Contents

Original Papers

Engagement and Clinical Improvement Among Older Adult Primary Care Patients Using a Mobile Intervention for Depression and Anxiety: Case Studies (e16341)
L Orr, Andrea Graham, David Mohr, Carolyn Greene. ......................................................... 4

A Digital Intervention for Adolescent Depression (MoodHwb): Mixed Methods Feasibility Evaluation (e14536)
Rhys Bevan Jones, Anita Thapar, Frances Rice, Becky Mars, Sharifah Agha, Daniel Smith, Sally Merry, Paul Stallard, Ajay Thapar, Ian Jones, Sharon Simpson. ................................................................. 13

Implementation Determinants and Outcomes of a Technology-Enabled Service Targeting Suicide Risk in High Schools: Mixed Methods Study (e16338)
Molly Adrian, Jessica Coifman, Michael Pullmann, Jennifer Blossom, Casey Chandler, Glen Coppersmith, Paul Thompson, Aaron Lyon. .................. 33

Design, Recruitment, and Baseline Characteristics of a Virtual 1-Year Mental Health Study on Behavioral Data and Health Outcomes: Observational Study (e17075)
Shefali Kumar, Jennifer Tran, Ernesto Ramirez, Wei-Nchih Lee, Luca Foschini, Jessie Juusola. ................................................................. 46

Assessment of Population Well-Being With the Mental Health Quotient (MHQ): Development and Usability Study (e17935)
Jennifer Newson, Tara Thiagarajan. .................................................................................... 84

Assessing Digital Risk in Psychiatric Patients: Mixed Methods Study of Psychiatry Trainees’ Experiences, Views, and Understanding (e19008)
Golnar Aref-Adib, Gabriella Landy, Michelle Eskinazi, Andrew Sommerlad, Nicola Morant, Sonia Johnson, Richard Graham, David Osborn, Alexandra Pitman. ................................................................. 122

Design of a Digital Comic Creator (It’s Me) to Facilitate Social Skills Training for Children With Autism Spectrum Disorder: Design Research Approach (e17260)
Gjís Terlouw, Job van ’t Veer, Jelle Prins, Derek Kuipers, Jean-Pierre Priele. ................................................................. 135

An Internet-Based Cognitive Behavioral Program for Adolescents With Anxiety: Pilot Randomized Controlled Trial (e13356)
Kathleen O’Connor, Alexa Bagnell, Patrick McGrath, Lori Wozney, Ashley Radomski, Rhonda Rosychuk, Sarah Curtis, Mona Jabbour, Eleanor Fitzpatrick, David Johnson, Arto Ohinmaa, Anthony Joyce, Amanda Newton. ................................................................. 153

The Effect of Shame on Patients With Social Anxiety Disorder in Internet-Based Cognitive Behavioral Therapy: Randomized Controlled Trial (e15797)
Haoyu Wang, Qingxue Zhao, Wenting Mu, Marcus Rodriguez, Mingyi Qian, Thomas Berger. ................................................................. 171
Effectiveness of an 8-Week Web-Based Mindfulness Virtual Community Intervention for University Students on Symptoms of Stress, Anxiety, and Depression: Randomized Controlled Trial (e18595)
Christo El Morr, Paul Ritvo, Farah Ahmad, Rahim Moineddin, MVC Team. ................................................................. 183

Efficacy of a Smartphone App Intervention for Reducing Caregiver Stress: Randomized Controlled Trial (e17541)
Matthew Fuller-Tyszkiewicz, Ben Richardson, Keriann Little, Samantha Teague, Linda Hartley-Clark, Tanja Capic, Sarah Khor, Robert Cummins, Craig Olsson, Delyse Hutchinson. ......................................................... 199

Remote Care for Caregivers of People With Psychosis: Mixed Methods Pilot Study (e19497)
Kristin Romm, Liv Nilsen, Kristine Gjermundsen, Marit Holter, Anne Fjell, Ingrid Melle, Arne Repål, Fiona Lobban. ......................................................... 217

Blended Digital and Face-to-Face Care for First-Episode Psychosis Treatment in Young People: Qualitative Study (e18990)
Lee Valentine, Carla McEnery, Imogen Bell, Shaunagh O'Sullivan, Ingrid Pryor, John Gleeson, Sarah Bendall, Mario Alvarez-Jimenez. ......................................................... 228

Strategies to Increase Peer Support Specialists' Capacity to Use Digital Technology in the Era of COVID-19: Pre-Post Study (e20429)
Karen Fortuna, Amanda Myers, Danielle Walsh, Robert Walker, George Mois, Jessica Brooks. ......................................................... 248

Viewpoints

Development of an Emotion-Sensitive mHealth Approach for Mood-State Recognition in Bipolar Disorder (e14267)
Henning Daus, Timon Bloecher, Ronny Egeler, Richard De Klerk, Wilhelm Stork, Matthias Backenstrass. ................................. 58

Digital Health Management During and Beyond the COVID-19 Pandemic: Opportunities, Barriers, and Recommendations (e19246)
Becky Inkster, Ross O’Brien, Emma Selby, Smriti Joshi, Vinod Subramanian, Madhura Kadaba, Knut Schroeder, Suzi Godson, Kerstyn Comley, Sebastian Vollmer, Bilal Mateen. ......................................................... 239

Tutorial

Methodological Challenges in Web-Based Trials: Update and Insights From the Relatives Education and Coping Toolkit Trial (e15878)
Heather Robinson, Duncan Appelbe, Susanna Dodd, Susan Flowers, Sonia Johnson, Steven Jones, Céu Mateus, Barbara Mezes, Elizabeth Murray, Naomi Rainford, Anna Rosala-Hallas, Andrew Walker, Paula Williamson, Fiona Lobban. ......................................................... 68

Review

Toward a Taxonomy for Analyzing the Heart Rate as a Physiological Indicator of Posttraumatic Stress Disorder: Systematic Review and Development of a Framework (e16654)
Mahnoosh Sadeghi, Farzan Sasangohar, Anthony McDonald. ......................................................... 103
Commentary

An Integrated Blueprint for Digital Mental Health Services Amidst COVID-19 (e21718)
Luke Balcombe, Diego De Leo
Engagement and Clinical Improvement Among Older Adult Primary Care Patients Using a Mobile Intervention for Depression and Anxiety: Case Studies

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Abstract

Background: Technology-based mental health interventions are an increasingly attractive option for expanding access to mental health services within the primary care system. Older adults are among the groups that could potentially benefit from the growing ubiquity of technology-based mental health interventions; however, older adults are perceived to be averse to using technology and have reported barriers to use.

Objective: The aim of this paper is to present a case study of 3 participants from a clinical trial evaluating IntelliCare, an evidence-based mobile intervention for depression and anxiety, among adults recruited from primary care clinics. Our report of these 3 participants, who were aged 60 years or older, focuses on their engagement with the IntelliCare service (ie, app use, coach communication) and clinical changes in depression or anxiety symptoms over the intervention period.

Methods: The 3 case study participants were offered IntelliCare with coaching for 8 weeks. The intervention consisted of 5 treatment intervention apps that support a variety of psychological skills, a Hub app that contained psychoeducational content and administered weekly assessments, and coaching for encouragement, accountability, and technical assistance as needed. The 3 case study participants were selected to reflect the overall demographics of participants within the trial and because their interactions with IntelliCare provided a good illustration of varied experiences regarding engagement with the intervention.

Results: The 3 participants’ unique experiences with the intervention are described. Despite potential barriers and experiencing some technical glitches, the participants showed proficient ability to use the apps, high levels of participation through frequent app use and coach interaction, and decreased depression and anxiety scores. At the end of the 8-week intervention, each of these 3 participants expressed great enthusiasm for the benefit of this program through feedback to their coach, and they each identified a number of ways they had seen improvements in themselves.

Conclusions: These 3 cases provide examples of older individuals who engaged with and benefitted from the IntelliCare service. Although the results from these 3 cases may not generalize to others, they provide an important, informed perspective of the experiences that can contribute to our understanding of how older adults use and overcome barriers to mental health technologies. The findings also contribute toward the ultimate goal of ensuring that the IntelliCare intervention is appropriate for individuals of all ages.

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KEYWORDS
mobile health; older adults; depression; anxiety; primary care; smartphone; mobile phone; text messaging
Introduction

Background
There is a pressing need for accessible and effective mental health treatment within the primary care system [1]. Typically, primary care is the first and often only point of contact for those with mental health conditions, particularly anxiety and depression, as opposed to specialty mental health professionals and clinics [2]. However, access to adequate mental health treatment remains limited. Scarce provider resources and varied geographic, economic, and health factors hinder patients’ ability to access treatment [3]. Those who do receive behavioral health treatment through primary care face barriers to adequate services [4]. As a result, technology-based mental health interventions are an increasingly attractive option.

Older adults are among the groups that could potentially benefit from the growing ubiquity of technology-based mental health interventions. Unfortunately, popular culture and conventional beliefs suggest that technology-based interventions are targeted toward younger people, with the perception that older people are averse to using technology [5,6]. Indeed, it has been shown that older adults are less likely to use internet-enabled technologies and smartphones compared with the national average. [7]. Furthermore, older adults have expressed apprehension regarding technology use [8]. Although telehealth and web-based interventions have demonstrated efficacy for addressing depression among older adults [9,10], important barriers remain to engaging older adults in technology-based interventions. Older adults report a variety of reasons for which they avoid using technology for mental health, including a desire for human contact [11]. Another study found that technology utilization among older adults is hindered by cost, complexity, ergonomic impediments, and a lack of interest [12]. Furthermore, design challenges, trust of the technology, familiarity, willingness to ask for help, and privacy have also been identified as barriers to the acceptance and use of health information technology by older adults [13].

Objectives
We conducted a clinical trial evaluating IntelliCare, an evidence-based mobile intervention for depression and anxiety, among adults recruited from primary care clinics at the University of Arkansas for Medical Sciences (UAMS) [14,15]. IntelliCare has been publicly available since 2014 and has shown favorable results in 2 previous trials, with past users demonstrating high engagement (>90% continued use through 8 weeks of treatment in coached deployments) and substantial improvements in depression symptoms from pre- to postintervention [16,17].

During the enrollment process for the clinical trial, we observed that 13.7% (n=20/146) of those enrolled in the study were aged 60 years or older. Therefore, we sought to understand how these older participants would fare with the IntelliCare intervention. Thus, as an initial step in this research, we conducted a case study of 3 enrolled participants aged 60 years and older, focusing specifically on their engagement with the IntelliCare service (ie, app usage, coach communication) and clinical changes in depression and anxiety symptoms over the intervention period.

Our objective was to illuminate these 3 individuals’ aptitude for using the IntelliCare intervention to improve their mental health, toward the ultimate goal of ensuring this intervention is appropriate for individuals of all ages.

Methods

Participants
This is a case study report of 3 participants of the 146 adults enrolled in a randomized controlled trial investigating the efficacy of the IntelliCare intervention among primary care patients with depression and/or anxiety [15]. The UAMS Institutional Review Board approved this study, and all participants provided informed consent.

To be included in the IntelliCare trial, participants presented to UAMS primary care within the past year; had elevated symptoms of depression or anxiety at screening, defined as a score 10 on the Patient Health Questionnaire-8 (PHQ-8), which excluded the item assessing suicidality [18], or a score 8 on the 7-item Generalized Anxiety Disorder scale (GAD-7) [19]; and had a compatible smartphone with an SMS text message and data plan. Participants were excluded if they were experiencing high suicidal risk (ie, had ideation, plan, and intent) on the baseline assessment, were currently receiving psychotherapy, had recent changes in psychotropic medication, had a psychiatric condition not suitable for participation, or had a visual, motor, or hearing impairment that prevented participation in study procedures. Enrolled participants were randomized to receive either the IntelliCare intervention immediately or after an 8-week waitlist period. As part of the research assessments, participants completed the PHQ-9 [20] and GAD-7 at baseline and every 4 weeks for 16 weeks.

For the 3 case studies, we observed 2 white participants and 1 African American participant, two of whom were identified as female and one as male. This subset reflects the overall demographics of participants within this trial, who were identified as 65.1% (n=95/119) white and 32.2% (n=47/146) African American and the majority (n=119/146, 81.5%) of whom were identified as female. All 3 case study participants were aged 60 years or older. We chose these 3 participants because their interactions with IntelliCare provided a good illustration of varied experiences regarding engagement with the intervention and overcoming previously identified barriers. More specifically, the participants who were selected highlighted specific instances of the ability to overcome barriers to technology use for mental and physical health among older adults identified in previous studies [11-13], which were observed through interactions with their coach during which these barriers were discussed. Participants not chosen for this case study spoke less of their experiences using the intervention and therefore provided less insight into their interactions with the technology.

The IntelliCare Intervention
All individuals enrolled in the IntelliCare study were offered the IntelliCare intervention, comprising a suite of mobile apps and live coaching, for 8 weeks. The version of IntelliCare used in this trial included a Hub app and 5 intervention apps, each
of which were designed to be used in brief, frequent interactions to support a variety of psychological skills. Screenshots of the apps are presented in Figure 1.

The Hub app facilitated participants’ engagement by supporting direct download and access to clinical apps, providing a library of information and psychoeducational materials, and administering weekly PHQ-8 surveys. The intervention apps provide basic information about anxiety and depression and employ evidence-based skills for managing symptoms. Each app focuses on a specific skill. The Thought Challenger app focuses on cognitive restructuring and helps users to identify unhelpful thoughts, recognize associated cognitive distortions, and substitute unhelpful thoughts with more realistic thoughts. Daily Feats focuses on goal setting by helping users create a list of daily goals (ie, feats) that they can check off throughout the day; as users complete feats each day, they earn streaks from which they can level up to get a new list of more advanced goals to accomplish. Worry Knot focuses on anxiety exposure. It helps users learn to experience thoughts about the past or future without increasing stress by associating the stressful thought with a neutral thought. My Mantra uses positive self-statements and personal pictures from the users’ phone to remind them of their values and the gratifying parts of their lives. Finally, Day to Day uses weekly positive psychology lessons tied to daily tips (ie, suggestions) to help challenge thinking, cultivate gratitude, activate pleasure, increase connectedness, and solve problems. Participants were encouraged to use the apps regularly, for a few minutes daily, to gain proficiency in learning the skills and practicing relevant strategies in their daily lives.

Figure 1. IntelliCare apps. Top row, left to right: Hub, Thought Challenger, Daily Feats. Bottom row, left to right: Worry Knot, My Mantra, Day to Day.

Coaching

All individuals were assigned a coach. The coaching protocol was defined by the IntelliCare Coaching Manual [21], which is based on the supportive accountability and efficiency models of coaching [22,23]. Coaches were bachelors-level individuals trained to deliver the intervention according to the IntelliCare Coaching Manual and supervised weekly by a licensed clinical psychologist. The coach provided encouragement and accountability for participants to use the apps, helped to problem-solve obstacles, recommended apps that would be most useful, and provided technical assistance as needed. The coach did not deliver psychotherapy but rather served as a guide to help the participant understand the apps and connect the skills to their goals.

Intervention Delivery

Upon entering the active intervention phase, participants received a welcome packet and completed a 30- to 45-min introductory telephone call with their coach. During that call,
the coach explained the format of the program, established an alliance, identified the participant’s unique goals for treatment, and ensured that the Hub app was properly installed on the participant’s phone. The coach also recommended one intervention app to begin using after assessing the participant’s preferences. The participant was encouraged to use the first app for 1 week. Each subsequent week, the coach recommended a new app for the participant to try. Following the initial introductory call, communication was conducted via SMS text messaging. Coaches messaged participants to provide positive reinforcement, encourage exploration of apps, make app recommendations, or problem-solve as issues arise. Participants were free to message the coach at any time and were told that responses would come within one business day (although the response time was often much shorter).

Over the course of the 8 weeks, coaches texted participants weekly, typically initiating 2 contacts per week and responding to participants’ SMS text messages as they came in. Usually, the first SMS text message from the coach at the beginning of each week was used to introduce a new app and provide a brief explanation for how it could be helpful in their daily lives. Afterward, another SMS text message midweek was sent to check in on their interaction with that app. The coach would inquire about any technical issues or barriers to use and ensure that the participant understood how to use the app as intended. At this time, the coach might help the participant brainstorm different areas of their lives to which they could apply the skills, based on the participant’s goals that were discussed during the initial phone call. Sometimes, a technical issue could cause the participant to feel frustrated and discouraged. The coach worked closely with the participant and the technical team to resolve technical issues, whether it was due to user error or a bug in the system. If the participant did not like the app, found it uninteresting, or thought it was a poor fit with their goals, the coach would suggest a different app to try. Participants could use as many apps as they saw fit with their needs and could discontinue using any app that did not fit with their goals. After 4 weeks, an optional midpoint telephone call with the coach was offered to check in on the participant’s progress toward goals and identify any barriers to app use.

