Range	0-50
Total	
Mean (SD)	18.00 (13.25)
Range	0-100
Patients seen weekly (Feb 2020)	
In-person	
Mean (SD)	16.38 (12.02)
Range	0-50
Remote/tele–mental health	
Mean (SD)	1.62 (5.51)
Range	0-50
Total	
Mean (SD)	17.68 (13.26)
Range	0-100
Patients seen weekly (current)	
In-person	
Mean (SD)	4.92 (9.01)
Range	0-50
Remote/tele–mental health	
Mean (SD)	10.09 (10.75)
Range	0-50
Total	
Mean (SD)	14.39 (14.41)
Range	0-85
Percent of week working remotely	
Mean (SD)	79.05 (32.01)
Range	1-100

Variables	Participants
Tele–mental health	
Reported not implementing tele–mental health in Dec 2019[c], n (%)	625 (80.44)
Reported not implementing tele–mental health in late Feb 2020[d], n (%)	580 (75.32)
Reported not implementing tele–mental health currently, n (%)	188 (22.07)
Reported easy access to IT[e] services, n (%)	657 (72.84)
Perceived adequacy of tele–mental health training[f]	
Mean (SD)	3.46 (1.32)
Range	1-5
Difficulty with tele–mental health implementation[g]	
Mean (SD)	3.07 (1.20)
Range	1-5
Likelihood of continuing to provide tele–mental health services[h]	
Mean (SD)	3.57 (1.36)
Range	1-5

[a]appt: appointment.

[b]N/A: not applicable.

[c]The valid percent is presented in the table; including missingness (14.0%), the raw value was 69.21%.

[d]The valid percent is presented in the table; including missingness (14.7%), the raw value was 64.23%.

[e]IT: information technology.

[f]Five-point Likert scale (1=*strongly disagree* to 5=*strongly agree*).

[g]Five-point Likert scale (1=*easy* or *not at all difficult* to 5=*very difficult*).

[h]Five-point Likert scale (1=*very unlikely* to 5=*very likely*).

Differences by Provider Level

Trainees (55/155, 35.48%) were more likely to cancel appointments than LPs (161/668, 24.14%; n=822, χ^2_1=8.36, *P*=.004). Trainees saw fewer patients weekly than LPs in February 2020 (trainee: EMM=10.22, LP: EMM=19.49; $F_{1,805}$=3.92, *P*=.048, η_p^2=0.005) and currently (trainee: EMM=13.38, LP: EMM=14.73; $F_{1,797}$=6.41, *P*=.01, η_p^2=0.008; Table 4).

Table 4. Results of chi-squares for practice adjustments and analyses of covariance for patients seen and tele–mental health factors during COVID-19 by provider level.

Variables	Trainee[a] (n=155)	Licensed practitioner (n=668)	*P* value
Practice adjustments, n (%)			
Tele–mental health/virtual appts[b] (vs in-person)	127 (81.94)	546 (81.86)	.98[c]
Rescheduling/postponing appts	77 (49.68)	320 (47.98)	.70[c]
Cancelling appts	55 (35.48)	161 (24.14)	.004[c]
Restrictions on appts (eg, by patient age, medical comorbidity, recent travel)	22 (14.19)	118 (17.69)	.30[c]
Precautionary measures (eg, personal protective equipment, social distancing)	8 (5.16)	40 (6.00)	.69[c]
Other adjustment (eg, expanding therapeutic services, education/training-related restrictions)	6 (3.87)	29 (4.35)	.79[c]
N/A[d] (no change in practice)	3 (1.94)	11 (1.65)	.80[c]
Patients seen weekly (Dec 2019), EMM[e] (SE)			
In-person	11.36 (0.99)	18.49 (0.45)	<.001
Remote/tele–mental health	0.55 (0.41)	1.23 (0.19)	.02
Total	11.85 (1.07)	19.53 (0.49)	<.001
Patients seen weekly (Feb 2020), EMM (SE)			
In-person	15.95 (0.43)	16.62 (0.19)	.04
Remote/tele–mental health	1.49 (0.31)	1.47 (0.14)	.62
Total	17.23 (0.43)	17.87 (0.19)	.048
Patients seen weekly (current), EMM (SE)			
In-person	3.98 (0.75)	5.00 (0.33)	.09
Remote/tele–mental health	6.77 (0.91)	10.87 (0.42)	<.001
Total	13.38 (0.87)	14.73 (0.39)	.01
Percent of week working remotely, EMM (SE)	86.26 (2.87)	77.84 (1.46)	.03
Tele–mental health			
Reported not implementing tele–mental health in Dec 2019, n (%)	129 (94.16)	438 (76.04)	<.001[c]
Reported not implementing tele–mental health in late Feb 2020, n (%)	115 (84.56)	411 (72.23)	.003[c]
Reported not implementing tele–mental health currently, n (%)	40 (27.03)	115 (17.24)	.02[c]
Easy access to IT[f] services, n (%)	123 (79.35)	475 (71.21)	.04[c]
Perceived adequacy of tele–mental health training, EMM (SE)	3.50 (0.12)	3.48 (0.05)	.71
Difficulty with tele–mental health implementation, EMM (SE)	3.28 (0.12)	3.00 (0.05)	.04
Likelihood of continuing to provide tele–mental health services, EMM (SE)	3.47 (0.12)	3.63 (0.05)	.34

[a]Trainee includes graduate-level practicum students, predoctoral interns, and postdoctoral fellows.