Clinical Management Dashboard

Throughout the 8 weeks, the coach monitored a dashboard that displayed the participant’s app usage, a record of the SMS text messages exchanged, and weekly depression scores. The dashboard also provided additional participant management tools. The coach could set scheduling reminders and utilize a notes section to record each participant’s initial goals and comments during the introductory and midpoint phone calls. The coach could also create a ticket to directly alert the technical team of any new issues involving the apps not working properly.

In terms of app usage, the coach could only see how frequently the participant engaged with the apps but could not see the data that were entered into the apps by the participant, except for the PHQ-8 responses. The coach utilized the app usage frequency data to determine if the participant needed encouragement to engage more often with their apps. The coach would also ask participants about their change in mood if the coach observed an increased depression score. This often led to a productive discussion about new goals to work on, life changes, or deeper issues that needed to be addressed by other means—in which case, the coach would talk to the participant about making an appointment with their primary care physician.

Results

Case Study 1

Participant A was a 69-year-old white man who was single, retired, and lived in an assisted living home. He reported that his highest level of education was a master’s degree. His presenting issues included concerns about not being active or social enough, having no friends, low motivation, low energy, and trouble falling asleep. His goals for treatment were to be more involved in “something” (eg, volunteering) and attend activities involving others, improve his self-esteem and impressions of his current life stage and situation, and build confidence to go back to church services.

Over the course of the intervention, Mr A consistently communicated with the coach. He almost always responded to the coach’s SMS text messages and frequently initiated SMS text messages to give the coach updates on his activities. He was also highly consistent in using the apps: he used them once or more per day on 52 out of 56 days. Mr A’s frequent and consistent level of app use is particularly notable given that, at the start of the program, he experienced some glitches with the technology that had to be resolved by the technical team. Specifically, he initially experienced technical issues with Daily Feats, the first app recommended to him. As this app focused on goal setting and achieving daily behavioral goals, it aligned with what he was hoping to accomplish in treatment. In SMS text message exchanges with his coach, he asked questions about how the app worked. The coach carefully explained the structure of the app, and Mr A showed frequent use throughout the first week. However, in week 2, he began to experience trouble with the tracking system in the app, which he proactively reported to the coach. This demonstrates a willingness to ask for help, a previously identified barrier to health technology use by older adults [13]. He described the issue, and the coach expressed regret for inconvenience and created a ticket describing the incident, which was sent to the technical team. The coach monitored updates from the technical team and reassured Mr A that they were working on the issue. Waiting for the glitch to resolve, the coach switched focus to Mr A’s next app, Day to Day, asking about his impression of it and congratulating him for his continued use of both apps. He expressed interest in this new app and noted how the two complement each other: “one is conceptual and the other puts thoughts into action.”

Over the course of the next few weeks, they moved to focus on his next few apps and scheduled a midpoint call. On the call, Mr A explained his continued trouble with the Daily Feats app while also discussing the other apps and his progress toward his goals. At the end of week 5, after the technical team had incorporated app updates, the coach asked him about Daily Feats. To demonstrate that the problems had been resolved, he shared a screenshot that showed his tracked progress of
completed goals. A few days later, he sent an SMS text message saying that he “finally leveled up,” which indicated that he had successfully completed 2 goals each day for at least five days in a row. Taken together, Mr A demonstrated aptitude for engaging with the intervention despite technical issues. Although Mr A initially expressed that these glitches were “disconcerting,” he overcame these obstacles and continued to use the apps on a near daily basis despite the barrier of usability challenges, including confusion about how to use some of the apps [12,13]. In fact, he indicated that Daily Feats was his favorite app, which was also reflected in his usage data as his most frequently used app. This shows his ability to overcome the barriers of lack of interest and familiarity with the technology [12,13].

The translation of skills to his daily life was evident through interactions with his coach. During his midpoint phone call at the end of week 4, he reported positive impressions of the intervention and progress toward his treatment goals. He said that he thought the apps were “great” and that the coaching aspect was a key part of the program. He reported that he was trying to be positive about social situations and liked that the apps helped him maintain positive thoughts. He demonstrated progress toward his treatment goals in that he was making plans to attend a community engagement workshop and was saying “yes” to opportunities to be in social situations. From this call, the coach observed a notable change in his tone of voice, which suggested that he had gained a heightened level of confidence and enthusiasm. In week 6, when reflecting on his progress with treatment in an SMS text message to the coach, he shared that it “feels like I’m on the road to wellville.”

At screening, Mr A had elevated depression and anxiety, with PHQ-8 and GAD-7 scores of 16 and 11, respectively. These scores were in the moderately severe depression and moderate anxiety ranges, respectively. When he began the intervention, his PHQ-9 and GAD-7 scores were 13 and 9, respectively. After completing the intervention, his PHQ-9 depression and GAD-7 anxiety scores were both 6 (ie, mild range). These scores are consistent with Mr A’s engagement with the intervention and his reported progress. Although he indicated that he still had challenges with his goal of becoming more social, his communications with the coach revealed that his overall outlook had become more positive, and he said he was making plans to get more involved.

Case Study 2

Participant B was a 60-year-old African American woman with an associate degree (ie, 2-year college degree), who was married and employed. In the initial coaching call, she reported feeling that she was not doing enough at work or getting things done on time, causing her to feel stressed about falling behind and trying to catch up. She also expressed anxiety about driving in traffic and feelings of sadness that her husband does not spend time to attend a community engagement workshop and was saying “yes” to opportunities to be in social situations. From this call, the coach observed a notable change in his tone of voice, which suggested that he had gained a heightened level of confidence and enthusiasm. In week 6, when reflecting on his progress with treatment in an SMS text message to the coach, he shared that it “feels like I’m on the road to wellville.”

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Through interactions with the coach, Mrs B made clear the many ways that she was making progress. She was able to easily identify the benefits of each app and expressed that the different skills helped her see the fallacies behind her negative thoughts, recognize patterns, redirect her focus, and change negative thoughts into positive ones. During her second week, when the coach asked what she thought of the assigned app for that week (Day to Day), she said that it helped her to notice her negative thoughts and differentiate between the reality of the thoughts and the negative thought patterns that contributed to her symptoms of anxiety and depression:

The day to day makes me think about the negative thoughts and what do they really mean or is my mind trying to make me feel bad about my life and the past.

During week 7, she also shared with the coach that she was able to successfully follow through taking action toward suggestions made by Day to Day, such as talking to a friend.

At screening, Mrs B had elevated anxiety, with a GAD-7 score of 8, indicating mild anxiety. When she began the intervention, her GAD-7 score was 4. After completing the intervention, her GAD-7 anxiety score was 0. Her depression scores also dropped from 9 at screening and 8 at onboarding to 1 following treatment.
During her final week, when reflecting on her progress with treatment, she said:

_The negative thoughts do not occur frequently like when I started the program. There was one issue that has been resolved and I can control the thought and not feel any resentment about the situation. It would trouble me daily and that's much better._

When asked about the most helpful skill that she learned in the intervention, she referred to the _Thought Challenger:_

_The steps of changing negative thoughts to positive ones. I was plagued by negative thoughts for almost a year daily._

Her ability to implement the skills to change maladaptive cognitions is an indication of her successes using the apps and coaching to reach her goals and improve her depression.

**Case Study 3**

Participant C was a 62-year-old white woman who was married and retired. She reported having an associate degree (ie, a 2-year college degree). She began the program wishing that she could work again because she was lonely all day at home. She felt she had no purpose, and her self-worth was low. She also reported experiencing migraines and insomnia, and she described a dysfunctional and chaotic extended family dynamic. Her goals for treatment were to be a more effective and assertive communicator, get better sleep, have less anxiety, take medications less frequently when upset, and improve her self-worth.

She used the apps regularly, with 3 days being the longest gap without app use. Over the course of the program, she demonstrated high engagement with coaching and frequently initiated contact with the coach to report on her progress. In week 2, when the coach asked Mrs C how she was feeling, she described positive changes in her interactions with her daughter and husband, noting that after repeatedly reading the material in her 2 apps, _Day to Day_ and _Daily Feats_, she had begun to think before she spoke. She said she was relearning how to act and react in situations.

The next day, she said she was proud to report that she had used one of the teaching tools to help an acquaintance who had expressed self-blame. Using the process described in the _Day to Day_ app lessons, she helped him to see a negative pattern in his thoughts and better assess the reality of the situation. She said that this exchange made her feel empowered that she could help others. When the coach asked if she had used any of the skills to work on her feelings of loneliness, she reported several examples of initiating social activities and plans for future volunteer activities. This shows how IntelliCare helped to address older adults’ desire for human contact [11] through interactions with the coach to discuss plans and take actions as well as following the suggestions from the apps to be involved in socialization.

Mrs C did an effective job of communicating her app preferences to the coach, which enabled them to identify relevant apps on which to focus. When beginning the week of using the _My Mantra_ app, she let the coach know that she did not like that app because she did not use the camera or photo functions on her phone. Consistent with the coaching protocol, which instructs coaches to help the participant stay engaged with something they find valuable rather than encourage use of an app they do not find appealing, the coach suggested Mrs C focus on a different app by asking which app was her favorite. Mrs C reported that she enjoyed using the _Thought Challenger_ app and decided to focus on that app instead. She then described how _Thought Challenger_ helped her remember that some of the negative things that her husband would say during arguments were not actually true. She was learning not to internalize these comments. In this example, Mrs C overcame the barrier of willingness to ask for help [13] and showed the ability to continue engaging in the intervention.

During the midpoint phone call, Mrs C mentioned the importance of the _Hub_ app lessons, noting that reading them repeatedly helped her to better understand and implement her new skills. Mrs C found the lessons to be so beneficial that she wanted to put a segment of it up on her wall at home. She planned to create a plaque with the words “action before motivation” because she said she had learned that if she waits until she feels like doing something, she would never get anything done. Her strides toward goals were made evident by her reports of being assertive in conversations with her daughters, not engaging in arguments with her husband when he gets “grumbly,” and using nonessential medications less often. These examples of increased insight, behavioral improvement, and heightened enthusiasm were encouraging indications of progress.

At the end of week 6, Mrs C described a situation where she demonstrated an increased ability to disengage from negative feelings. She shared feeling hurt and left out when her sisters did not invite her to vacation with them. She reported that normally, this experience would have bothered her for a long time. However because of what she learned through _Worry Knot_ and _Thought Challenger_, she said the situation was not going to get her down because she had several positive things in her life and she had been accomplishing goals each day. Instead, she said she was able to enjoy the weekend with her husband.

Finally, she shared positive progress in addressing her anxieties using _Worry Knot_. These skills made her feel stronger mentally and more at ease. She said that she no longer had to reach for a medication to calm down and instead used the skills from the app to think about more neutral situations such as brushing her teeth. This showed that she employed the app’s skill of relating to some things to think about more neutral situations as brushing her teeth. This showed that she employed the app’s skill of relating to some things to think about more neutral situations as brushing her teeth. She shared feeling hurt and left out when her sisters did not invite her to vacation with them. She reported that normally, this experience would have bothered her for a long time. However because of what she learned through _Worry Knot_ and _Thought Challenger_, she said the situation was not going to get her down because she had several positive things in her life and she had been accomplishing goals each day. Instead, she said she was able to enjoy the weekend with her husband.

As she began her final week of coaching, she shared that a year prior, she had been on the verge of suicide and said:

_The intervention gives me tools to help myself […] I am happy and sleeping again. I can refer back to the program and find self help […] I can talk to people and make sure they understand how I am feeling. I don’t hide the hurt. This is the best thing that ever could have happened for me. I am a happy person._

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JMIR Ment Health 2020 | vol. 7 | iss. 7 | e16341 | p.9

(page number not for citation purposes)
setting goals everyday. I am a worthy person of friendship and love.

These statements show her substantial growth toward improved self-worth, better sleep, less medication use, and better communication.

Her assessment of her progress matched her symptom scores. At screening, Mrs C had elevated depression and anxiety, with PHQ-8 and GAD-7 scores of 17 and 13, respectively. These scores were in the moderately severe depression and moderate anxiety ranges. When she was onboarded to the intervention, her PHQ-9 and GAD-7 scores were 11 and 8, respectively. After completing the intervention, her PHQ-9 depression and GAD-7 anxiety scores were both 0, which showed that she progressed to full remission.

In the final days of her intervention, Mrs C further discussed her progress with her goals for treatment as well as her plans for the future in SMS text messages to the coach. Having already joined several clubs and found ways to be less lonely, she said she planned to continue using the apps and setting goals. She further noted:

*I feel stronger mentally and realized you can’t live from the past but grow on the knowledge of it. What has happened in life has happened and to keep going forward and not back. […] I don’t focus on the past and do the “what ifs.”*

Mrs C began the program with low opinions about herself and a dim outlook on her life in general. As the intervention progressed, the coach watched as Mrs C changed her perception and applied the skills to her daily life. As made evident through her SMS text message correspondence, Mrs C reached all of her goals and had concrete plans to maintain them after coaching ended.

Discussion

Principal Findings

Previous studies have shown that multiple barriers might lead older adults to avoid using technology to support mental health, including a desire for human contact, complexity, trust in the technology, and design challenges [11-13]. In this study, we presented case studies of 3 individuals over the age of 60 years who fared well with a digital mental health intervention in terms of engagement with the technology and coaching, and progress toward their goals. Despite potential barriers and experiencing some technical glitches, these participants showed proficient ability to use the apps, high levels of participation through frequent app use and coach interaction, and decreased symptom scores through the intervention.

The 3 cases also demonstrated how different users have different ways of learning, and therefore, engage with the apps in unique ways. These individual preferences for different learning and engagement methods were accommodated through the use of a platform that contained multiple apps. For example, Mrs C found that reading the psychoeducational content was most helpful for her, whereas Mr A connected better with the app that gave him short and simple lists of goals that he could complete daily and check off his list. At the end of the 8-week intervention, all 3 participants expressed great enthusiasm for the benefit of this program through feedback to their coach, and they each identified a number of ways they had seen improvements in themselves.

There may be several reasons why these 3 participants performed well with the intervention. The first may be the benefit of having a coach who encouraged participants to use the apps over 8 weeks. Human contact is a feature that older adults have previously indicated that they are seeking to address their mental health [11]. Future development of mobile mental health technology for older adults may benefit from the incorporation of human contact. Remote engagement using SMS text messaging and phone calls can better facilitate person-to-person contact, which cuts out the time and cost of travel, missed work because of appointments, and limited scheduling availability. SMS text messaging within this study was a noninvasive form of contact, which gave the participants the option to respond at their convenience, or not at all. The choice to engage was optional, which may have relieved the pressure to participate immediately and gave the participants the liberty to converse with the coach as their schedule allowed. The cost of managing coaching services is small but may be further mitigated by automating some aspects of the service (eg, SMS text messages that are routinely sent). The costs associated with managing this service may also be offset by avoiding more expensive mental health services.

Second, in this study, participants engaged with the apps over a much longer duration than in prior research on mental health technologies among older adults, which focused on first impression encounters of the technologies over a few hours [11]. As seen with the apps that had glitches, the 3 case study participants were able to take the time to work through the problems and continued using the apps regardless.

Issues with complexity, familiarity, willingness to ask for help, trust in the technology, privacy, and design challenges have also been found to be a hindrance to older adults’ use of technology to manage their health [12,13]. IntelliCare addresses design challenges by implementing simple-to-use apps that take very little time to complete. The participants were repeatedly prompted to ask for help through noninvasive SMS text messages from their coach. The coach was unable to see any information entered into the apps, which provided privacy and may have increased trust with the intervention. Participants were urged to use each app daily to increase familiarity, and the coach provided accountability and encouragement to continue use. Any trouble they encountered could be discussed with the coach.

Limitations

This study is intended to demonstrate the processes of coaching in older adults using a digital mental health service. Given that there are only 3 cases, these findings may not be generalizable to all older adults. For example, these participants each had some amount of college education, which may have contributed to their success with the intervention. We did not collect data regarding their level of previous experience with mobile technology, which may vary considerably in this population.
Conclusions
These 3 cases provide examples of older individuals who engaged with and benefitted from the IntelliCare service. Although results from the 3 cases may not generalize to others, they provide an important, informed perspective of the experiences that can contribute to our understanding of how older adults use and overcome barriers to mental health technologies. These 3 cases offer detailed usability feedback for future intervention and technology design. Although this case study cannot determine whether all older adults can overcome these barriers, perhaps it may encourage and inform continued development of mobile mental health services for older adults. Evaluating intervention use metrics and clinical outcomes among the full subset of older adults in this study represents an important next step.

Acknowledgments
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Conflicts of Interest
DM has accepted honoraria from Apple Inc and has an ownership interest in Actualize Therapy, which has a license from Northwestern University for IntelliCare. AG has received consulting fees from Actualize Therapy. The other authors have no conflicts of interest to declare.

References


Abbreviations

**GAD-7**: 7-item Generalized Anxiety Disorder scale  
**PHQ-8**: Patient Health Questionnaire-8  
**UAMS**: University of Arkansas for Medical Sciences

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A Digital Intervention for Adolescent Depression (MoodHwb): Mixed Methods Feasibility Evaluation

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Abstract

Background: Treatment and prevention guidelines highlight the key role of health information and evidence-based psychosocial interventions for adolescent depression. Digital health technologies and psychoeducational interventions have been recommended to help engage young people and to provide accurate health information, enhance self-management skills, and promote social support. However, few digital psychoeducational interventions for adolescent depression have been robustly developed and evaluated in line with research guidance.