[b]appt: appointment.

[c]Based on Bonferroni adjustment for chi-square tests.

[d]N/A: not applicable.

[e]EMM: estimated marginal mean.

[f]IT: information technology.

Trainees (86.26%) reported working remotely for a larger percentage of the week than LPs (77.84%; $F_{1,626}$=5.00, *P*=.03, η_p^2=0.008). In both December 2019 (n=713, χ^2_1=22.31, *P*<.001) and February 2020 (n=705, χ^2_1=8.81, *P*=.003), trainees (December: 129/155, 94.16%; February: 115/155, 84.56%) were more likely than LPs (December: 438/668, 76.04%; February: 411/668, 72.23%) to *not* use tele–mental health. Of those using tele–mental health, trainees (EMM=3.28) reported having more implementation difficulty than LPs (EMM=3.00; $F_{1,641}$=4.13, *P*=.04, η_p^2=0.006).

Differences by Provider Type

Psych/DL providers (321/367, 87.47%) were more likely and neuropsychologists (94/144, 65.73%) were less likely than expected to use tele–mental health or virtual instead of in-person appointments (n=663, χ^2_2=36.43, *P*<.001). SW/ML providers (44/153, 28.76%) were less likely and neuropsychologists (115/144, 80.42%) were more likely than expected to reschedule or postpone appointments (n=663, χ^2_2=85.37, *P*<.001). SW/ML providers (24/153, 15.69%) were less likely and neuropsychologists (62/144, 43.36%) were more likely than expected to cancel appointments (n=663, χ^2_2=36.28, *P*<.001; Table 5).

Table 5. Results of chi-squares for practice adjustments and analyses of covariance for patients seen and tele–mental health factors during COVID-19 by provider type.

Variables	(1) Social workers/master's providers (n=153)	(2) Psychologists/doctoral providers (n=367)	(3) Neuropsychologists (n=144)	*P* value
Practice adjustments, n (%)				
Tele–mental health/virtual appts[a] (vs in-person)	133 (86.93)	321 (87.47)	94 (65.73)	<.001[b]
Rescheduling/postponing appts	44 (28.76)	161 (43.90)	115 (80.42)	<.001[b]
Cancelling appts	24 (15.69)	77 (20.98)	62 (43.36)	<.001[b]
Restrictions on appts (eg, by patient age, medical comorbidity, recent travel)	21 (13.73)	55 (14.91)	37 (25.87)	.006[b]
Precautionary measures (eg, personal protective equipment, social distancing)	14 (9.15)	18 (4.88)	5 (3.42)	.07[b]
Other adjustment (eg, expanding therapeutic services, education/training-related restrictions)	6 (3.92)	17 (4.61)	7 (4.79)	.91[b]
N/A[c] (no change in practice)	2 (1.31)	6 (1.63)	3 (2.05)	.87[b]
Patients seen weekly (Dec 2019), EMM[d] (SE)				
In-person	22.09 (0.86)	19.64 (0.56)	9.89 (0.89)	<.001[e,f]
Remote/tele–mental health	1.25 (0.30)	1.08 (0.18)	0.46 (0.30)	.006[e]
Total	23.12 (0.90)	20.61 (0.58)	10.28 (0.93)	<.001[e,f]
Patients seen weekly (Feb 2020), EMM (SE)				
In-person	17.96 (0.42)	17.70 (0.27)	16.73 (0.46)	.03[f]
Remote/tele–mental health	2.01 (0.34)	1.53 (0.21)	0.75 (0.34)	.03[e]
Total	19.97 (0.44)	18.93 (0.28)	17.34 (0.48)	<.001[e,f]
Patients seen weekly (current), EMM (SE)				
In-person	6.76 (0.72)	4.69 (0.45)	4.83 (0.77)	.04[g]
Remote/tele–mental health	14.71 (0.84)	12.20 (0.52)	3.45 (0.85)	<.001[e,f,g]
Total	18.66 (0.83)	15.81 (0.53)	12.07 (0.91)	<.001[e,f,g]
Percent of week working remotely, EMM (SE)	80.17 (3.06)	80.03 (1.89)	70.84 (3.22)	.06
Tele–mental health				
Reported not implementing tele–mental health in Dec 2019, n (%)	102 (82.26)	231 (70.86)	108 (89.26)	<.001[b]
Reported not implementing tele–mental health in late Feb 2020, n (%)	91 (73.98)	214 (65.64)	103 (88.03)	<.001[b]
Reported not implementing tele–mental health currently, n (%)	14 (9.66)	42 (11.90)	57 (42.54)	<.001[b]
Easy access to IT[h] services, n (%)	102 (66.67)	253 (68.94)	111 (77.62)	.08[b]
Perceived adequacy of tele–mental health training, EMM (SE)	3.35 (0.11)	3.59 (0.07)	3.48 (0.12)	.23
Difficulty with tele–mental health implementation, EMM (SE)	2.99 (0.10)	2.97 (0.07)	3.26 (0.14)	.14
Likelihood of continuing to provide tele–mental health services, EMM (SE)	3.69 (0.11)	3.70 (0.07)	3.43 (0.12)	.16

[a]appt: appointment.

[b]Based on Bonferroni adjustment for chi-square tests.

[c]N/A: not applicable.

[d]EMM: estimated marginal mean.

[e]Significant difference between 2 and 3.

[f]Significant difference between 1 and 3.

[g]Significant difference between 1 and 2.

[h]IT: information technology.

In both February 2020 ($F_{2,648}$=11.20, P<.001, η_p^2=0.033) and currently ($F_{2,644}$=31.15, P<.001, η_p^2=0.088), neuropsychologists (February: EMM=17.34; current: EMM=12.07) saw fewer patients weekly than Psych/DL providers (February: EMM=18.93; current: EMM=15.81), who saw fewer than SW/ML providers (February: EMM=19.97; current: EMM=18.66). In December 2019 (n=571, χ^2_2=19.26, P<.001) and February 2020 (n=566, χ^2_2=21.73, P<.001), Psych/DL providers (December: 231/367, 70.86%; February: 214/367, 65.64%) were less likely and neuropsychologists (December: 108/144, 89.26%; February: 103/144, 88.03%) were more likely than expected to *not* use tele–mental health. Currently, SW/ML providers (14/153, 9.66%) and Psych/DL providers (42/367, 11.90%) were less likely and neuropsychologists (57/144, 42.54%) were more likely than expected to *not* use tele–mental health (n=632, χ^2_2=70.77, P<.001).

Differences by Setting

Providers in AMCs (112/172, 65.12%) were more likely and those in private practice (76/196, 38.78%) were less likely than expected to reschedule or postpone appointments (n=528, χ^2_3=28.05, P<.001). AMC providers (61/172, 35.47%) were more likely and CMH providers (9/70, 12.86%) were less likely than expected to cancel appointments (n=528, χ^2_3=16.40, P=.001; Table 6).

Table 6. Results of chi-squares for practice adjustments and analyses of covariance for patients seen and tele–mental health factors during COVID-19 by setting.

Variables	(1) AMC[a] (n=172)	(2) CMH[b] (n=70)	(3) PP[c] (n=196)	(4) VA[d] (n=90)	*P* value
Practice adjustments, n (%)					
Tele–mental health/virtual appts[e] (vs in-person)	152 (88.37)	63 (90.00)	169 (86.22)	78 (86.67)	.83[f]
Rescheduling/postponing appts	112 (65.12)	29 (41.43)	76 (38.78)	48 (53.33)	<.001[f]
Cancelling appts	61 (35.47)	9 (12.86)	44 (22.45)	20 (22.22)	.001[f]
Restrictions on appts (eg, by patient age, medical comorbidity, recent travel)	35 (20.35)	14 (20.00)	25 (12.76)	11 (12.22)	.13[f]
Precautionary measures (eg, personal protective equipment, social distancing)	4 (2.33)	4 (5.71)	9 (4.59)	3 (3.33)	.55[f]
Other adjustment (eg, expanding therapeutic services, education/training-related restrictions)	6 (3.49)	1 (1.43)	8 (4.08)	6 (6.67)	.39[f]
N/A[g] (no change in practice)	1 (0.58)	1 (1.43)	1 (0.51)	1 (1.11)	.85[f]
Patients seen weekly (Dec 2019), EMM[h] (SE)					
In-person	15.52 (0.88)	23.71 (1.36)	17.33 (0.83)	15.99 (1.21)	<.001[i,j,k]
Remote/tele–mental health	1.14 (0.37)	2.06 (0.60)	0.68 (0.34)	1.69 (0.51)	.02
Total	16.41 (0.98)	25.35 (1.53)	17.96 (0.93)	17.47 (1.36)	<.001[i,j,k]
Patients seen weekly (Feb 2020), EMM (SE)					
In-person	16.13 (0.38)	16.71 (0.60)	17.53 (0.36)	16.70 (0.52)	.45
Remote/tele–mental health	1.42 (0.29)	1.86 (0.47)	1.46 (0.27)	1.60 (0.40)	.31
Total	17.21 (0.42)	19.00 (0.67)	18.77 (0.40)	17.86 (0.58)	.16
Patients seen weekly (current), EMM (SE)					
In-person	4.09 (0.61)	3.23 (0.99)	4.92 (0.57)	3.90 (0.85)	.77
Remote/tele–mental health	8.31 (0.84)	16.10 (1.36)	13.25 (0.78)	10.28 (1.16)	<.001[i,l]
Total	13.03 (0.76)	15.42 (1.20)	17.79 (0.71)	14.19 (1.05)	<.001[i,l]
Percent of week working remotely, EMM (SE)	84.33 (2.56)	75.07 (4.20)	81.60 (2.41)	82.05 (4.33)	.35
Tele–mental health					
Reported not implementing tele–mental health in Dec 2019, n (%)	130 (87.84)	42 (75.00)	125 (70.22)	51 (65.38)	<.001[f]
Reported not implementing tele–mental health in late Feb 2020, n (%)	123 (84.25)	43 (72.88)	115 (66.09)	41 (53.95)	<.001[f]
Reported not implementing tele–mental health currently, n (%)	36 (21.95)	7 (10.14)	21 (10.94)	10 (11.63)	.01[f]
Easy access to IT[m] services, n (%)	160 (93.02)	52 (74.29)	58 (29.59)	73 (81.11)	<.001[f]
Perceived adequacy of tele–mental health training, EMM (SE)	3.59 (0.10)	3.40 (0.16)	3.70 (0.10)	3.90 (0.13)	.11
Difficulty with tele–mental health implementation, EMM (SE)	3.21 (0.10)	3.26 (0.15)	2.60 (0.09)	3.25 (0.13)	<.001[j,l,n]
Likelihood of continuing to provide tele–mental health services, EMM (SE)	3.55 (0.10)	3.66 (0.16)	3.56 (0.10)	3.89 (0.14)	.33

[a]AMC: academic medical center.