Objective: We aimed to evaluate the feasibility, acceptability, and potential impact of a theory-informed, co-designed digital intervention program, MoodHwb.

Methods: We used a mixed methods (quantitative and qualitative) approach to evaluate the program and the assessment process. Adolescents with or at elevated risk of depression and their parents and carers were recruited from mental health services, school counselors and nurses, and participants from a previous study. They completed a range of questionnaires before and after the program (related to the feasibility and acceptability of the program and evaluation process, and changes in mood, knowledge, attitudes, and behavior), and their Web usage was monitored. A subsample was also interviewed. A focus group was conducted with professionals from health, education, social, and youth services and charities. Interview and focus group transcripts were analyzed using thematic analysis with NVivo 10 (QSR International Pty Ltd).

Results: A total of 44 young people and 31 parents or carers were recruited, of which 36 (82%) young people and 21 (68%) parents or carers completed follow-up questionnaires. In all, 19 young people and 12 parents or carers were interviewed. Overall, 13 professionals from a range of disciplines participated in the focus group. The key themes from the interviews and groups related to the design features, sections and content, and integration and context of the program in the young person’s life. Overall, the participants found the intervention engaging, clear, user-friendly, and comprehensive, and stated that it could be integrated...
into existing services. Young people found the “Self help” section and “Mood monitor” particularly helpful. The findings provided initial support for the intervention program theory, for example, depression literacy improved after using the intervention (difference in mean literacy score: 1.7, 95% CI 0.8 to 2.6; P<.001 for young people; 1.3, 95% CI 0.4 to 2.2; P=.006 for parents and carers).

Conclusions: Findings from this early stage evaluation suggest that MoodHwb and the assessment process were feasible and acceptable, and that the intervention has the potential to be helpful for young people, families and carers as an early intervention program in health, education, social, and youth services and charities. A randomized controlled trial is needed to further evaluate the digital program.

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KEYWORDS
adolescent; depression; internet; education; early medical intervention; feasibility study

Introduction

Prevention and Management of Adolescent Depression
Adolescent depression is common and is associated with social and educational impairments, deliberate self-harm, and suicide. It can also mark the beginning of long-term mental health difficulties [1]. Early treatment and prevention of adolescent depression is therefore a major public health concern [2]. However, many adolescents with depression do not access interventions, and engaging young people in prevention and early intervention programs is challenging [1,3,4].

Guidelines for the prevention and management of depression in young people [5,6] stress the need for good information and evidence-based psychosocial interventions for the young person, family, and carer. There has been growing interest in psychoeducational interventions, which deliver accurate information to individuals, families, and carers about mental health or a specific diagnosis, management and prognosis, and relapse prevention strategies [6-8]. The American Academy of Child and Adolescent Psychiatry (2007) “Practice parameter for the assessment and treatment of children and adolescents with depressive disorders” describes psychoeducation as the “education of family members and the patient about the causes, symptoms, course, and different treatments of depression and the risks associated with these treatments as well as no treatment at all. Education should make the treatment and decision-making process transparent and should enlist parent and patient as collaborators in their own care.” [6] Although the risk factors and possible causes of adolescent depression are complex, a family history of depression, psychosocial stress, and a previous history of depression increase individual risk, and these groups could be targeted for such strategies [9].

Findings from a systematic review concluded that psychoeducational interventions were effective in improving the clinical course, treatment adherence, and psychosocial functioning of adults with depression [10]. However, a systematic review of such interventions for adolescent depression [11] showed that there were few existing programs. This is an important gap in the literature because depression is common in young people, and its presentation and management are different from those of adults [1].

Digital Mental Health
Digital health or electronic health (eHealth) has been identified as a key area of future clinical practice and research in adolescent depression, especially to improve reach and access to therapies at relatively low cost [8,12]. There is evidence to support the use of some digital interventions for adolescent depression, and they have been recommended in treatment and prevention guidelines [5,13-16]. However, to our knowledge, there is no digital psychoeducational intervention that has been co-designed and specifically developed for adolescents with depression, or those at elevated risk, or developed and evaluated in line with key guidance of digital and complex interventions [17-20].

Here, we describe an early stage evaluation of MoodHwb, a digital psychosocial intervention co-designed with, and for young people with, or at elevated risk of depression, and their families and carers [21,22]. The main aim of this analysis was to examine whether the program and assessments were feasible and acceptable. This is a crucial step to support the refinement of the prototype and design of a randomized controlled trial [20]. This work could also help to inform the development and evaluation of other digital technologies in this field.

Methods

The Digital Intervention: MoodHwb
MoodHwb was designed to engage young people (and families and carers) by using developmentally appropriate language, illustrations, animations, and interactive components. It also aims to promote self help, help-seeking where appropriate, and social support. Although it was founded primarily on psychoeducation, it also includes elements of cognitive behavioral therapy, positive psychology, and interpersonal, family systems and behavioral change theories. It is multi-platform and is available as an app, which includes the interactive components and a mobile-friendly version of the main site.

The program was co-designed using a series of interviews and focus groups with potential users: young people (with depressive symptoms or at high risk), parents, carers, and professionals from health, education, social, and youth services and charities. It was also informed by the systematic review noted earlier [11]; person-centered guidelines for developing digital interventions [17-19]; design, educational, and psychological theory; a logic
model; and consultations with a digital media company and clinical/research experts.

The program includes sections on mood and depression, possible reasons for low mood and depression, self-management (including planning, problem solving, and lifestyle approaches), finding help, and other issues commonly experienced alongside depression (eg, anxiety; Figures 1 and 2). There is also a section for families, carers, friends, and professionals, in part to promote social support.

On the welcome screen, there are separate user pathways for the young person (“I’m here for myself”) and for the parent, carer or another person concerned about a young person (“I’m here for someone else;” Figure 1). The user is then asked questions (eg, regarding their mood and anxiety), and the answers (1) are stored in the “My profile” section, and (2) help to signpost the relevant subsections on the subsequent dashboard screen. Along with this “Mood monitor,” there are other interactive elements: a goal setting element (“My goals”) and a section to save links to helpful resources (“Stuff I like;” Figure 3).

MoodHwb is available in English and Welsh (hwb is the Welsh translation for hub, and can also mean a lift or boost—HwbHwyliau is the Welsh name for the program). The program and the design and development process are described further by Bevan Jones et al [21,22].

**Figure 1.** MoodHwb welcome screen (main image/left) and open menu (right).
Study Design

A mixed methods (quantitative and qualitative) approach was taken to assess the feasibility, acceptability, and potential effectiveness of the program. Data were collected from the following: (1) semistructured interviews with young people, parents and carers who used the intervention, (2) a focus group with professionals, (3) Web usage data, and (4) pre intervention and post intervention questionnaires.

Ethical and Health Board Approval

The Dyfed-Powys (Wales, the United Kingdom) and Cardiff University School of Medicine Research Ethics Committees gave a favorable opinion for the research project. Research and development approval was granted by Cwm Taf, Cardiff and Vale, Abertawe Bro Morgannwg, Aneurin Bevan, Hywel Dda, and Powys University Health Boards (UHBs), 6 of the 7 UHBs in Wales. The authors of the questionnaires were contacted where approval was required.

Participants

We planned to approach around 40 young people, as this sample size was considered sufficient to allow assessment of acceptability and feasibility in a relatively broad sample of the target group. Young people were recruited from specialist Child and Adolescent Mental Health Services (CAMHS), primary
Eligibility Criteria

Young people had to be at least 13 years of age, and to have either (1) a current or past history of depression or (2) be at elevated risk of depression due to a family history of recurrent depression in a parent. The parents and carers of these young people were also invited to take part. Participants were not eligible if they were unable to understand the intervention or questions/discussions (eg, because of insufficient understanding of English).

Professionals from health, education, social, and youth services and charities were approached if they worked with young people with mental health difficulties.

Recruitment and Consent

Eligible young people were identified by their CAMHS and primary mental health practitioners and school counselors and nurses, and provided with letters and information sheets. Individuals from the EPAD study (who had consented to being contacted about other research) were sent a letter and information sheet inviting them to participate. Interested young people and their parents or carers sent a completed reply card to the study team, who then telephoned the young person and parent or carer to discuss the project further. Participants were given the choice of meeting the study team to discuss the project and complete the consent forms in person, or to do this via post. Signed consent was obtained from young people above the age of 16 years, and signed parent and guardian consent and child assent from those under 16 years. Professionals from the appropriate services were identified and sent a letter and information sheet, inviting them to participate, with a reply card as above.

Procedures

Consenting participants were provided a link to the program via email, and they created their own passwords. Parents and carers could create separate accounts to their children. Participants were informed that they could use the program as they wished (MoodHwb includes a section and animation to introduce the program to the user). Young people continued to attend sessions with their practitioner or counselor, if they were seeing someone. They were given access for a minimum of 2 months to allow them sufficient time to work through the program. Professionals were provided with a link to the program 2 weeks before their focus group.

Interviews and Focus Group

Semistructured Interviews With Young People, Parents, and Carers

Young people were asked whether they would like to be interviewed alone or with a parent or carer. The parent or carer was also asked whether they would like to be interviewed separately. Interviews were held either at Cardiff University or a location convenient for the participant (eg, home and school) and lasted up to 90 min. All interviews were completed by RBJ. The interviews were informal, and interviewees had access to MoodHwb on a mobile device.

Sampling Frame

Adolescents were selected for interview based on their usage of MoodHwb (ie, frequent or occasional), age, gender, service or charity involvement, and primary language (English, Welsh). The range of characteristics and number of interviews completed ensured a broad spread of viewpoints.

Focus Group With Professionals

The group session was held at Cardiff University and was facilitated by RBJ and a colleague. The session lasted approximately 120 min. The program was projected on a screen during the group session. We aimed for a balance of professionals in terms of services and charities, gender, and primary language (English, Welsh).

The interviews and focus group were all audio recorded digitally and transcribed; participants could also write or draw their thoughts.

Web Usage Data

Individual user interactions with the website were captured from bespoke analytics developed by the digital media company.

Pre Questionnaires and Post Questionnaires

Adolescent participants and their parents or carers were asked to complete questionnaires before and after having access to MoodHwb (after approximately 2 months). As with the consent forms, participants were given the choice of completing the questionnaires in person or via post (with phone or email support if required). Parents and carers completed questions about their child and about themselves.

Measures

The main outcomes of the evaluation related to the feasibility and acceptability of the digital program and of the evaluation process. Secondary outcomes included the potential effect on mood, knowledge, attitudes, and behavior after using the program.

Feasibility and Acceptability of the Program

The feasibility of the program was assessed in part through information on usage. This consisted of (1) Web data, including the number of visits to each section, language used on each visit (English/Welsh), and user pathway (for self or another person); and (2) self-reported questionnaire data, including the frequency of use, sections looked at the most often, language option chosen (English, Welsh, both), average time spent on the site each time, and use with others (eg, parent, carer, friend, professional). Participants were also asked about technical issues they experienced in the interviews and focus group.

The acceptability of the program was assessed in the interviews, focus group, and feedback questionnaire. The interview topic guide covered (1) general views of the program, (2) specific strengths, (3) areas to develop further regarding the design and content of each section, and (4) integration into services and charities. The interviewing was iterative; where new themes...

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JMIR Ment Health 2020 | vol. 7 | iss. 7 | e14536 | p.17

(page number not for citation purposes)
emerged, they were incorporated into the subsequent interviews. The focus group discussion outline evolved from this guide.

**Feasibility and Acceptability of the Evaluation Process**

Assessment of the feasibility of the evaluation process included information related to the recruitment (number and range of participants) and retention of participants, as well as the completeness of data. Participants were also asked about the acceptability of the process in the interviews and via the pre intervention and post intervention questionnaires (eg, regarding their views on the number of questions).

**Potential Impact**

Standardized questionnaires were used to explore changes in depression literacy and stigma, help-seeking behavior, self-efficacy, behavioral activation, depression and anxiety symptoms, and general behavior (see Table 1 for the list of measures [24-32]).

### Table 1. Content of standardized questionnaires (pre intervention and post intervention).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Questionnaire</th>
<th>Rater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>Self-Efficacy Questionnaire for Depression in Adolescents [27]</td>
<td>Child self-report</td>
</tr>
<tr>
<td>Behavioral activation</td>
<td>Behavioral Activation for Depression Scale [28]</td>
<td>Child self-report</td>
</tr>
<tr>
<td>Depression symptoms (child)</td>
<td>Mood and Feelings Questionnaire [29]</td>
<td>Child self-report; parent/carer about child</td>
</tr>
<tr>
<td>General behavior, strengths, and difficulties</td>
<td>Strengths and Difficulties Questionnaire [31]</td>
<td>Child self-report; parent/carer about child</td>
</tr>
<tr>
<td>Depression and anxiety symptoms (parent or carer)</td>
<td>Hospital Anxiety and Depression Scale [32]</td>
<td>Parent/carer self-report</td>
</tr>
</tbody>
</table>

**Data Analysis**

**Qualitative Analysis**

The interview and focus group transcripts were analyzed using a thematic analysis approach [33]. To ensure reliability of coding, all transcripts were coded by RBJ, and 40% of transcripts were double coded independently by SSA. Coding a proportion of interviews (from around 10% of transcripts) is a standard approach to improve coding reliability [34,35], and we agreed this higher proportion in advance as it was likely to increase the rigor of coding. We did not measure concordance in a quantitative way (eg, using kappa statistic), as this is controversial in qualitative research [36]. Agreement on concepts and coding was also sought with other authors (SS, AT, and BM). Initial ideas on the coding framework were discussed among the team; the draft framework was applied to some of the data and refined as coding proceeded. Codes were applied to broad themes, which were then broken down further into subcodes. Transcripts were closely examined to identify the key themes and associated subthemes. Thematic analysis was supported by the computer-assisted NVivo qualitative data analysis software (version 10, QSR International Pty Ltd).

**Quantitative Analysis**

Quantitative data from the questionnaires and Web usage were analyzed and presented descriptively with summary statistics (means, percentages). Paired sample t-tests were used to explore changes in outcome scores between the pre intervention and post intervention questionnaires (the prescores were subtracted from the postscores). Findings from the Shapiro-Wilk test did not show statistical evidence to suggest a deviation from normality for any of the reported outcomes. Mean differences and confidence intervals were presented for these analyses. When generating sum scores for the individual pre questionnaires and post questionnaires, missing values were replaced with the mean value for that individual, provided there was less than 10% of missing data. All analyses were conducted using Stata statistical software (version 14, StataCorp LP).

**Results**

**Participants**

Figure 4 shows the flow of participants in the quantitative evaluation phase. In total, 59 young people expressed an interest in participating in the evaluation phase, and 44 consented to participate (75%). Of those who consented to participate, 36 young people (82%) completed either the post intervention or feedback questionnaire (ie, 2 of the young people completed only one questionnaire). In all, 31 parents or carers provided consent to participate, of whom 21 (68%) completed either the post intervention or feedback questionnaire (ie, all but one of the parents or carers completed both questionnaires).
The characteristics of participating young people are presented in Table 2. The ratio of females to males was approximately 4:1. The majority (29/31, 94%) of the parents and carers who participated were mothers. In all, 45% (14/31) of the parents and carers were receiving treatment for depression, and 72% (21/29) had been treated for depression during their lifetime. Of those who participated in the previous development phase, 17 young people and 6 parents or carers consented to participate in the evaluation (ie, 39% of young people and 19% of parents and carers who consented to participate). The levels of missing data are shown in the footnotes of the tables below, where relevant.
Table 2. Characteristics of young people participating in the study at baseline (N=43).

<table>
<thead>
<tr>
<th>Characteristicsa</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recruitment source, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>School counselor or nurse</td>
<td>8 (19)</td>
</tr>
<tr>
<td>Primary mental health team</td>
<td>6 (14)</td>
</tr>
<tr>
<td>Specialist CAMHSb</td>
<td>10 (23)</td>
</tr>
<tr>
<td>EPADc study</td>
<td>13 (30)</td>
</tr>
<tr>
<td>Volunteer</td>
<td>6 (14)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>16.3 (2.36)</td>
</tr>
<tr>
<td>Median</td>
<td>16</td>
</tr>
<tr>
<td>Range</td>
<td>13-23</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>34 (79)</td>
</tr>
<tr>
<td>Male</td>
<td>9 (21)</td>
</tr>
<tr>
<td><strong>Currently getting help, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>School counselor or nurse</td>
<td>14 (33)</td>
</tr>
<tr>
<td>General practitioner</td>
<td>9 (21)</td>
</tr>
<tr>
<td>Youth worker</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Social worker</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Mental health worker</td>
<td>14 (33)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Baseline depressive symptoms (MFQd), mean (SD)</td>
<td>34.4 (15.46)</td>
</tr>
<tr>
<td>Currently attending sessions for psychological therapy for low mood/depressione, n (%)</td>
<td>21 (62)</td>
</tr>
<tr>
<td>Currently prescribed medication for depressione, n (%)</td>
<td>13 (38)</td>
</tr>
<tr>
<td>Past treatment for depressione, n (%)</td>
<td>9 (22)</td>
</tr>
</tbody>
</table>

aData available for 43 out of 44 participants, as one participant did not complete the pre intervention questionnaire.
bCAMHS: Child and Adolescent Mental Health Services.
cEPAD: Early Prediction of Adolescent Depression.
dMFQ: Mood and Feelings Questionnaire.
eNumber with missing data was 1 for MFQ, 9 for psychological therapy, 9 for medication, and 2 for past treatment.

Descriptive information about interview and focus group participants is provided in Table 3. A total of 19 young people were interviewed; the ratio of females to males was approximately 3:1. Approximately two-thirds of the young people were interviewed along with their parents or carers (11 mothers, 1 father). In all, 9 of those interviewed spoke Welsh fluently. A total of 13 professionals from a range of disciplines participated in the focus group.
Table 3. Characteristics of young people interviewed and professionals in the focus group.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interviews for young people (n=19)</strong></td>
<td></td>
</tr>
<tr>
<td>Recruitment source, n (%)</td>
<td></td>
</tr>
<tr>
<td>Mental health service or school counselor/nurse</td>
<td>13 (68)</td>
</tr>
<tr>
<td>EPAD(^a) group (parent with depression)</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>16.5 (1.78)</td>
</tr>
<tr>
<td>Median</td>
<td>16</td>
</tr>
<tr>
<td>Range</td>
<td>14-19</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>14 (74)</td>
</tr>
<tr>
<td>Male</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>18 (95)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Seen alone, n (%)</td>
<td></td>
</tr>
<tr>
<td>7 (37)</td>
<td></td>
</tr>
<tr>
<td>Seen with parent or carer, n (%)</td>
<td></td>
</tr>
<tr>
<td>12 (63)</td>
<td></td>
</tr>
<tr>
<td>Interview location, n (%)</td>
<td></td>
</tr>
<tr>
<td>Home address</td>
<td>12 (63)</td>
</tr>
<tr>
<td>Cardiff University</td>
<td>6 (32)</td>
</tr>
<tr>
<td>School</td>
<td>1 (5)</td>
</tr>
<tr>
<td><strong>Focus group for professionals (n=13)</strong></td>
<td></td>
</tr>
<tr>
<td>Profession, n (%)</td>
<td></td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Mental health nurse (secondary care)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Primary mental health worker</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Social worker</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Educational psychologist</td>
<td>2 (15)</td>
</tr>
<tr>
<td>School nurse</td>
<td>1 (8)</td>
</tr>
<tr>
<td>School counselor</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Teacher</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Youth worker and community wellbeing officer</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Charity worker (emotional well-being and mental health manager)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (77)</td>
</tr>
<tr>
<td>Male</td>
<td>3 (23)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>13 (100)</td>
</tr>
</tbody>
</table>

\(^a\)EPAD: Early Prediction of Adolescent Depression.
Use of the Program

Web Usage Data

Analytics from the digital company revealed that the most common section accessed by young people, parents and carers was “What are mood and depression?” (27% of total use). The other sections were accessed approximately half as often (range 12%-17%). Overall, 16% of usage was in Welsh and 84% was in English. Most participants used the program for themselves (78% of use) and 22% for another person.

Questionnaire Data

The questionnaire findings on usage are presented in Table 4.

In total, 21% (7/34) of young people used it once or twice a week, 44% (15/34) used it once or twice a month, and 26% (9/34) used it once or twice overall. Parents and carers used it less frequently, with most (11/20, 55%) using it only once or twice. A total of 30% (6/20) of parents and carers used it once or twice a month, and 10% (2/20) used it once or twice a week. Most young people (19/35, 54%), parents and carers (12/20, 60%) used it for half an hour at a time and most young people used it alone (29/33, 88%). Parents and carers were more likely to use it with others (7/19, 37%).

Both groups reported looking the most at the “Self help,” “What are mood and depression?,” and “Possible reasons” sections. Young people also reported they looked at the “Mood monitor,” and parents and carers looked at the “Families, carers, friends, professionals” section.

Interviews and Focus Group

There were some difficulties related to the compatibility of the program with certain devices and operating systems, especially NHS computers. Some experienced difficulties with internet access at home or on mobile devices.
Table 4. Use of program (questionnaire data).

<table>
<thead>
<tr>
<th>Use of program</th>
<th>Young people&lt;sup&gt;a&lt;/sup&gt;(n=35), n (%)</th>
<th>Parents or carers&lt;sup&gt;b&lt;/sup&gt;(n=20), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nearly every day</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3-4 times a week</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Once or twice a week</td>
<td>7 (21)</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Once or twice a month</td>
<td>15 (44)</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Once or twice overall</td>
<td>9 (26)</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Not used</td>
<td>1 (3)</td>
<td>1 (5)</td>
</tr>
<tr>
<td><strong>For how long the program was used each time?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Several hours</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>About an hour</td>
<td>10 (29)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>About half an hour</td>
<td>19 (54)</td>
<td>12 (60)</td>
</tr>
<tr>
<td>Few minutes</td>
<td>7 (20)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Not used</td>
<td>1 (3)</td>
<td>2 (10)</td>
</tr>
<tr>
<td><strong>Sections looked at the most</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My profile</td>
<td>16 (47)</td>
<td>3 (16)</td>
</tr>
<tr>
<td>What are mood and depression?</td>
<td>17 (50)</td>
<td>13 (68)</td>
</tr>
<tr>
<td>Possible reasons</td>
<td>15 (44)</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Self help</td>
<td>23 (68)</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Where to get help</td>
<td>8 (24)</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Other health issues</td>
<td>9 (26)</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Families, carers, friends, professionals</td>
<td>7 (21)</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Mood monitor</td>
<td>22 (65)</td>
<td>4 (21)</td>
</tr>
<tr>
<td>Stuff I like</td>
<td>9 (26)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>My goals</td>
<td>7 (21)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>The app</td>
<td>10 (29)</td>
<td>3 (16)</td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>27 (79)</td>
<td>18 (95)</td>
</tr>
<tr>
<td>Welsh</td>
<td>2 (6)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Both</td>
<td>5 (15)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Use with others</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used with others</td>
<td>4 (12)</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Parent or carer</td>
<td>3 (9)</td>
<td>N/A</td>
</tr>
<tr>
<td>Friend</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Professional</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Young person</td>
<td>N/A&lt;sup&gt;c&lt;/sup&gt;</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Partner</td>
<td>N/A</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Data available for 35 out of 36 young people. The number with missing data was 1 for frequency of use, 1 for sections looked at the most, 1 for language, and 2 for use with others.

<sup>b</sup>Data available for 20 out of 21 parents/carers. The number with missing data was 1 for sections looked at the most, 1 for language, and 1 for use with others.

<sup>c</sup>Participants could select more than one response option.
Views/Acceptability of the Program (Results of Interviews and Focus Group)

The overarching themes in the interviews and later in the focus group were as follows: (1) design features, (2) sections and content, and (3) integration and context. These themes were influenced by the primary issues the research team wished to explore, to help refine the content and design of MoodHwb. The overall feedback from participants is presented later, with verbatim examples listed in Table 5. Specific suggestions on changes to the program are described in Multimedia Appendix 1. Many of those who had participated in the development phase commented that they were pleased to see that suggestions made in the codevelopment group sessions had been adopted in the prototype.

Key Theme 1: Design Features

Overall Design, Navigation, and Ease of Use

In general, all interview and focus group participants made favorable comments about MoodHwb and stated that it seemed helpful for young people, families and carers. Some noted they were surprised by the high quality, and that they had reservations about it previously because it might be “academic,” “dry,” or “overwhelming.” Most found the overall design attractive, and more interesting and appropriate than designs for existing resources (quote 1).

Overall, participants felt that the program was clearly and consistently structured, easily navigated and user-friendly. They noted that the design and layout made it easy to identify what was relevant. Participants found the color coding, progress bar (see Figure 2), and quizzes particularly engaging (quote 2), but suggested that some elements could be better signposted.

Interactive Elements and Personalization

Figure 3 presents screenshots from the interactive elements of the program.

Initial Questions and Mood Monitoring

Nearly all praised the mix of rating scales (and corresponding face icons) and multiple-choice questions at the start of the program (which could also be answered subsequently to monitor mood), particularly for their functionality, ease of use, and “fun” element. Some noted that this was their favorite aspect (quote 3). Several professionals approved the message for the user to seek help, if they indicated they had thoughts of self-harm.

“Stuff I Like”

Some young people had used this to add songs and images, and felt that it helped to personalize the program. However, others had not done so, because they already bookmarked sites they found interesting.

Goal Setting

Most found “My goals” to be helpful and motivating. They liked how it was possible to add the number of activities, and to note when they were completed (quote 4).

A few noted that their use of these interactive elements phased out over time, and that reminders and rewards might increase engagement. They also noted these components could be explained and personalized further.

Dashboard and Profile Section

“My profile” was described as helpful, particularly to group together strengths and difficulties and save links to resources. Professionals noted that this section helped users to reflect on and add perspective to their situation (quote 5).

Illustrations and Animations

Young people, parents and carers described the illustrations and animations as “friendly” and “sophisticated” without being “patronizing.” The characters were designed to appeal to a diverse audience, with abstract minimal features. All young people stated they preferred the illustrative approach to a more photographic one (quote 6).

In summary, participants, in particular young people, gave favorable feedback on the design features, including the overall presentation, structure, and interactive and graphic elements. They also suggested the areas to develop further, including the navigation, personalized components, interactive and audiovisual elements, reminders, and rewards, and “native app.”

Key Theme 2: Sections and Content

Language, Tone, and Amount of Information

On the whole, participants agreed that the language used was accessible, simple, and jargon-free, but “not too dumbed down.” Many approved of the general tone, stating it was “sensitive” and “affirming” (quote 7).

In general, participants were pleased with the content, and found it comprehensive. They liked the flow of information, and how text was broken up (eg, by illustrations), “bite size,” and “short and snappy.”

Professionals praised the “extensive,” “authoritative,” and “reliable” information. There were mixed views regarding the amount of text—some felt there was too much, others that it was appropriate (quote 8).

Personal Stories

All participants made favorable comments about the personal stories, and how they were from a range of perspectives (quote 9). Young people, parents, carers, and a small number of the professionals suggested adding stories from “celebrities,” and including photos, animations, videos, or comic strips.
### Key theme 1: Design features

**Overall design, navigation, and ease of use**

1. “I was really pleasantly surprised with it...It was great and I can definitely see people using it and wanting to use it. I was very impressed with it. Yeah, I wish I could criticise a bit more, but I can’t.” (19-year-old female)

2. “[It’s] accessible to a whole range of people...[They] very quickly understand where they needed to go.” (Mother of a 15-year-old female)

**Interactive elements and personalization**

3. “It was good to be able to see how you’ve been each day...It’s just helpful to track, that’s not something I would usually do.” (19-year-old female)

4. “That was really helpful for myself because I’ve been trying to get out of the house and do more...That was one of my favourite parts...It's quite motivating.” (16-year-old female)

5. “I like the fact that there was space for the young person to add their own contacts, so they then had ownership of it; it’s given them a bit of responsibility.” (Primary mental health worker: female)

**Illustrations and animations**

6. “I think the illustrations...are very good...it’s not a chore to go and look at the website...It’s not that it’s childish, but...it’s less serious, I think it’s easier to use.” (16-year-old female)

### Key theme 2: Sections, content

**Language, tone, and amount of information**

7. “It’s not too complicated, so teenagers can understand it and relate to it...There’s no ridiculously big words and [it’s not too] scientific. It’s a good style of writing to keep teenagers reading.” (17-year-old female)

8. “We’ve got to be careful not to lower it too much because they’ve actually got onto this website because they’re needing information.” (Educational psychologist: female)

**Personal stories**

9. “I do like the personal stories because then you feel like you’re not the only person that’s going through a hard time. You can maybe relate as well.” (16-year-old male)

**Sections**

10. “I’ve used it a lot since being diagnosed and it helps me to understand what depression is and some of the reasons.” (15-year-old female)

11. “It’s not something, especially if you’re in a really low mood, you particularly want to think about...It’s just talking about things that you try and avoid basically.” (16-year-old female)

12. “What’s really good is it’s relevant...it can be due to all sorts of different things so...for a young person coming to realize actually it’s not just about me and now and just one thing.” (Psychiatrist: female)

13. “The sections I went to is perfect, it’s exactly how I imagined it to be, like self help, I particularly like that section.” (16-year-old male)

14. “My only concern with that is you run the risk then of the people who are a bit paranoid is self-diagnosis...and become panic and anxious.” (Mother of a 17-year-old female)

15. “What I really liked about it is that the fact that it’s talking more about the family... It’s recognizing that the children’s mental health difficulties don’t come in isolation.” (Psychiatrist: female)

16. “From a friend’s perspective, it’s quite difficult to start a conversation about depression.” (14-year-old male)

### Key theme 3: Integration and context

**Targeted versus universal**

17. “Whoever looks at it it’s gonna be beneficial. There’s a lot of information on there that even if you haven’t got a mental health problem or maybe you know someone or even if you’re just curious.” (19-year-old female)

**Use with families, carers, and friends**

18. “In mine and my friends’experiences, the hardest people to talk to would be parents, so I like this because it’s a way that you can use the account separately, but learn the same things.” (15-year-old female)

**Integration with services**

19. “It’s there to back it up at home...So between the sessions you’ve got this at home to use...A safety net or when I stop CAMHS sessions then it’s just there when I need it.” (14-year-old female)

20. “A big part of our work is psychoeducation and so it would be great to know that there’s a reliable, moderated place that you can send them, because at the moment we tend to use sites that are adult-based and we’re having to cut and paste.” (Psychiatrist: female)
Sections
Figure 1 shows how the sections are displayed on the welcome screen, and Figure 2 presents screenshots of two of the subsections.

What Are Mood and Depression?
Participants approved of the information on the difference between sadness and depression, how to identify difficulties and associated metaphors (quote 10). Some noted that those with depression might be reluctant to engage with the subject matter (quote 11).

Possible Reasons for Low Mood and Depression
Professionals were particularly pleased with this “exploratory” section (Figure 2; quote 12).

Help Sections
Several stated that the self help section was “motivational” and their favorite section (quote 13), and some asked for more self help approaches in specific situations. Professionals approved of the description of services and professionals (Figure 2), and of signposting to resources.

Other Health Issues
Most noted that the information was important and comprehensive, particularly on anxiety, eating and weight issues, and physical health. However, a few asked for more specific information (eg, on panic), while others were concerned that some users might worry unnecessarily (quote 14).

Families, Carers, Friends, and Professionals
Parents, carers, and professionals praised the “holistic” and “systemic” approach and highlighted the parental mental health subsection (quote 15). Some suggested adding more information on how to talk to a family member or friend (quote 16).

Generally, participants approved of most aspects of the content, including the language, tone, personal stories, and the individual sections of the program. Areas to improve upon related to the specific information and amount of text in general.

Key Theme 3: Integration and Context
Targeted Versus Universal
Most participants (and all professionals) thought that MoodHwb would be engaging and helpful for anyone who was interested in learning more about mood and depression (quote 17). Some of those who had not experienced depressive difficulties (from the EPAD study) did not think the program was as relevant to them, while some of those who had completed CAMHS therapy saw MoodHwb as especially helpful as an early intervention in a range of settings for those who were starting to experience difficulties.

Use With Families, Carers, and Friends
Most young people had separate user accounts to their parents and carers; some suggested adding the option to monitor someone else’s mood and share information. Participants felt that the program could help with communication between young people and their family, carers and friends (quote 18).

Integration With Services
Many felt that MoodHwb could be used in schools, particularly personal, social and health education lessons – and suggested including a “teacher area” within the program. The school-based professionals stated that it could address the “big gap” in resources and training for teachers. However, some young people noted that associating it with schools might make it less appealing.

Some noted that the use of MoodHwb could complement existing services, for example, by allowing young people to reflect on their entries with counselors, General Practitioners, and primary mental health and specialist CAMHS practitioners (quote 19).

All health care professionals felt that the intervention could be used at their workplace—especially at the school and primary care level. Some noted that it could be helpful for those no longer in services, waiting for an appointment or who did not meet the criteria for mental health services. An educational psychologist noted that the digital program would be relevant for children in care, especially as “they’re moving around a lot” (quote 20).

Many professionals highlighted the challenge of keeping the program up to date. One psychiatrist advised that many professionals were not IT-literate and might be reluctant to recommend it.

In summary, most participants felt that all young people, families and carers should have access to MoodHwb, and it would be especially helpful as an early intervention in a range of settings for those who were starting to experience difficulties.