[b]CMH: community mental health.

[c]PP: private practice.

[d]VA: Veterans Affairs.

[e]appt: appointment.

[f]Based on Bonferroni adjustment for chi-square tests.

[g]N/A: not applicable.

[h]EMM: estimated marginal mean.

[i]Significant difference between 1 and 2.

[j]Significant difference between 2 and 3.

[k]Significant difference between 2 and 4.

[l]Significant difference between 1 and 3.

[m]IT: information technology.

[n]Significant difference between 3 and 4.

AMC providers (EMM=13.03) were currently seeing fewer patients weekly than providers in CMH settings (EMM=15.42) and private practice (EMM=17.79; $F_{3,511}$=8.63, P<.001, η_p^2=0.048). In December 2019, AMC providers (130/172, 87.84%) were more likely than expected to *not* use tele–mental health (n=460, χ^2_3=19.26, P<.001). In February 2020, AMC providers (123/172, 84.25%) were more likely and VA providers (41/90, 53.95%) were less likely than expected to *not* use tele–mental health (n=455, χ^2_3=25.18, P<.001). Providers in AMCs (160/172, 93.02%) and VAs (73/90, 81.11%) were more likely and those in private practice (58/196, 29.59%) were less likely than expected to have easy access to IT staff and services (n=528, χ^2_3=180.22, P<.001). Of providers using tele–mental health, those in private practice (EMM=2.60) reported less implementation difficulty than providers in all other settings (AMC: EMM=3.21, CMH: EMM=3.26, VA: EMM=3.25; $F_{3,438}$=9.93, P<.001, η_p^2=0.064).

Discussion

Transition to Tele–mental Health and Group Differences

This study highlights how US mental health providers have changed their practices within the rapidly evolving context of COVID-19, during which there have been increased mental health needs [7] as well as large-scale technological availability enabling tele-adaptation of services [35]. The authors hypothesized that mental health providers overall would increase the number of services provided via tele–mental health and that certain providers would be better able to adapt to tele–mental health services than others. Exploratory results were provided to describe how this transition has differed across specific mental health service lines. These findings may inform future mental health practices and policies as the outbreak continues to evolve worldwide.

Overall, the context of COVID-19 has led to widespread change in the mental health field, with all but 2.11% (19/903) of providers in this study making practice adjustments. Unsurprisingly, the most prominent change involved a transition from in-person to remote or virtual appointments. Consistent with prior research [24,25], this study found that tele–mental health was a relatively underused resource prior to this pandemic, even through late February 2020. In line with the hypotheses, results indicated a rapid transition to tele–mental health services during the pandemic, with uptake of tele–mental health by approximately 80% of respondents by late March or early April 2020. The expediency and scope of this transition rate was striking compared to that of tele–mental health initiatives during previous US emergency situations, such as the September 11, 2001, terrorist attacks [36] and Hurricane Katrina in 2005 [37]. This may have resulted from the unique context of stay-at-home policies and the easing of logistical barriers during the pandemic, such as increased tele–mental health reimbursement [34]. In addition, approximately 55% of providers in this study perceived having adequate tele–mental health training, which was substantially higher than in previous reports (ie, 21%-28%) [27,38]. This may reflect an overall movement toward increased tele–mental health training over time or more recent training specifically in response to COVID-19.

In this study, providers' transition to tele–mental health appeared to be more than a stopgap measure limited to the pandemic context. The majority endorsed a desire to continue implementing tele–mental health services in the future, despite more than one-quarter reporting lack of easy access to IT services and nearly half endorsing implementation difficulty. Importantly, respondents overall saw fewer patients weekly in late March or early April 2020 than prior to the pandemic. This suggests that COVID-19–related disruptions have reduced treatment capacity (at least at the beginning of the pandemic) while mental health needs have surged [6].

Consistent with the second hypothesis, transition to tele–mental health services differed by provider type. Specifically, SW/ML providers transitioned to tele–mental health services at a higher rate than both Psych/DL providers and neuropsychologists. This may be explained by varying scopes of practice. Psychologists, and particularly neuropsychologists, are more likely than SW/ML providers to conduct testing and evaluation services, which have been associated with lower tele–mental health uptake [25]. Interestingly, in this study, this differential uptake did not seem to be associated with group differences in IT service access, perceived adequacy of tele–mental health training, or ease of implementation (for those using tele–mental health). Moreover, despite differential uptake, all provider types were equally likely to want to implement tele–mental health in the future. A speculative explanation for these findings may be providers' anticipation of future development of assessments that are more compatible with tele-based platforms.

Exploratory analyses helped to further characterize how COVID-19 may be differentially affecting mental health providers' practices. Prior to the COVID-19 pandemic, trainees were less likely than LPs to implement tele–mental health, but by late March or early April 2020, there were no differences in tele–mental health uptake. This differential speed of transition may be due to implementation of new policies (eg, perhaps LPs were prioritized in executing new technological advances). There were few differences in specific practice adjustments between trainees and LPs, which is logical given that trainees work under the supervision and license of LPs. A difference that did emerge, however, was that trainees appeared to be

"protected" during COVID-19, such that they tended to work remotely more and saw fewer patients, above and beyond baseline differences.

With regard to practice setting, providers in AMCs were more likely than expected to cancel or postpone appointments and to see fewer patients compared to providers in private practice or CMH settings. One possible explanation for this is that mental health providers in AMCs are often part of a larger system with many types of providers, so the temporary decrease in billable services may be more financially tolerable than in private practice or CMH settings. This could have decreased the incentive for AMC providers to transition to tele–mental health services instead of using temporary measures until the pandemic resolved. Notably, however, by late March or early April 2020, AMC providers were facilitating tele–mental health services at the same rate as other providers. VA providers appeared to be relatively early adopters of tele–mental health, with higher than expected tele–mental health implementation in late February 2020; this may relate to the VA's historical focus on telepsychology [25]. Despite lower rates of easy access to IT services, private practice providers had less implementation difficulty than those in all other settings explored in this study. It is possible that the relatively high autonomy and relatively low institutional oversight in private practice allowed for easier adoption of tele–mental health.

Consistent with previous recommendations [18-20], nearly 70% of practitioners in this study endorsed providing additional therapeutic services specifically to treat patients' COVID-19–related concerns; these services most commonly included individual therapy, resource distribution (eg, pamphlets), crisis care, and nonclinical support groups (eg, social media). Of note, only a small subset of practitioners endorsed offering additional mental health services specifically to medical providers. This is concerning given the importance of addressing the psychological impact among at-risk groups such as frontline health care workers [19]. One possibility is that medical providers may not have sought mental health treatment yet, given the recency of the pandemic relative to survey dissemination and data collection. It is probable that the need for mental health services, particularly by health care workers, will increase over time as the physical symptoms of COVID-19 eventually remit and the psychological distress likely remains [15,16].

Implications

Encouragingly, study results indicated that mental health practitioners demonstrated the ability to transition to tele–mental health services rapidly and at relatively high rates. Lower uptake by practitioners who are more likely to provide testing and evaluation services may be mitigated by working with companies to consider tele–mental health services when developing new cognitive or psychological tests and psychometric norms. This likely presented a barrier particularly for neuropsychologists, given that over 40% were not using tele–mental health by late March or early April 2020. Another key barrier to tele–mental health implementation described in previous literature has been a lack of training or education [23,32,33]. Although a higher percentage of respondents endorsed receiving adequate tele–mental health training relative to prior studies [27,38], almost half did not feel this way. This indicates an area for improvement in graduate programs and training experiences preparing individuals for mental health fields.

Given the low percentage of mental health providers offering additional therapeutic services specifically to medical providers, it will be important to make a concerted effort to identify and develop targeted mental health treatments for individuals and groups at increased risk of psychological distress related to COVID-19. This may include frontline health care workers, individuals who became unemployed, those with personal experiences with the virus, and those in geographic hot spots.

More generally, consistent with prior work [27], results from this study indicate widespread interest in continuing tele–mental health services following the COVID-19 pandemic. This could allow for increased accessibility for individuals with historically lower access to medical or mental health services (eg, due to lack of transportation, funds, or health literacy), such as those in rural locations or with low socioeconomic status. Interdisciplinary work among providers, institutions, test development companies, legislators, and insurance companies will be necessary in this endeavor.

Limitations and Future Directions

Despite the valuable information previously noted, this study has limitations that warrant disclosure. The sample consisted predominantly of individuals identifying as White, heterosexual, married, and/or cisgender women. Almost half were from the southern region of the United States, and many were doctoral-level providers. Although the sample reflected demographic characteristics of other large-scale surveys of neuropsychologists [39] and psychologists [40], there are limits to generalizability given that this study's sample represents a small proportion of the approximately 1.6 million US mental health professionals (ie, psychologists, counselors, social workers, and psychiatrists) as of May 2019 [41].

Other limitations included the timing of this study, which occurred relatively early in the pandemic, and the fact that analyses did not account for differential implementation of stay-at-home orders across states. However, data were collected within a relatively short time frame (ie, 12 days from survey distribution to closure of data collection), and neither completion date nor region was consistently correlated with study variables. The survey asked respondents to compare their current workload to that of December 2019, when providers may have seen fewer patients because of the holiday season. However, this would have underestimated differences between patient volumes pre–COVID-19 and during the pandemic. Future research should track COVID-19–related practice adjustments over time, as well as providers' perceptions of their effectiveness in hindsight.

Finally, this study focused on mental health providers' practical responses to COVID-19. It will also be important to characterize their emotional responses, given that mental health providers tend to generally have relatively high levels of job-related stress, which can impact their desire and ability to continue providing therapeutic services [42]. Recognizing that providers do not

exist in a vacuum, contextualizing this within how institutions responded to the pandemic would enable a more comprehensive characterization of mental health providers' response during COVID-19.

Overall, in the context of the current pandemic, mental health providers were able to rapidly adjust their practice, predominantly by shifting to tele–mental health services. Despite differences in tele–mental health uptake based on provider characteristics, the majority were interested in continuing to provide such services in the future. This may offer an opportunity to expand therapeutic services to those in need even beyond the COVID-19 pandemic.

Acknowledgments

JJM receives support by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number U54GM104942.