Views and Acceptability of the Program (Results of Feedback Questionnaire)
Overall, young people reported that the program was helpful, especially with finding ways to help themselves (Multimedia Appendix 2). When asked to select all the sections they found particularly helpful, most young people identified “Self help” (26/35, 74%), followed by “Mood monitor” (21/35, 60%), “What are mood and depression?” (19/35, 54%), and “Possible reasons” (19/35, 54%). The sections identified as the least helpful were “Stuff I like” (13/35, 37%), “Families, carers, friends, professionals” (7/35, 20%), and “My goals” (7/35, 20%), although interview feedback about these sections was more favorable. In total, 51% (17/33) downloaded the accompanying app and 14% (5/35) felt this was one of the most useful components.

Findings were similar for parents and carers; they felt that the young person found it helpful overall and selected “Self help” (9/21, 43%) and the “Mood monitor” (8/21, 38%) as the most useful for the young person. Overall parents and carers found the program helpful for themselves (Multimedia Appendix 2). The sections identified as most helpful were “Possible reasons” (13/21, 62%), “What are mood and depression?” (11/21, 52%), “Where to get help” (9/21, 43%), “Families, carers, friends, professionals” (8/21, 38%), and “Self help” (8/21, 38%).
Overall, young people, parents, and carers felt that the amount of information included in each section was adequate (Multimedia Appendix 2). Both groups rated the ease of use and clarity highly, and approved of the design elements, although parents and carers were slightly less positive than young people (Multimedia Appendix 2).

Acceptability of Interviews and Questionnaires
During the interviews, young people stated they were able to discuss the program openly and appreciated that they could choose the location, and whether they were seen with their parents or carers. They found it helpful to be able to navigate through the program as it was discussed.

Data on acceptability of questionnaires were available for 43 young people and 30 parents or carers at baseline, and 34 young people and 19 parents or carers at follow-up. Most felt the number of questions was “about right.” Young people at follow-up were more likely to rate the questionnaires as having a “few too many questions” than at baseline, possibly due to the additional burden of the feedback questions.

Potential Effect of the Program (Comparison of Pre intervention and Post intervention Questionnaires)
Table 6 summarizes the results from the pre intervention and post intervention standardized questionnaires. It is important to note that these findings are considered exploratory given the small sample size and lack of power.

Young People
Levels of depression literacy were higher after using the program (difference in means 1.7, 95% CI 0.8 to 2.6). Although the differences were small, several other scores also improved, particularly regarding self-efficacy and depressive symptoms.

Parents and carers
Parents’ and carers’ own depression literacy improved after using the program (difference in means 1.3, 95% CI 0.4 to 2.2). Parent-rated scores of their children’s mood and behavior were similar or slightly worse after using the intervention. Overall, parent-rated scores of their child’s depression, anxiety, and behavior were lower than children’s self-rated scores.
Table 6. Comparison of pre intervention and post intervention questionnaires.

<table>
<thead>
<tr>
<th>Outcomes (Questionnaires)</th>
<th>Pre intervention, mean (SD)</th>
<th>Post intervention, mean (SD)</th>
<th>Difference in means (95% CI)</th>
<th>t test (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young people&lt;sup&gt;a&lt;/sup&gt; (n=35)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression literacy (ADKQ)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>9.1 (1.95)</td>
<td>10.8 (2.24)</td>
<td>1.7 (0.8 to 2.6)</td>
<td>3.82 (29)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Depression stigma (DSS)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>30.3 (6.39)</td>
<td>29.4 (5.89)</td>
<td>−0.7 (−3.2 to 1.7)</td>
<td>−0.62 (32)</td>
<td>.54</td>
</tr>
<tr>
<td>Self-efficacy (SEQ-DA)&lt;sup&gt;d&lt;/sup&gt;</td>
<td>30.3 (6.67)</td>
<td>32.0 (8.85)</td>
<td>1.7 (−1.0 to 4.5)</td>
<td>1.28 (33)</td>
<td>.21</td>
</tr>
<tr>
<td>Help-seeking (GHSQ)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>69.2 (15.2)</td>
<td>71.8 (14.04)</td>
<td>2.6 (−3.1 to 8.4)</td>
<td>0.95 (28)</td>
<td>.35</td>
</tr>
<tr>
<td>Depression (MFQ)&lt;sup&gt;f&lt;/sup&gt;</td>
<td>36.5 (15.13)</td>
<td>33.9 (16.48)</td>
<td>−2.6 (−7.2 to 2.0)</td>
<td>−1.16 (33)</td>
<td>.26</td>
</tr>
<tr>
<td>Behavioral activation (BADS)&lt;sup&gt;g&lt;/sup&gt;</td>
<td>71.9 (24.07)</td>
<td>72.7 (29.13)</td>
<td>0.8 (−8.5 to 10.2)</td>
<td>0.18 (34)</td>
<td>.86</td>
</tr>
<tr>
<td>Anxiety (SCARED)&lt;sup&gt;h&lt;/sup&gt;</td>
<td>42.2 (18.04)</td>
<td>40.6 (18.46)</td>
<td>−1.6 (−5.4 to 2.2)</td>
<td>−0.87 (34)</td>
<td>.39</td>
</tr>
<tr>
<td>Behavior (SDQ)&lt;sup&gt;i&lt;/sup&gt;</td>
<td>17.4 (6.33)</td>
<td>17.4 (6.63)</td>
<td>0.06 (−1.5 to 1.7)</td>
<td>0.08 (33)</td>
<td>.94</td>
</tr>
<tr>
<td>Parent/carer rated about their child&lt;sup&gt;j&lt;/sup&gt; (n=20)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression (MFQ)</td>
<td>21.8 (15.47)</td>
<td>24.2 (14.3)</td>
<td>2.4 (−2.1 to 7.0)</td>
<td>1.13 (16)</td>
<td>.27</td>
</tr>
<tr>
<td>Anxiety (SCARED)</td>
<td>22.3 (15.41)</td>
<td>23.5 (12.32)</td>
<td>1.13 (−2.9 to 5.1)</td>
<td>0.60 (17)</td>
<td>.56</td>
</tr>
<tr>
<td>Behavior (SDQ)</td>
<td>12.8 (7.24)</td>
<td>13.3 (5.14)</td>
<td>0.5 (−1.4 to 2.4)</td>
<td>0.55 (19)</td>
<td>.59</td>
</tr>
<tr>
<td>Parent rated about themselves&lt;sup&gt;k&lt;/sup&gt; (N=20)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression literacy (ADKQ)</td>
<td>9.6 (2.11)</td>
<td>11.0 (1.74)</td>
<td>1.3 (0.4 to 2.2)</td>
<td>3.07 (18)</td>
<td>.006</td>
</tr>
<tr>
<td>Depression stigma (DSS)</td>
<td>30.4 (8.24)</td>
<td>30.2 (7.71)</td>
<td>−0.2 (−1.7 to 1.4)</td>
<td>−0.23 (17)</td>
<td>.82</td>
</tr>
<tr>
<td>Depression (HADS)&lt;sup&gt;l&lt;/sup&gt;</td>
<td>14.4 (8.61)</td>
<td>15.6 (8.79)</td>
<td>1.2 (−1.1 to 3.5)</td>
<td>1.13 (18)</td>
<td>.27</td>
</tr>
</tbody>
</table>

<sup>a</sup>Data available for 35 out of 36 young people. The number with missing data was 5 for the ADKQ, 2 for the DSS, 1 for the SEQ-DA, 6 for the GHSQ, 1 for the MFQ, 0 for the BADS, 0 for the SCARED, and 1 for the SDQ.

<sup>b</sup>ADKQ: Adolescent Depression Knowledge Questionnaire.

<sup>c</sup>DSS: Depression Stigma Scale.

<sup>d</sup>SEQ-DA: Self-Efficacy Questionnaire for Depression in Adolescents.

<sup>e</sup>GHSQ: General Help-Seeking Questionnaire.

<sup>f</sup>MFQ: Mood and Feelings Questionnaire.

<sup>g</sup>BADS: Behavioral Activation for Depression Scale.

<sup>h</sup>SCARED: Screen for Child Anxiety Related Emotional Disorders.

<sup>i</sup>SDQ: Strengths and Difficulties Questionnaire.

<sup>j</sup>Data available for 20 out of 21 parents/carers. The number with missing data was 3 for the MFQ, 2 for the SCARED, 0 for the SDQ, 1 for the ADKQ, 2 for the DSS, and 1 for the HADS.

<sup>k</sup>HADS: Hospital Anxiety and Depression Scale.

**Discussion**

We aimed to conduct an early-stage evaluation of a novel digital psychosocial intervention for adolescent depression and to assess the feasibility and acceptability of the assessment process that will be used in a future trial.

**The Digital Intervention: MoodHwb**

Most participants noted that the program was engaging, clear, easy to navigate, and well structured, and praised the graphic and animated approach. The content was described as comprehensive, motivational, holistic, and accessible to young people—and also relevant to families, carers and professionals in a range of services. Young people found it easier to use overall and were better able to understand the design elements, although parents, carers and professionals found it acceptable. Nearly all who completed the follow-up used the program, with most young people using it alone and for at least half an hour at a time over the course of the study (minimum of 2 months), which is favorable in terms of adherence in eHealth [12]. Participants did not use it frequently; however, they found it helpful overall, and its use might vary according to the context and needs of the user (e.g., the stage and severity of their difficulties) [37].

There were reports of improved depression literacy, self-efficacy (especially regarding self-help strategies and knowing where to get help), and depressive symptoms—giving preliminary support...
for the intervention program theory [22]. There was no clear evidence of potential negative effects from using the program.

These results were consistent with a recent systematic review of psychoeducational interventions in adolescent depression [11], which found that these programs can be acceptable and feasible and can influence a range of outcomes. Overall, the development and initial evaluation of MoodHwb fills a knowledge gap identified in the review (particularly of digital programs) and meets the need for good health information and evidence-based psychosocial interventions [5].

MoodHwb might be particularly helpful when a young person starts to experience difficulties and first presents to services—for example to school counseling or nursing, primary care/mental health, youth, or social services. However, given that the majority of young people with depression do not access services [38], digital health interventions such as this could help improve reach and access to therapies. The program could also complement other approaches, for example, in the management of severe or chronic difficulties. It fits with the guided self help approach (as it can be used either independently or with another person) and the increasing interest in personalized medicine [39].

This evaluation will be used to inform the refinement of MoodHwb, with the aim of improving the user engagement with it. The suggestions for improvement made by participants were discussed with the digital media company and research team. The issues were prioritized according to the level of importance given to them by the participants, and whether they would improve the acceptability, feasibility, and ease of use of the program. Other considerations were the program aims, underlying theory and evidence, technical difficulty, and time, resources, and funds required to make the changes.

The main revisions considered included improving the navigation and audiovisual/interactive elements, making it more personalized, developing the app version of the program, and expanding the self help and anxiety sections (Multimedia Appendix 1). Ahead of a large trial, we would also need to ensure the program has the required technical specifications (eg, compatibility with devices and operating systems, adequate database capacity, and easy access to the app).

The Evaluation Process

Strengths

One of the main strengths of the project relates to the rigorous mixed methodology, which followed guidance for complex interventions [20] for both the development and initial evaluation reported here. There was also a collaborative, person-based, and iterative approach [17] for the intervention development.

Another strength was the diverse range of participants from recruitment centers in urban and rural areas, including in areas with several ethnicities and areas of deprivation. Efforts were made to engage young people, families, and carers by offering to see them where convenient. There was also contact afterwards to promote retention and adherence (eg, email, text, phone). The recruitment target of 40 young people was met, and there was a good retention rate (82% of young people). The digital media team was available to address technical issues during the study.

Limitations

The research and digital media teams were involved throughout the project, and it is possible that their personal views could have influenced the development and evaluation process. Considering the number of centers visited, only a small number of potential participants were referred, which may have led to a biased sample. Several of those who initially showed interest did not go on to participate, and often no reason was given. This might reflect the difficulty in engaging young people in mental health research, or that the program might be more useful for certain subgroups or contexts. More females than males participated, although this might reflect in part that depression is more common in females in adolescence [1].

Participants might have reported more favorable responses because they were seen by, or in regular contact with, the researchers. Some had participated in the development phase, which may have influenced their opinion of the program (those who had been involved in its development generally gave favorable feedback on the prototype). Outcomes were assessed via self-report and response bias could be an issue, for example, where participants provide socially desirable answers. Young people might have been less likely to give candid responses in the presence of parents or carers, although they were given the option of being seen alone.

The results of the questionnaires must be interpreted with caution given the small sample size and limited power. It would have been interesting to explore how factors (eg, age, gender, severity/history of difficulties, family history, and involvement of parent and carer) might have influenced the results; however, the exploration of subgroups was not feasible given the sample size. It is also possible that some of those whose symptoms or behavior improved may have done so in any case over time, or due to other interventions or factors.

Conclusions

This early mixed methods evaluation found that the co-designed prototype of MoodHwb and assessment process were feasible and acceptable. The findings will be used to refine the intervention and inform the design of a randomized controlled trial [20]. If proven to be effective, MoodHwb could ultimately be rolled out as an early intervention program in health, education, social, and youth services and charities to help young people, families, carers, friends, and professionals.
Acknowledgments
The authors would like to thank all the young people, parents, carers, professionals, and researchers who participated in the study. Will Richards and Andrew Price (Made by Moon digital media company), Mike Clague (Carbon Studio animation company), and Dyfan Williams (graphic designer) helped to develop the program and accompanying literature, and the authors thank them for their work. The authors would like to thank Emma Rengasamy (medical student) for helping to facilitate the professionals’ focus group. This work was supported by the Welsh Government through Health and Care Research Wales, and the authors thank them for their support. RBJ was supported by a National Institute for Health Research/Health and Care Research Wales Programme Fellowship (NIHR-FS-2012). SS was supported by a Medical Research Council Strategic Award (MC-PC-13027, MC_UU_12017_14, MC_UU_12017_1, SPHSU11, and SPHSU14). BM was supported by the NIHR Biomedical Research Centre at the University Hospitals Bristol NHS Foundation Trust and the University of Bristol. DS is supported by a Lister Institute Prize Fellowship (2016-2021). IJ is Director of the National Centre for Mental Health, and the authors thank the center for its support. The funders had no role in the study design or conduct of the study or in the writing of the manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Table 1: Suggestions for the further development of the program; Table 2: Further quotes from the interviews and focus group.

Multimedia Appendix 2
Questionnaire feedback on program.

References

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Abbreviations

- CAMHS: Child and Adolescent Mental Health Services
- eHealth: electronic health
- EPAD: Early Prediction of Adolescent Depression
- UHBs: University Health Boards
Implementation Determinants and Outcomes of a Technology-Enabled Service Targeting Suicide Risk in High Schools: Mixed Methods Study

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Abstract

Background: Technology-enabled services (TESs), which integrate human service and digital components, are popular strategies to increase the reach and impact of mental health interventions, but large-scale implementation of TESs has lagged behind their potential.

Objective: This study applied a mixed qualitative and quantitative approach to gather input from multiple key user groups (students and educators) and to understand the factors that support successful implementation (implementation determinants) and implementation outcomes of a TES for universal screening, ongoing monitoring, and support for suicide risk management in the school setting.

Methods: A total of 111 students in the 9th to 12th grade completed measures regarding implementation outcomes (acceptability, feasibility, and appropriateness) via an open-ended survey. A total of 9 school personnel (school-based mental health clinicians, nurses, and administrators) completed laboratory-based usability testing of a dashboard tracking the suicide risk of students, quantitative measures, and qualitative interviews to understand key implementation outcomes and determinants. School personnel were presented with a series of scenarios and common tasks focused on the basic features and functions of the dashboard. Directed content analysis based on the Consolidated Framework for Implementation Research was used to extract multilevel determinants (ie, the barriers or facilitators at the levels of the outer setting, inner setting, individuals, intervention, and implementation process) related to positive implementation outcomes of the TES.

Results: Overarching themes related to implementation determinants and outcomes suggest that both student and school personnel users view TESs for suicide prevention as moderately feasible and acceptable based on the Acceptability of Intervention Measure and Feasibility of Intervention Measure and as needing improvements in usability based on the System Usability Scale. Qualitative results suggest that students and school personnel view passive data collection based on social media data as a relative advantage to the current system; however, the findings indicate that the TES and the school setting need to address issues of privacy, integration into existing workflows and communication patterns, and options for individualization for student-centered care.

Conclusions: Innovative suicide prevention strategies that rely on passive data collection in the school context are a promising and appealing idea. Usability testing identified key issues for revision to facilitate widespread implementation.

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KEYWORDS
technology-enabled services; suicide prevention; school-based mental health; user-centered design; mobile phone

Introduction

Background
Suicide is the second leading cause of death for adolescents, and the rate of suicide in the United States has increased in recent years [1,2]. Suicidal thoughts and behaviors (including suicidal ideation, nonsuicidal self-injury, and suicide attempts) increase dramatically during adolescence and are unfortunately common. Data suggest that 17% of US high school students seriously consider suicide each year, and approximately 9% report a suicide attempt [3]. Despite this being a common health concern, our ability to predict suicide is poor [4].