Authors' Contributions

JM contributed as senior author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questions.
[DOCX File , 127 KB - mental_v7i9e21237_app1.docx]

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Abbreviations

AMC: academic medical center
ANCOVA: analysis of covariance
CMH: community mental health
EMM: estimated marginal mean
IT: information technology
LP: licensed practitioner
N/A: not applicable
Psych/DL: psychologists/doctoral-level
SW/ML: social workers/master's-level
VA: Veteran Affairs

Edited by J Torous; submitted 22.06.20; peer-reviewed by J Lipschitz, N Benson; comments to author 03.09.20; revised version received 10.09.20; accepted 10.09.20; published 01.10.20.

Please cite as:
Reilly SE, Zane KL, McCuddy WT, Soulliard ZA, Scarisbrick DM, Miller LE, Mahoney III JJ
Mental Health Practitioners' Immediate Practical Response During the COVID-19 Pandemic: Observational Questionnaire Study
JMIR Ment Health 2020;7(9):e21237
URL: https://mental.jmir.org/2020/10/e21237/
doi:10.2196/21237
PMID:32931440

Viewpoint

Digital Phenotyping to Enhance Substance Use Treatment During the COVID-19 Pandemic

Michael Hsu[1], MD; David K Ahern[2], PhD; Joji Suzuki[3], MD

[1]Department of Psychiatry, Brigham and Women's Hospital, Boston, MA, United States

[2]Digital Behavioral Health and Informatics Research Program, Brigham and Women's Hospital, Boston, MA, United States

[3]Division of Addiction Psychiatry, Brigham and Women's Hospital, Boston, MA, United States

Corresponding Author:
Michael Hsu, MD
Department of Psychiatry
Brigham and Women's Hospital
75 Francis Street
Boston, MA, 02115
United States
Phone: 1 617 732 5000
Email: mhsu7@partners.org

Abstract

Due to the COVID-19 pandemic, many clinical addiction treatment programs have been required to transition to telephonic or virtual visits. Novel solutions are needed to enhance substance use treatment during a time when many patients are disconnected from clinical care and social support. Digital phenotyping, which leverages the unique functionality of smartphone sensors (GPS, social behavior, and typing patterns), can buttress clinical treatment in a remote, scalable fashion. Specifically, digital phenotyping has the potential to improve relapse prediction and intervention, relapse detection, and overdose intervention. Digital phenotyping may enhance relapse prediction through coupling machine learning algorithms with the enormous amount of collected behavioral data. Activity-based analysis in real time can potentially be used to prevent relapse by warning substance users when they approach locational triggers such as bars or liquor stores. Wearable devices detect when a person has relapsed to substances through measuring physiological changes such as electrodermal activity and locomotion. Despite the initial promise of this approach, privacy, security, and barriers to access are important issues to address.

(JMIR Ment Health 2020;7(10):e21814) doi:10.2196/21814

KEYWORDS

digital phenotyping; digital psychiatry; addiction; psychiatry; coronavirus; COVID-19; digital health; treatment; drugs; substance use disorder

Introduction

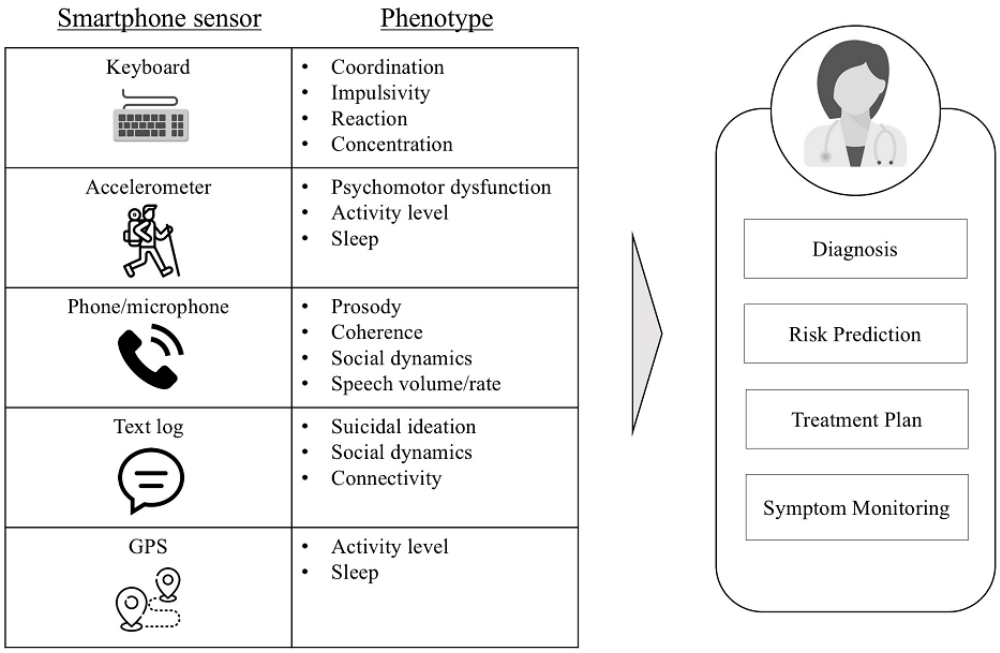
The COVID-19 pandemic has presented unprecedented challenges to the addiction community. First, drug-seeking behaviors can increase exposure to COVID-19. The converse is also true in that pulmonary sequelae from methamphetamine or tetrahydrocannabinol (THC) use may confer higher risk for contracting COVID-19 and may lead to more severe comorbidities for those infected with the virus [1]. Secondly, the COVID-19 pandemic is likely heightening the risk of substance use relapse [2]. Many substance users now live in greater isolation with fewer social supports, diminished access to substance use treatment, and fewer distractions from substance use [3]. Quarantine and social distancing are associated with fear, anxiety, and boredom, which are known risk factors for relapse [4]. Finally, the COVID-19 pandemic has limited our ability to monitor patients' progress and deliver adequate care. In our outpatient addiction center, we have suspended toxicology testing, which was critical in monitoring adherence to treatments such as buprenorphine. Whereas we previously relied heavily on in-person group treatment, most visits are now conducted on the internet and on an individual basis.

To address the clinical gap engendered by the pandemic, we recommended that our patients pursue web- or audio-based Alcoholics Anonymous and Narcotics Anonymous groups, which are largely unvetted substitutes, as well as evidence-supported web-based therapies such as cognitive behavioral therapy [5,6]. The Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug

Enforcement Administration (DEA) have administered policies enabling virtually supported, take-home buprenorphine induction and have created opportunities for patients to access a buprenorphine hotline [7] and virtual bridge clinic (currently implemented at our institution). Whether these efforts can serve as adequate substitutes for in-person addiction treatment remains to be seen; meanwhile, we need additional, scalable strategies to assist in substance use monitoring and treatment in ways that are practical and acceptable.

Digital phenotyping or behavioral sensing [8] uses passively collected, real-time data (eg, GPS tracking, social patterns, typing patterns) from patients' smartphones to inform clinical assessment, predict changes in clinical status, and deliver on-demand interventions in a scalable, cost-effective manner (Figure 1). Smartphone ownership is nearly ubiquitous in the United States, even among individuals with substance use disorders, and possesses a vast array of functionality that can be leveraged for clinical purposes [9,10].

Figure 1. Digital phenotyping implements smartphone sensors to collect passive data that can then inform clinical diagnosis, risk prediction, treatment, and symptom monitoring [11].



Digital phenotyping is an especially attractive clinical tool for substance use treatment during the COVID-19 pandemic, as it not only operates remotely but is also convenient for patients (no active input required), is not administratively burdensome, and may be an effective way to address historic challenges in detecting problematic substance use behaviors and delivering timely clinical interventions. Digital phenotyping has shown initial success in relapse prediction for schizophrenia [12], bipolar disorder [13,14], and mood disorder detection [14]. We describe three broad applications of digital phenotyping for addiction treatment, highlighting their potential clinical use, state of evidence, and next steps for implementation.

Application 1: Relapse Prediction and Intervention

Digital phenotyping has significant potential to enhance relapse prediction. Even before the COVID-19 pandemic, relapse was common, with prevalence rates ranging from 40% to 75% depending on the substance and the definition used in the study [15-17]. Machine learning tools based on survey responses of demographics, alcohol use, and psychological factors have 77% predictive accuracy for alcohol relapse [18]. Activity-based analysis, also known as location-based activity, analyzes how individuals' locational or GPS data correlate with their affect, thoughts, and behavior. Dr David Epstein's group combined passive geographical input with machine learning tools to predict opioid drug craving or stress 90 minutes into the future among patients with opioid use disorder on maintenance buprenorphine or methadone; they achieved a positive predictive value of 0.93 [19]. Another ongoing study by Curtin et al [20] implements digital phenotyping based on machine learning tools and contextualized static and dynamic risk signals to predict lapse in opioid use disorder. Activity-based analysis can theoretically be personalized based on regions of risk that are specific to the individual.

Automated messages can be sent to patients who are flagged as being at high risk of relapse, including warning messages, motivational messages, or recommendations to schedule follow-up appointments. A-CHESS (Addiction-Comprehensive Health Enhancement Support System), a multifeature randomized controlled trial–backed mobile app suite that supports alcohol recovery, delivers an alert to patients when their GPS indicates they are approaching a liquor store or bar [21]. Clinicians can also use this data to triage limited administrative resources by prioritizing follow-up to higher-risk patients.

While digital phenotyping shows initial promise in enhancing relapse prediction, nearly all studies to date have been pilot studies conducted in selected patient populations. Further studies highlighting population-level outcomes such as hospitalization and prediction accuracy, especially when coupled with clinical interventions, are needed. Prior to clinical implementation, patient acceptability and feasibility of use in the clinical setting should be further explored. Other dynamic factors for substance use relapse, such as one's social environment, can be incorporated to fine-tune the predictive power of these interventions [22].

Application 2: Relapse Detection

Digital phenotyping can potentially be used to detect when a patient has relapsed. One pilot study of 30 emergency room patients demonstrated that a biosensor that collects electrodermal activity, locomotion data, and skin temperature was able to detect opioid use and distinguish between heavy and nonheavy opioid users [23]. Another study describes a wearable biosensor that can monitor alcohol consumption through detection of ethyl glucuronide in human sweat, although further population-based studies are needed to establish its acceptability and efficacy [24]. Heart-rate variability (HRV) has also been shown to be linked to alcohol use and smoking; however, specificity is an issue, as HRV is also impacted by affective disorders and trauma [25].