High schools provide a convenient and accessible setting to promote mental health, as most children attend high schools, removing practical barriers for mental health services and promoting care for traditionally underserved groups [5-9]. Thus, schools have the potential to play an essential role in supporting the identification and treatment of youth with mental health difficulties. School is also the most common community setting where suicidal ideation is identified [10]; however, the majority of schools demonstrate poor adherence to gold standard practices related to the identification and treatment of youth at risk [11,12]. Many high schools do not adopt recommended suicide prevention strategies because of practical concerns, such as the capacity to manage false positives, lack of knowledge of evidence-based practices, fear, stigma, as well as legal and ethical issues [11,13].

Technology-enabled services (TESs) hold promise for adolescent suicide prevention because of their capacity to support best practices while achieving population health and may help address many of the practical concerns that act as barriers to the adoption of suicide prevention strategies (ie, cognitive load, burden, and costs). TESs are characterized by having both a human service component (eg, therapist-delivered psychotherapies) and a digital component (eg, dashboard app) that supports, or is supported by, the service [14]. A broad range of support falls under the category of TES, including web- or app-based supports for posttraumatic stress disorder treatment (eg, Prolonged Exposure Coach), interventions for insomnia (Cognitive Behavioral Therapy for Insomnia Coach), and substance use disorders (reSET) [15,16]. Efficacy trials indicate that TESs yield effects commensurate with well-established psychological interventions for depression, anxiety, and suicidal ideation/behavior [17-19]. Nearly all teens are heavy users of smartphones and other digital technologies and use these technologies for health-related concerns [20]. Furthermore, adolescents are seeking TES to manage their health [21]. TES via text-based extensions (eg, Text4Strength with Sources of Strength) of suicide prevention programs show initial feasibility, safety, and utility from the adolescent perspective [22].

High schools represent a key setting for which TES can be effectively adapted and applied. An important suicide prevention research priority is to evaluate how TES may address many of the challenges that schools face in adopting suicide prevention strategies. For example, TES that automatically and continuously monitors social media (SM) data and requires virtually no staff or resources such as time in the classroom to execute may be valuable in reducing the burden of universal screening. Furthermore, strategies that rely on student-generated SM data may reduce common concerns about specific suicide or emotional health screening tools [23,24]. Furthermore, as TES does not rely on explicit reports of suicidal ideation or behavior, the potential for student stigmatization is substantially reduced. A platform that allows for passive data aggregation and monitoring is ongoing rather than linked to one particular assessment time point, facilitating an identification approach that aligns with the episodic nature of suicidality [23-25]. For these reasons, strategic monitoring of SM, has the potential to have a considerable impact on public health via scalable early detection and intervention to decrease adolescent suicide rates.

Although research on the efficacy of TES for mental health broadly—and suicide prevention specifically—is promising [21], school settings have experienced few benefits from TES. Much of this is likely because of insufficient attention to (1) end users’ priorities and experiences regarding aspects of the technology and the human service and (2) the implementation strategies that promote their adoption and sustained use [14,26].

To improve TES implementation, developers are increasingly turning to the methods of human-centered design (HCD) to identify and address problematic system design and its impact on otherwise appealing and effective products [27]. HCD includes a set of approaches that ground the development process in information about the needs and desires of people who will ultimately use a product, with the goal of creating compelling, intuitive, and effective innovations [28,29].

Usability testing, a hallmark of HCD, provides an opportunity for representative end users to interact with the technology, complete specific tasks, and generate information about the functionality and presentation. Owing to the potential impact of TES usability on implementation outcomes [30], we prioritized this determinant in the study design.

Objectives
The goal of this research was to evaluate the implementation outcomes of acceptability, feasibility, and appropriateness from the primary users of a TES (Quinn Therapeutic) for school-based suicide prevention (ie, school staff and students). These perceived implementation outcomes are critical precursors to adoption and use [30] and can be most effectively assessed at early project stages before actual implementation occurs [31]. As articulated by Proctor et al [31], acceptability is defined as perceptions that an innovation is agreeable, palatable, or satisfactory; feasibility is the extent to which a new innovation can be successfully used or carried out within a given agency or setting; and appropriateness refers to the innovation’s fit, relevance, and compatibility with the setting, staff, and target problem. We also evaluated implementation determinants, including usability factors, driving our primary implementation outcomes. Our specific research questions were as follows: (1) What key, multilevel factors in the school context should drive...
the adaptation and implementation of a student-monitoring dashboard interface of the Quinn Therapeutic and (2) What changes to the digital dashboard interface are needed to maximize its acceptability, feasibility, appropriateness, and ultimate usability for school systems? We focus on the dashboard interface for applying HCD as the most salient and user-facing feature of TES.

**Methods**

**Participants and Procedures**

Participants were drawn from an urban area in the Pacific Northwest. Recruitment of participants occurred through past and ongoing research partnerships. Interested principals and/or school counselor leads were presented with the information regarding study procedures in an initial meeting and then recontacted if they were interested in having students and school personnel the opportunity to participate. Recruitment of clinician participants was done in the winter of 2018, with user testing procedures completed in February and March; student recruitment and study student data collection procedures were performed in May 2018. All procedures were approved by our institutional review board (study 3246).

**Procedures for School Personnel: User Testing**

In total, 9 school personnel whose responsibilities are most proximal to school-based suicide screening—school nurses, counselors, social workers, and administrators—were invited to participate in the laboratory-based user testing of our student-monitoring dashboard.

School personnel were included to identify key aspects of the Quinn Therapeutic system that were most in need of redesign. Drawing from established models of user testing [32], participants were presented with a series of scenarios that contain common tasks to accomplish. Tasks focused on the primary features of the dashboard system (ie, open exploration, identifying a student at risk for suicide, and identifying the risk status of a new student). During the task completion, participants used a think-aloud data collection technique [33], describing their processes and experiences as they navigate the system. Anticipated and actual task difficulties were assessed consistent with Albert and Dixon’s [34] method. During system testing, participants rated on a 5-point scale (ranging from 1=very easy to 5=very difficult) the expected difficulty of each task. Following task completion, participants rated the experienced difficulty on the same scale. We used prompts such as What are you thinking about? What details are you looking for? and What is your impression of this task to elicit information. Following the completion of the task and their post-task rating, we asked several follow-up questions including, Why did you answer the way you did? Was there anything confusing, usual, or difficult to understand about this task? as well as additional questions specific to individualized tasks. Each session concluded with a qualitative open-ended interview to gather additional feedback about the system and implementation determinants as well as completion of standardized measures of implementation outcomes and system usability (system usability scale; SUS [35]).

**Procedures for Students: Social Media Data and Survey**

Following school administrator approval, 111 students were recruited from a private high school in an urban area of the Pacific Northwest. Students were eligible to participate if they attended high school and used 1 of 5 popular SM platforms (Twitter, Facebook, Instagram, Reddit, and Tumblr) on a weekly basis.

The opportunity for participation was presented in an all-class assembly. A brief orientation to the procedures was given, and assent was obtained from youth. Parents/caregivers received a letter from the principal informing of study procedures and the option to opt out their high school from the study procedures. Youth who provided consent were given access to the University of Washington OurDataHelps website to donate SM data and complete questionnaires regarding their preferences for the Quinn Therapeutic dashboard. Students opted for study participation through the OurDataHelps website [36]. This website provided study information and provided a web-based data collection platform. The components of student data collection included SM data donation, and questionnaires regarding emotional health, implementation outcomes, and SM use and preferences were completed via a web or mobile platform. Following the presentation, eligible students were given 1 week to access the survey platform and complete study procedures. Students received US $30 for participation.

**Materials: Quinn Therapeutic Dashboard**

Quinn Therapeutic is a TES that aggregates patient-generated SM data to detect and monitor suicide risk, visualize data over time, and provide feedback to clinicians, which may be particularly suitable in the high school context [37-39]. Quinn Therapeutic’s core digital and human service features are outlined below (Table 1). The technology relies on deep learning (a subset of machine learning algorithms), which enable a computer to discover and use patterns in data, trained, and optimized using SM data [40]. The aggregated SM data and risk ratings based on machine learning algorithms are presented in a student-monitoring dashboard interface, which clinicians log into to view estimated student risk status, data over time, and SM content driving ratings of risk. The dashboard’s purpose is to allow school personnel to monitor student suicide risk over time. Core functions are represented in the web-based supplement. A timeline shows the overall data contribution for the population; there is a search function for finding specific students, and tabs categorize students with high risk for ease of viewing the at-risk population with past suicidal ideation and self-harm. School personnel can also view individuals, including their suicide risk level over time (ie, risk level graph), source SM data that generate the risk ratings, the strength and valence of sentiment (ie, sentiment graph), and students self-reported diagnostic and suicide risk information. Quinn Therapeutic’s predictive algorithms have been developed and evaluated in users who donate their data to an online portal as well as publicly available data from Twitter and demonstrated impressive accuracy in distinguishing those with identifying self-reported suicide attempts from those who did not report this history [41]. The algorithms demonstrated the capability to separate users who would attempt suicide from neurotypical
controls. Evaluating SM data from the month before a suicide attempt, the area under the curve (AUC) from receiver operating characteristics for this binary decision task was 0.89, and for all available SM data, AUC was 0.94 (an AUC of 1 is perfect prediction) [42]. Quinn Therapeutic human service components include measurement-based care, crisis prevention planning, and risk management, all of which align with recommendations for the identification and management of adolescent suicide risk [43]. As a first step in evaluating the application of Quinn Therapeutic TES in the school setting, the current project focused only on an early prototype of Quinn Therapeutic’s digital technology component.

Table 1. Quinn Therapeutic technology specifications.

<table>
<thead>
<tr>
<th>Data aggregation</th>
<th>Ongoing data capture from five SM* platforms—Facebook, Instagram, Twitter, Reddit, and Tumblr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Digital platform components</strong></td>
<td></td>
</tr>
<tr>
<td>Risk prediction</td>
<td>Relies on deep learning, specifically refined for suicide-specific predictions from multiple cohorts</td>
</tr>
<tr>
<td>Visualization of progress</td>
<td>Student-monitoring dashboard interface for selected school personnel</td>
</tr>
<tr>
<td>Data security and privacy</td>
<td>Health Insurance Portability and Accountability Act–compliant cloud-based server, opt in participation, and meets recommendations for ethical use of SM data [44]</td>
</tr>
<tr>
<td><strong>Service components</strong></td>
<td></td>
</tr>
<tr>
<td>Measurement-based care</td>
<td>Ongoing monitoring through passive data collection</td>
</tr>
<tr>
<td>Crisis prevention planning</td>
<td>Use of real-time data to understand past prompting events and plan for future</td>
</tr>
<tr>
<td>Suicide-specific assessment and treatment</td>
<td>Maintains top priority of safety at the time it is needed</td>
</tr>
</tbody>
</table>

*SM: social media.

For user testing sessions, school personnel viewed the student-monitoring dashboard populated with dummy data. The dashboard allows for data visualization of the posterior probability (range 0-1) representing the likelihood that each individual SM post was written by someone at risk of suicide and status updates that were analyzed with machine learning algorithms developed in prior work [42]. Cohort data, individual monitoring data (time series and risk rating), and source content (SM posts/behavior) that generated ratings were viewed via the dashboard.

**Measures**

Multimedia Appendix 1 provides information regarding the measures by the reporter as well as the sample items.

**Demographics**

Participants self-reported their age, ethnicity/race, sexual orientation, and gender. In addition, school personnel reported their role in the school context and the years of experience in that role.

**Implementation Outcomes**

**Acceptability**

The 4-item acceptability of intervention measure [45] was used to assess school personnel’s perception of acceptability, including liking, approving, and welcoming use of the dashboard. Items were rated on a 5-point Likert scale (1=completely disagree and 5=completely agree). Prior psychometric evaluation suggested acceptable measurement model fit and high reliability [45], and internal consistency in this study was strong (α=.93).

**Appropriateness**

The 4-item intervention appropriateness scale [45] was used to assess school personnel’s perception of fit with items related to fit for the setting, applicability to their work, and a good match for the needs of the users. Items were rated on a 5-point Likert scale (1=completely disagree and 5=completely agree). Prior psychometric evaluation suggested acceptable measurement model fit and high reliability [45], and internal consistency in this study was excellent (α=.97).

**Feasibility**

The 4-item feasibility of intervention measure [45] was used to assess school personnel’s perception of acceptability, including possible, doable, and easy use of the dashboard. Items were rated on a 5-point Likert scale (1=completely disagree and 5=completely agree). Internal consistency in this study was strong (α=.91).

**Implementation Determinants**

**Usability**

School personnel completed the SUS following user testing. The SUS is a 10-item measure, with scores ranging from 0 to 100, with scores greater than 70 considered acceptable. The SUS is the best-researched and most sensitive usability measure available [35]. Internal consistency in this study was strong (α=.83).

**Additional Determinants**

Following user testing sessions, school personnel participants were asked a series of open-ended questions about what they saw as the positive aspects, the negative aspects, and specific suggestions for improvement based on other technologies with which they interacted. Questions focused on acceptability, feasibility, and appropriateness were asked to understand the reasons for their interview responses. Students completed the Preferences, Relationships, and Interventions using Social Media, a 22-item questionnaire developed by this team that assessed the use and frequency of SM platforms, priorities regarding intervention options, and open-ended questions around
the ways to improve system alignment with the needs and expectations of students in their school.

**Data Analysis Plan**

Descriptive statistics, including means and SDs, were calculated for quantitative measures. Qualitative content was coded using the Consolidated Framework for Implementation Research (CFIR) [46]. The CFIR is a commonly used framework that organizes constructs that have been associated with effective implementation. It has been widely used as a practical guide to evaluate implementation efforts in preparation for or during active studies [46]. The codebook template was used to understand the multilevel determinants of implementation. Determinants include aspects of the innovation (eg, evidence strength and relative advantage), outer context (eg, external policies and incentives), the inner organizational context (eg, implementation climate and tension for change), characteristics of the individuals operating within target settings (eg, attitudes and efficacy), and process of change in the organization (eg, engagement strategies and change agents) [47-51]. School personnel interviews were audio recorded, transcribed, and coded with directed content analysis. In total, 4 coders were trained to conduct directed content analysis based on the CFIR codebook by reviewing the codebook and example codes, reviewing the school personnel’s responses to each question from the same two transcripts, identifying potential codes, and independently coding. Consensus among the four coders for the two transcripts was achieved through open dialog [52]. Following consensus on the two transcripts, two coding team members who had completed the consensus coding were split into two groups. The remaining transcripts were coded independently and then the two groups met to review codes in consensus meetings. A consensus coding process was used to reduce biases, groupthink, and errors [53]. This coding approach was used, as many qualitative researchers consider it to be more valid for analyzing human communication, as it explicitly uses coding ambiguities to prompt discussion and increases confidence in complex data compared with interrater reliability [54].

**Results**

**Participants**

The demographic characteristics of the participants are included in Tables 2 and 3.
Table 2. Summary of demographics and clinical characteristics for student participants (N=111).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Students</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex at birth, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>40 (36.0)</td>
</tr>
<tr>
<td>Female</td>
<td>71 (64.0)</td>
</tr>
<tr>
<td>Intersex</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>40 (36.0)</td>
</tr>
<tr>
<td>Female</td>
<td>71 (64.0)</td>
</tr>
<tr>
<td>Transgender male</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Transgender female</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>16.5 (1.13)</td>
</tr>
<tr>
<td><strong>Sexual orientation, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Asexual</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Bisexual or pansexual</td>
<td>16 (14.4)</td>
</tr>
<tr>
<td>Gay or lesbian</td>
<td>4 (3.6)</td>
</tr>
<tr>
<td>Heterosexual or straight</td>
<td>83 (74.8)</td>
</tr>
<tr>
<td>Other(^a)</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>5 (4.5)</td>
</tr>
<tr>
<td><strong>Ethnicity (Hispanic or Latino), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>103 (92.8)</td>
</tr>
<tr>
<td>Hispanic, of Spanish Origin or Latino</td>
<td>5 (4.5)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3 (2.7)</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>63 (56.8)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>10 (9.0)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>15 (13.5)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Other, not specified above</td>
<td>7 (6.3)</td>
</tr>
<tr>
<td>Unknown or prefer not to answer</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>12 (10.8)</td>
</tr>
<tr>
<td><strong>Number of suicide attempts, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>106 (95.5)</td>
</tr>
<tr>
<td>1</td>
<td>2 (1.8)</td>
</tr>
<tr>
<td>2</td>
<td>3 (2.7)</td>
</tr>
</tbody>
</table>

\(^a\)Sexual orientation: other: heterosexual and bicurious (n=1) and questioning (n=1).
Table 3. Summary of demographics for school personnel participants (N=9).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>School personnel, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Female</td>
<td>7 (78)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>4 (44)</td>
</tr>
<tr>
<td>35-44</td>
<td>4 (44)</td>
</tr>
<tr>
<td>55-64</td>
<td>1 (11)</td>
</tr>
<tr>
<td><strong>Ethnicity (Hispanic or Latino)</strong></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>9 (100)</td>
</tr>
<tr>
<td>Hispanic, of Spanish Origin or Latino</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>7 (78)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0 (0)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other, not specified above</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Degree</strong></td>
<td></td>
</tr>
<tr>
<td>Bachelor’s</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Master’s</td>
<td>7 (78)</td>
</tr>
<tr>
<td><strong>Professional Role</strong></td>
<td></td>
</tr>
<tr>
<td>School counselor</td>
<td>3 (33)</td>
</tr>
<tr>
<td>Mental health counselor</td>
<td>2 (22)</td>
</tr>
<tr>
<td>School administrator</td>
<td>1 (11)</td>
</tr>
<tr>
<td>Other$^a$</td>
<td>3 (33)</td>
</tr>
<tr>
<td><strong>Years in role</strong></td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>3 (33)</td>
</tr>
<tr>
<td>4-6</td>
<td>3 (33)</td>
</tr>
<tr>
<td>7-9</td>
<td>2 (22)</td>
</tr>
<tr>
<td>≥20</td>
<td>1 (11)</td>
</tr>
</tbody>
</table>

$^a$Professional role: other: school nurse (n=2) and community-based behavioral health partner (n=1).

Implementation Outcomes

School personnel gave the student-monitoring dashboard moderate scores, on average, for acceptability (mean 3.69, SD 0.85; range 2.25-5.00), appropriate (mean 3.72, SD 1.09; range 2.00-5.00), and feasibility (mean 3.78, SD 0.75; range 2.25-4.75) of implementation in their setting, indicating school personnel viewed the student-monitoring dashboard as moderately appropriate for the school setting.

Determinants of Implementation

To understand the reasons for ratings of core implementation outcomes, qualitative themes at the level of the innovation, outer setting, inner setting, individual characteristics, and engagement were summarized (Multimedia Appendix 2). The following three themes emerged: (1) compatibility with culture, values, and norms in the school setting; (2) additional attention needed to confidentiality and privacy; and (3) flexibility in the way to support students. The majority of the qualitative codes related to the first theme, that is, the organizational context, culture, resources, and structure (161/350, 46.0% of school personnel...
comments and 118/222, 53.2% of student comments). Specific comments highlight positive aspects of the system being compatible with culture and values/norms in the school setting. For example, a student indicated:

- The system would be great if it helps a student personally and on their phone, and includes lots of student choice. [coded innovation characteristics, adaptability]

However, both participant groups reported difficulty in managing confidentiality and privacy within this context and adequately managing the workflow. For example, 1 clinician stated:

- A barrier to implementation in that we are not an organization that is accessible. This level of oversight is appealing in some ways and so I wonder if it creates an expectation of supervision or the impression of supervision where it’s not always available. [coded inner setting, available resources]

A student’s perspective highlighted:

- If people feel like they can’t be themselves on the social media because they don’t trust the system to keep their confidentiality then I don’t think they’d use it. If students didn’t use the social media then the system wouldn’t work at all. [coded outer setting, external policy]

The second theme highlighted the need for careful attention to how information would be used within the school setting and remain confidential. Some expressed uncertainty about the extent to which machine learning can discern the complexities of unstructured text and nuanced communication occurring on SM platforms:

- In today’s society the young generation us [sic] tend to make jokes about suicide in a way to relieve stress so I’m afraid something like that will be taken the wrong way. [coded innovation characteristics, evidence strength]

School personnel and students noted wanting clarity on how the TES would impact internal communications and other external systems outside the school, including the district and outside resources (e.g., therapists outside of the school and crisis responding).

The third theme relates to the potential for an approach similar to this to expand options for youth at risk. Overall, 34.0% of school personnel comments and 18.0% of student comments highlight the innovative aspects of using passive and ongoing data collection in this way. Themes of positive comments related to the relative perceived advantage of a technology-based solution compared with the status quo as well as the ability to provide individualized solutions and options for youth who appear distressed and/or suicidal. One student noted:

- It would allow social media to be safer and less stressful for people who have a lot of anxiety about it. [coded innovation characteristics, relative advantage]

Another student stated the asset of flexibility:

- I think that the best thing this system could do was just be an option for people who are struggling to go and have someone or something that could help them and be there for them. [coded inner setting, available resources]

### Prototype Interface Usability

#### Task Difficulty

Most tasks were estimated to be moderately easy (mean-range 3.78-4.22), with the exception of isolating a date range (mean-pre 3.00 and mean-post 2.22). Users found the task of free exploration and navigation of the dashboard, similar to or easier than they had anticipated. The majority of users found the task of identifying posts within a set time frame more difficult than they anticipated.

#### Task Success

All 100% of participants identified the students and the risk level. Two-thirds of the participants correctly identified previous suicide risk, and about half of the participants were able to flag concerning posts.

### System Usability Scale Usability

School personnel’s scores on the platform ranged from 22.5 to 75, with a mean of 54.17 (SD 16.58), showcasing the divergent opinions from school personnel on the system’s overall usability and an overall unacceptable rating of current usability of the prototype dashboard interface (acceptable ratings >70). Feedback after each testing scenario and during the formal qualitative interview highlighted several common issues, themes, and needed modifications identified by the participants for a subsequent version of the interface (e.g., difficulty in isolating specific periods within the interface).

#### Discussion

### Principal Findings

In this study, high school students and school personnel provided feedback on implementation determinants and outcomes to facilitate the redesign of a TES to support suicide risk identification and prevention. Universal emotional health screening is recognized as an essential component of a multilayer system of support and behavioral health framework [55]. Universal emotional health screening may facilitate the identification of undetected difficulties [56]: however, emotional health screening is rarely conducted in school settings because of feasibility, burden on school personnel, and lack of knowledge of best practices. A solution that supports accurate, ongoing, and passive screening for youth risk, clinical decision making, and improved communication and that fits within the school context would be a great asset toward facilitating identification and triage of students at risk for suicide. Through mixed qualitative and quantitative approaches, our study identified a number of strengths of the digital component of the Quinn Therapeutic TES. We additionally identified several challenges related to the school context and concerns regarding fit within workflow and the network of communications around protected health information such as suicidality. Three primary
themes identified by students and school personnel were (1) compatibility with culture, values, and norms in the school setting; (2) additional attention needed to confidentiality and privacy; and (3) flexibility in the way to support students. With regard to compatibility with the culture, students, and school personnel highlighted that this approach aligned with the school’s value to support well-being and help achieve goals related to caring for the whole student. However, both stakeholders reported a need for additional information about the data and processes for analysis, interpretation, communication, and human responses were requested. Student concerns regarding confidentiality were centered on how school personnel would manage communications, not sharing data with a company for purposes of suicide prevention. Along with other researchers, before the widespread acceptance of a system that was supported by existing data sources such as SM, additional education regarding the validity of psychologically relevant data can be measured via SM language. Finally, both school personnel and students found appeal in TES flexibility, including the ability for multiple options for enrollment and strategies to support students.

Several researchers have suggested that digital innovations that rely on machine learning strategies similar to the one evaluated in this research would provide significant advances in the field [4,57-60]. In addition, programs that rely on suicide risk prediction algorithms have been deployed in the Veteran’s administration. This program, called Recovery Engagement and Coordination for Health—Veterans Enhanced Treatment, uses medical record data and applies machine learning to identify those at a statistically elevated risk for suicide or other adverse outcomes. At present, there is an active clinical trial of the program (NCT03280225). The evaluation of the application of machine learning algorithms to medical records for the prediction of suicide attempts has demonstrated good performance [61]. Few programs have been designed to provide rigorous evaluation of the usability and other implementation determinants for the use of a technology-based solution to universal suicide screening in the school context. Several limitations must be considered when interpreting the results. First, the sample of users was small, and not representative, as it was limited to participants from a small private school in an urban area. Second, we coded perceptions of the intervention implementation following scenario-based user testing, not actual implementation of the intervention, and, therefore, may not be valid for real-world implementation. Finally, we only included primary end users, that is, students and school personnel who would be involved in responding to suicide risk directly and, therefore, did not include other important stakeholders such as teachers and parents.

Conclusions

Strategies to make suicide prevention efforts in high schools scalable, sustainable, and supportive may benefit from attention to how technology can facilitate and aid human efforts. This research evaluated a system that aggregates existing data sources—SM data—to provide ongoing monitoring of suicide risk based on machine learning algorithms. Primary users—high school students and school personnel—highlighted the potential advantages of providing individualized solutions and options for youth compared with the current suicide prevention strategy within the school (which included gatekeeper training, mental health awareness group, and onsite counseling support). However, the management of private and sensitive communications in the school context and limited functionality of the prototype dashboard dampened enthusiasm for widespread implementation. Although further investment in an improved user interface may improve some of the concerns, the large fundamental challenge facing this and similar TES is a lack of understanding and policy surrounding the privacy and use of sensitive communications in the school context. Widespread agreement on community norms and commonly accepted guidelines for how and when to use this sort of data will be necessary for the widespread adoption of any similar TES.

Acknowledgments

This research was supported by the American Foundation of Suicide Prevention Linked Standard Grant and the Agency for Healthcare Research and Quality (grant no. K12HS022982).

Conflicts of Interest

GC is an employee and a shareholder of Qntfy.

Multimedia Appendix 1

Measures, QT user function, and qualitative coding examples.

[DOCX File, 83 KB - mental_v7i7e16338_app1.docx]

Multimedia Appendix 2

Qualitative coding reference table.

[XLSX File (Microsoft Excel File), 25 KB - mental_v7i7e16338_app2.xlsx]

References


36. OurDataHelps. URL: https://ourdatahelps.org/ [accessed 2019-07-17]


41. OurDataHelps. URL: https://ourdatahelps.org/ [accessed 2020-03-30]


Abbreviations

- **AUC**: area under the curve
- **CFIR**: Consolidated Framework for Implementation Research
- **HCD**: human-centered design
- **SM**: social media
- **SUS**: system usability scale
- **TES**: technology-enabled services

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Design, Recruitment, and Baseline Characteristics of a Virtual 1-Year Mental Health Study on Behavioral Data and Health Outcomes: Observational Study

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Abstract

Background: Depression and anxiety greatly impact daily behaviors, such as sleep and activity levels. With the increasing use of activity tracking wearables among the general population, there has been a growing interest in how data collected from these devices can be used to further understand the severity and progression of mental health conditions.

Objective: This virtual 1-year observational study was designed with the objective of creating a longitudinal data set combining self-reported health outcomes, health care utilization, and quality of life data with activity tracker and app-based behavioral data for individuals with depression and anxiety. We provide an overview of the study design, report on baseline health and behavioral characteristics of the study population, and provide initial insights into how behavioral characteristics differ between groups of individuals with varying levels of disease severity.

Methods: Individuals who were existing members of an online health community (Achievement, Evidation Health Inc) and were 18 years or older who had self-reported a diagnosis of depression or anxiety were eligible to enroll in this virtual 1-year study. Participants agreed to connect wearable activity trackers that captured data related to physical activity and sleep behavior. Mental health outcomes such as the Patient Health Questionnaire (PHQ-9), the Generalized Anxiety Disorder Questionnaire (GAD-7), mental health hospitalizations, and medication use were captured with surveys completed at baseline and months 3, 6, 9, and 12. In this analysis, we report on baseline characteristics of the sample, including mental health disease severity and health care utilization. Additionally, we explore the relationship between passively collected behavioral data and baseline mental health status and health care utilization.

Results: Of the 1304 participants enrolled in the study, 1277 individuals completed the baseline survey and 1068 individuals had sufficient activity tracker data. Mean age was 33 (SD 9) years, and the majority of the study population was female (77.2%, 994/1288) and identified as Caucasian (88.3%, 1137/1288). At baseline, 94.8% (1211/1277) of study participants reported experiencing depression or anxiety symptoms in the last year. This baseline analysis found that some passively tracked behavioral traits are associated with more severe forms of anxiety or depression. Individuals with depressive symptoms were less active than those with minimal depressive symptoms. Severe forms of depression were also significantly associated with inconsistent sleep patterns and more disordered sleep.

Conclusions: These initial findings suggest that longitudinal behavioral and health outcomes data may be useful for developing digital measures of health for mental health symptom severity and progression.

(JMIR Ment Health 2020;7(7):e17075) doi:10.2196/17075

KEYWORDS
mental health; anxiety; depression; behavioral data
**Introduction**

**Background**

The increasing use of wearable devices capable of tracking behavioral activities like steps and sleep bring opportunities for a more nuanced understanding of the impact of mental health conditions on daily life. Conventional approaches to behavioral research in the form of periodic surveys or outreach cannot provide sufficient information on the day-to-day or real-world experiences of people with mental health conditions. However, current wearable activity devices can passively capture behavioral information with time granularities to the minute and even second level, and there is growing interest in how these data can be used and applied in research and health care settings [1]. Data from these devices are usually collected passively and continuously, and can provide unique longitudinal insights into an individual’s behavior (eg, sleep and activity patterns) that cannot be measured by traditional methods. Researchers have begun to leverage activity trackers, health and fitness apps, and other digital technologies in clinical and health outcome studies to collect behavioral data and analyze it alongside more conventional types of health outcomes and clinical data [2]. These joint data sets can then be used to identify various behavioral characteristics and patterns associated with different health conditions and can help provide a better understanding of disease status, onset, and progression, thus potentially leading to improved screening and monitoring techniques, therapeutic innovations, and disease management [3].

A therapeutic area of particular interest is mental health, specifically depression and anxiety, as these conditions impact an individual’s daily activities, behaviors, and health-related quality of life. Mental health illnesses affect nearly 20% of the adult population in the United States [4], and depression is forecasted to be the second leading cause of disability throughout the world in 2020 [5]. Mental health illnesses are a risk factor for many other chronic diseases and place a significant burden on the individual, their community, and the overall health care system [5]. Given that mental health illnesses can have a bidirectional relationship with health behaviors such as sleep and physical activity [6,7], it is a particularly appropriate therapeutic area to explore to further understand how passively collected behavioral data can be used to provide insight into an individual’s overall health outcomes.

**Prior Work**

Previous studies have shown a correlation between self-reported physical activity levels and mental health illnesses, yet few studies have evaluated passively collected activity tracker–based data in individuals with mental health illnesses [8]. One small study analyzed self-reported health outcomes and smartphone sensor data and found correlations between changes in depression symptoms and speech patterns, geospatial activity, and sleep [8]. A recent larger study used tracking devices and heart rate monitors to understand how passively collected data correlated with a traditional patient-reported questionnaire, and found that increased physical activity was associated with better psychological well-being [9]. However, despite these initial signals, digital measures of mental health status, or digital signals and algorithms that can identify or characterize disease onset, severity, and progression, have yet to be precisely developed and validated [10].

**Goal of This Study**

To better understand the relationship between behaviors and health outcomes for individuals with mental health conditions, and to begin to develop digital measures of mental health status, symptoms, and severity, we designed and launched a virtual 1-year prospective observational study where we collected self-reported health outcomes and utilization data alongside activity tracker–based behavioral data for individuals with depression or anxiety. This study has been fully recruited and data collection has been completed. The purpose of this manuscript is two-fold. First, this manuscript provides an overview of the study design, outlines the purely virtual operationalization of the protocol, and reports baseline health and behavioral characteristics of the study population. Second, this manuscript provides initial insights into how behavioral characteristics differ between groups of individuals with varying levels of disease severity.

**Methods**

**Study Overview**

This 1-year prospective observational study was designed with the objective of creating a novel longitudinal data set that combines self-reported health outcomes, health care utilization, and quality of life data with app- and activity tracker–based behavior data for individuals with depression and anxiety to support novel research exploring possible associations between longitudinal objective measures of health behaviors and self-reported mental health status.

This study was conducted completely virtually using a novel online study platform (Achievement Studies, Evidation Health Inc.). Achievement is currently available in the United States with a research community of users that range in age from 18 to >80 years. Individuals have collectively self-reported on over 900,000 conditions. Achievement members can connect their activity trackers and fitness and health apps to the platform; as members log activities and use their activity trackers, they accumulate points that are redeemable for monetary rewards. Additionally, Achievement users are recruited for various studies based on the study criteria and can access Achievement on the web as well as through iPhone and Android apps. In this study, individuals were able to access the online study platform to complete study procedures and keep track of their progress throughout the study through the use of any web-enabled device. Participants were able to reach out to research staff with questions via email or phone before and during the enrollment process, and could continue to reach out throughout the study. This study was approved by the Solutions Institutional Review Board.

**Recruitment and Screening**

We invited existing members of the Achievement online health community to participate in this study. Individuals who lived in the United States, were at least 18 years of age, and...
self-reported a diagnosis of depression or anxiety were eligible for the study. To assess their eligibility, potential participants completed a set of screener questions on the online study platform. If deemed eligible, they were then asked to sign an electronic informed consent form on the online study platform to enroll in the study.