Once the system has detected potential relapse, an automated message can then be relayed to accountability partners (eg, family or friends), front-line staff, or clinicians. Third parties can reach out to patients who have a strong signal of relapse or repeated signals of relapse to confirm and ascertain the nature of the relapse, provide counsel over the phone, set up follow-up appointments, or offer appropriate addiction services. Wearable biosensors could potentially be used as a proxy for urine toxicology screening when monitoring for substance use, especially for patients at high risk for contracting COVID-19. Importantly, clinicians should empower patients to decide how their data will be used and obtain appropriate consent before it can be shared with third parties.

Application 3: Early Overdose Detection

Physical distancing during the COVID-19 pandemic can be life-threatening for individuals who use opioids due to increased overdose deaths from using in isolation, supply chain disruptions, and increased relapse [7,26]. Nandakumar et al [27] developed a potentially lifesaving contactless mobile phone app to detect opioid overdose by measuring respiratory rate using a short-range active sonar through a mobile phone. Their algorithm was able to detect 19/20 (95%) of simulated overdoses in the operating room. Although this proof-of-concept app is promising, further population-based studies are needed to optimize and demonstrate its efficacy.

In theory, a device could automatically alert emergency medical services (EMS), authorized friends, and clinicians of a potential opioid overdose. Providers should empower patients to decide who is notified of the overdose, as patients may not want EMS or police to be automatically informed. Instead, they may prefer friends, neighbors, providers, or other public health professionals to be alerted first. In this case, third parties can check in with the patient, and if there is no response within a certain time frame and appropriate concern for overdose, they can administer naloxone (if they are trained to do so and are in the vicinity) and consider whether to bring the patient to the emergency room or involve first responders.

Limitations to Digital Phenotyping

There are several notable limitations to digital phenotyping and barriers to implementation that should be addressed. First, security and privacy are critically important concerns. Data stored on a mobile phone or cloud service may be vulnerable to security threats such as password compromise, while data uploaded to an electronic medical record system may be accessed by third parties [11,28]. Although call log, GPS, and accelerometer data are often anonymized by application developers, a theoretical risk remains that third parties can identify individuals based on raw data [29]. Clinicians should thoroughly vet digital phenotyping applications based on the App Evaluation Model developed by the American Psychiatric Association to ensure the safety and privacy of identifiable patient data [30,31]. Providers should protect patient data and counsel patients regarding privacy risks, especially for vulnerable individuals such as those with mental illness or substance use disorders.

Second, further studies are needed to assess the acceptability and feasibility of digital phenotyping among patients with substance use disorders. As is the case with all digital health technologies, the clinical efficacy of an app does not always translate to user adoption. Lowering barriers to entry such as improving user friendliness and addressing technology illiteracy are important.

Third, inequality of access to smartphone technology is problematic, especially among individuals who are of lower socioeconomic status, aged 85 years or older, widowed, Medicaid recipients, Black or Hispanic, and have disabilities [32]. However, many state Medicaid programs now offer free mobile phones to eligible recipients, and federal programs such as the Federal Communications Commission's Lifeline Program offer a subsidy for cellular and data service plans to low-income individuals [33,34]. Lack of broadband access may be a barrier, especially for rural and underserved communities [35]. Further research on these barriers to access is needed to devise apt solutions to equip even the most marginalized and vulnerable populations with digital technology.

Finally, there are salient administrative and financial barriers to clinical implementation. While there may be long-term cost savings in the reduction of health care use and less labor-intensive means of substance use monitoring, introducing any new health technology requires an initial resource investment. Patients and staff need to be trained on the technology and the clinical integration of the data streams generated by digital phenotyping applications. To move beyond resource-rich academic and research settings, clinician time and use of digital phenotyping will need reimbursement by payors,

which requires demonstrating the clinical and financial value of the technology to insurance companies. This supports the call for methodologically rigorous studies to determine how the initially promising experimental outcomes of digital phenotyping translate to real-world clinical value.

Conclusions

Digital phenotyping has tremendous potential to augment substance use treatment, especially during the COVID-19 pandemic. Specifically, this technology can help address significant challenges in improving care for substance use disorders in the areas of relapse prediction and intervention, relapse detection, and overdose detection. Despite the promise and potential of digital phenotyping, many studies thus far have been proof-of-concept or pilot studies in siloed patient populations; more robust, generalizable experiments are needed to demonstrate clinical efficacy, acceptability, and feasibility. Iterative observation and experimentation can allow for further refinement of the underlying technology and how it will be clinically integrated. Concerns of privacy, security, equity, and sustainability need to be addressed.

Acknowledgments

This work was supported by an NIH/NIDA grant (K23DA042326).

Conflicts of Interest

None declared.

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Abbreviations

A-CHESS: Addiction-Comprehensive Health Enhancement Support System
DEA: Drug Enforcement Administration
EMS: emergency medical services
HRV: heart-rate variability
SAMHSA: Substance Abuse and Mental Health Services Administration
THC: tetrahydrocannabinol

Edited by J Torous; submitted 28.06.20; peer-reviewed by S Sanchez, B Johnson; comments to author 25.07.20; revised version received 14.08.20; accepted 25.09.20; published 26.10.20.

Please cite as:
Hsu M, Ahern DK, Suzuki J
Digital Phenotyping to Enhance Substance Use Treatment During the COVID-19 Pandemic
JMIR Ment Health 2020;7(10):e21814
URL: http://mental.jmir.org/2020/10/e21814/
doi:10.2196/21814
PMID:33031044

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org