**Data Collection**

Once enrolled in the study, participants were asked to complete a baseline questionnaire, which consisted of questions about their health status, health care utilization, and treatment patterns. The baseline questionnaire also included questions from the Patient Health Questionnaire (PHQ-9) [11] and the Generalized Anxiety Disorder Questionnaire (GAD-7) [12] to detect and assess depression and anxiety severity levels, respectively.

Participants were then asked to connect at least one of the following activity trackers or fitness and health apps to their study dashboard: Fitbit, Withings (formerly Nokia Health), Garmin, Jawbone, Misfit, MyFitnessPal, or Apple Health. Since all participants were existing members of the online health community, most already had apps and trackers connected, but they were given the option to connect additional apps and trackers. Participants were not required to connect a tracker or app to continue in the study. As part of the consent process, participants were informed that the behavioral data included in the research analysis would consist of app- and tracker-based data. We did not analyze weight and food logging data from various per-patient behavioral variables outlined in Table 1 because these data types were not commonly available in the study sample.

After enrolling in the study and for the 1-year duration of the study, participants were asked to complete a set of online follow-up assessments. These assessments consisted of questions regarding the participant’s health status, health care utilization, and treatment patterns, and changes in treatment, and included the PHQ-9 and GAD-7 questionnaires.

At the 3-month, 6-month, 9-month, and 12-month (study end) time points of the study, participants were asked to complete online follow-up assessments. These assessments consisted of questions regarding the participant’s health status, health care utilization, and changes in treatment, and included the PHQ-9 and GAD-7 questionnaires.

**Table 1. Behavioral variables.**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Walk metrics</strong></td>
<td></td>
</tr>
<tr>
<td>Daily steps</td>
<td>Number of steps a participant takes in a 24-hour period</td>
</tr>
<tr>
<td>CV&lt;sup&gt;a&lt;/sup&gt; daily steps</td>
<td>Coefficient of variation of steps; measures variability of daily steps</td>
</tr>
<tr>
<td>Steps intensity</td>
<td>Percent difference between median and 75th percentile day of daily steps</td>
</tr>
<tr>
<td>Low step days</td>
<td>Percent of days with fewer than 500 steps walked</td>
</tr>
<tr>
<td>High step days</td>
<td>Percent of days with more than 10,000 steps walked</td>
</tr>
<tr>
<td><strong>Sleep metrics</strong></td>
<td></td>
</tr>
<tr>
<td>Daily sleep</td>
<td>Number of hours a participant sleeps in a 24-hour period (may include naps)</td>
</tr>
<tr>
<td>CV daily sleep</td>
<td>Coefficient of variation of daily sleep; measures variability of daily sleep</td>
</tr>
<tr>
<td>Daily sleep intensity</td>
<td>Percent difference between median and 75th percentile day of daily sleep</td>
</tr>
<tr>
<td>Low sleep days</td>
<td>Percent of days with fewer than 4 hours slept</td>
</tr>
<tr>
<td>High sleep days</td>
<td>Percent of days with more than 9 hours slept</td>
</tr>
</tbody>
</table>

<sup>a</sup>CV: coefficient of variation.

**Measurements**

In this study, the two validated patient-reported outcomes that we focus on are the 9-item PHQ-9 and the 7-item GAD-7, both of which can be self-administered. The PHQ-9 asks participants to rate on a scale of 0 (not at all) to 3 (nearly every day) the 9 DSM-IV criteria for depression. The GAD-7 asks individuals to assess the extent to which they have been bothered by various anxiety-related symptoms on a scale of 0 (not at all) to 3 (nearly every day).

To examine how tracker-based behavioral characteristics are associated with disease severity, we used four primary methods to classify participants based on the severity of their mental health condition(s). Methods 1 and 2 were based on thresholds of the two validated self-reported health outcomes questionnaires (PHQ-9 and GAD-7). In Method 1, we categorized participants based on their baseline PHQ-9 score; participants either had “depressive symptoms” (defined as having a PHQ-9 score ≥10) or “minimal depressive symptoms” (defined as having a PHQ-9 score <10) [11]. In Method 2, we categorized participants based on their baseline GAD-7 score; participants either had “anxiety symptoms” (defined as having a GAD-7 score ≥10) or “minimal anxiety symptoms” (defined as having a GAD-7 score <10) [12]. Methods 3 and 4 were based on self-reported health care utilization and treatment. In Method 3, we categorized participants as “no hospitalization history” or “history of hospitalization” based on whether they had any self-reported history of a mental health-related hospitalization in the last year. For Method 4, we categorized participants as “on medications” or “no medications” based on whether they were taking mental health–related medications at study baseline.

For the baseline behavioral data analysis, we calculated the various per-patient behavioral variables outlined in Table 1 using daily step counts and daily sleep data from activity trackers. We did not analyze weight and food logging data from apps and trackers because these data types were not commonly available in the study sample.
Statistical Analyses

We present the baseline demographics, health outcomes, and activity tracker–based behavioral characteristics of the participant population. Baseline sociodemographic factors, health status, and health care utilization were calculated for all enrolled participants who completed the baseline assessment. In addition, we present cross-sectional analysis based on the baseline activity tracker–based behavioral characteristics calculated for all participants who had completed the baseline assessment and used an activity tracker or fitness and health app for at least 60 of the 90 days prior to study enrollment. This threshold was set to ensure that any behavioral characteristics or patterns inferred from tracker-based behavioral data were based on a robust set of participant data rather than sparse data points. Since data collected from a variety of consumer wearable devices and apps was used in this study, no advanced preprocessing was completed. The activity tracker behavioral characteristics in this analysis focus on step and sleep data; Table 1 defines the behavioral variables examined in this analysis.

To understand how the classification methods based on validated patient reported outcomes (Methods 1 and 2) were associated with the health care utilization classification methods (Methods 3 and 4), we calculated the number of mental health–related hospitalizations and proportion of participants on mental health–related medications at baseline for each of the two groups in Methods 1 and Methods 2. We evaluated differences in the number of hospitalizations using independent $t$ tests (two-tailed). We evaluated the differences in medication usage rates using a two-proportion z-test. The metrics in Table 1 were calculated for each group within each of the four classes; between-group comparisons were performed using the Mann-Whitney U test. $P$ values were corrected for false discovery rates to minimize the Type 1 error rate from the multiple comparisons using the Benjamini-Hochberg procedure. All statistical tests with false discovery rate–corrected $P$ values <.001 ($q$ value <.05) were considered statistically significant. These results were then used to identify which behavioral variables were significantly different between groups across the four classification methods. Statistical analyses were conducted in Stata 13.1 and Python 3.5.

Results

Study Sample

Study recruitment, screening, and enrollment occurred between April 6, 2017, and May 26, 2017. A total of 1742 potential participants initiated the online screener questionnaire (Figure 1). Of those, 81.9% (1426/1742) were deemed eligible for the study. A total of 1304 individuals completed informed consent and were enrolled in the study. Of the individuals enrolled in the study, 98.8% (1288/1304) started the baseline assessment, 97.9% (1277/1304) completed the baseline assessment, 95.8% (1249/1304) connected an activity tracker to the Achievement Studies Platform, and 81.9% (1068/1304) had activity tracker–based data for at least 60 of the 90 days prior to study enrollment. Since data collected from a variety of consumer wearable devices and apps was used in this study, no advanced preprocessing was completed. The activity tracker behavioral characteristics in this analysis focus on step and sleep data; Table 1 defines the behavioral variables examined in this analysis.

To understand how the classification methods based on validated patient reported outcomes (Methods 1 and 2) were associated with the health care utilization classification methods (Methods 3 and 4), we calculated the number of mental health–related hospitalizations and proportion of participants on mental health–related medications at baseline for each of the two groups in Methods 1 and Methods 2. We evaluated differences in the number of hospitalizations using independent $t$ tests (two-tailed). We evaluated the differences in medication usage rates using a two-proportion z-test. The metrics in Table 1 were calculated for each group within each of the four classes; between-group comparisons were performed using the Mann-Whitney U test. $P$ values were corrected for false discovery rates to minimize the Type 1 error rate from the multiple comparisons using the Benjamini-Hochberg procedure. All statistical tests with false discovery rate–corrected $P$ values <.001 ($q$ value <.05) were considered statistically significant. These results were then used to identify which behavioral variables were significantly different between groups across the four classification methods. Statistical analyses were conducted in Stata 13.1 and Python 3.5.

Baseline demographic, behavioral, and clinical characteristics are presented in Tables 2 and 3. The mean age of participants was 33 (SD 9) years, and the majority of the study population was female (77.2%, 994/1288) and identified as Caucasian (88.3%, 1137/1288). Participants reported on average 2.2 mental health diagnoses. The most frequently reported diagnoses were depression, with no further specification (53.3%, 687/1288); anxiety, with no further specification (47.8%, 616/1288); and generalized anxiety disorder (43.7%, 563/1288). Common comorbidities included asthma (19.7%, 252/1277), hypertension (16.1%, 206/1277), and insomnia (15.0%, 191/1277).

At baseline, 94.8% (1211/1277) of study participants reported experiencing depression or anxiety symptoms in the last year. A total of 40.4% of the study population (516/1277) had moderate to severe anxiety (GAD-7 score $\geq 10$) and 43.7% of the study population (558/1277) had moderate to severe depression (PHQ-9 score $\geq 10$). Approximately half of the participants were taking prescription medications for anxiety or depression and 29.2% (373/1277) were currently undergoing therapy for their anxiety or depression. Based on activity tracker data from 90 days prior to study enrollment, participants walked on average 7527 (SD 3282) steps and slept 6.92 (SD 1.63) hours in a 24-hour period.
Figure 1. Study flow.

Patients assessed for eligibility (initiated online screener) (n=1742)

Did not complete screener (n=184)

Eligible based on screening criteria (n=1426)

Excluded by screening criteria (n=132)

Completed informed consent/Enrolled in study (n=1304)

Started but did not complete baseline assessment (n=11)

Completed baseline assessment (n=1277)

Connected an activity tracker (n=1249)

Had activity tracker-based data for at least 60 of the 90 days prior to study enrollment (n=1068)

Figure 2. Geographic distribution of study participants. Point size is scaled by the number of participants per zip code.
Table 2. Baseline demographics and behavioral characteristics of enrolled participants.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics (n=1288)</strong></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>33 (9)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>994 (77)</td>
</tr>
<tr>
<td>Male</td>
<td>288 (22)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (1)</td>
</tr>
<tr>
<td><strong>Race/ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>22 (2)</td>
</tr>
<tr>
<td>Asian</td>
<td>27 (2)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>1137 (88)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>39 (3)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>57 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (1)</td>
</tr>
<tr>
<td><strong>Behavioral characteristics (n=1068)</strong></td>
<td></td>
</tr>
<tr>
<td>Daily steps, mean (SD)</td>
<td>7527 (3282)</td>
</tr>
<tr>
<td>Daily sleep (hours), mean (SD)</td>
<td>6.92 (1.63)</td>
</tr>
</tbody>
</table>
Table 3. Clinical characteristics of enrolled participants.

<table>
<thead>
<tr>
<th>Participant group and clinical characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responses from participants that started the baseline assessment (n=1288)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>BMI category, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt;18.5)</td>
<td>25 (2)</td>
</tr>
<tr>
<td>Normal weight (18.5-24.9)</td>
<td>396 (31)</td>
</tr>
<tr>
<td>Overweight (25-29.9)</td>
<td>371 (29)</td>
</tr>
<tr>
<td>Obese (&gt;30)</td>
<td>496 (39)</td>
</tr>
<tr>
<td><strong>Mental health diagnosis, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Anxiety, no further specification</td>
<td>616 (48)</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>93 (7)</td>
</tr>
<tr>
<td>Depression, no further specification</td>
<td>687 (53)</td>
</tr>
<tr>
<td>Generalized anxiety disorder</td>
<td>563 (44)</td>
</tr>
<tr>
<td>Major depressive disorder</td>
<td>214 (17)</td>
</tr>
<tr>
<td>Obsessive-compulsive disorder</td>
<td>109 (9)</td>
</tr>
<tr>
<td>Panic disorder, with or without agoraphobia</td>
<td>156 (12)</td>
</tr>
<tr>
<td>Phobic anxiety disorder</td>
<td>21 (3)</td>
</tr>
<tr>
<td>Postpartum depression</td>
<td>69 (5)</td>
</tr>
<tr>
<td>Posttraumatic stress disorder</td>
<td>207 (16)</td>
</tr>
<tr>
<td>Other</td>
<td>113 (9)</td>
</tr>
<tr>
<td>Number of mental health diagnoses, mean (SD)</td>
<td>2.21 (1)</td>
</tr>
<tr>
<td><strong>Responses from participants that completed the baseline assessment (n=1277)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Anxiety severity based on the Generalized Anxiety Disorder Questionnaire (GAD-7) score, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Minimal or no anxiety (0-4)</td>
<td>302 (24)</td>
</tr>
<tr>
<td>Mild anxiety (5-9)</td>
<td>459 (36)</td>
</tr>
<tr>
<td>Moderate anxiety (10-14)</td>
<td>290 (23)</td>
</tr>
<tr>
<td>Severe anxiety (15-21)</td>
<td>226 (18)</td>
</tr>
<tr>
<td><strong>Depression severity based on the Patient Health Questionnaire (PHQ-9) score, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Minimal or no depression (0-4)</td>
<td>272 (21)</td>
</tr>
<tr>
<td>Mild depression (5-9)</td>
<td>447 (35)</td>
</tr>
<tr>
<td>Moderate depression (10-14)</td>
<td>305 (24)</td>
</tr>
<tr>
<td>Moderately severe depression (15-19)</td>
<td>163 (13)</td>
</tr>
<tr>
<td>Severe depression (20-27)</td>
<td>90 (7)</td>
</tr>
<tr>
<td>Symptoms of anxiety or depression in the past year, n (%)</td>
<td>1211 (95)</td>
</tr>
<tr>
<td><strong>Common comorbidities, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>252 (20)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>206 (16)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>191 (15)</td>
</tr>
<tr>
<td>Irritable bowel syndrome</td>
<td>169 (13)</td>
</tr>
<tr>
<td>Gastroesophageal reflux disease (GERD)</td>
<td>159 (13)</td>
</tr>
<tr>
<td>Currently taking prescription medications for anxiety or depression, n (%)</td>
<td>673 (53)</td>
</tr>
<tr>
<td><strong>Types of therapies utilized for anxiety or depression, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>One-on-one psychotherapy or counseling, in-person</td>
<td>308 (24)</td>
</tr>
<tr>
<td>Psychotherapy or counseling through a mobile or online app</td>
<td>11 (1)</td>
</tr>
</tbody>
</table>
Disease Severity, Health Care Utilization, and Medication Use

Baseline health care utilization for subgroups of the study population based on the disease severity classification methods (Methods 1 and 2) is presented in Table 4. Participants with depressive symptoms (based on PHQ-9) reported on average 0.011 more mental health–related hospitalizations in the past year than participants with minimal depressive symptoms, although this was not statistically significant (0.025 versus 0.014; $t_{1275}=-1.16, P=.25$). Similarly, participants with anxiety symptoms (based on GAD-7) reported 0.003 more mental health–related hospitalizations in the past year than participants with minimal depressive symptoms, although this was not statistically significant (0.021 versus 0.017; $t_{1275}=-0.43, P=.67$).

Participants with depressive symptoms were significantly more likely to be taking a mental health–related medication at baseline (57.9% versus 48.7%; $z=-3.27, P=.001$, two-tailed). A higher proportion of individuals with anxiety symptoms were taking mental health–related medications than those with minimal anxiety symptoms; however, this difference did not reach statistical significance (54.8% versus 51.3%; $z=-1.26, P=.21$, two-tailed).

Table 4. Health care utilization, medication usage, and disease severity.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Method 1</th>
<th>Method 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimal depressive symptoms (n=719)</td>
<td>Depressive symptoms (n=558)</td>
</tr>
<tr>
<td>Mental health–related hospitalizations in past year, mean (SD)</td>
<td>0.014 (0.16)</td>
<td>0.025 (0.19)</td>
</tr>
<tr>
<td>Taking mental health–related medication at study baseline, n (%)</td>
<td>350 (48.7)$^a$</td>
<td>323 (57.9)$^a$</td>
</tr>
</tbody>
</table>

$^aP=.001$.

Behavioral Analysis

The baseline behavioral metrics for subgroups of the study population based on the four classification methods is presented in Tables 5 and 6. Individuals with depressive symptoms were less active than those with minimal depressive symptoms. On average, individuals with depressive symptoms took 603 fewer steps per day than those with minimal depressive symptoms ($u=155751.0, P<.001$) and had 4.3% fewer high step days than those with minimal depressive symptoms ($u=154478.0, P<.001$). Individuals taking depression- or anxiety-related medication at baseline were also less active than those who were not taking medication. On average, individuals taking medication took 429 fewer steps per day than those who were not taking medication ($u=127449.0, P<.001$). Individuals with depressive symptoms or taking depression- or anxiety-related medication had more inconsistent sleep patterns, as measured by a higher coefficient of variation (CV) for daily sleep and higher daily sleep intensity, compared to those with minimal depressive symptoms or not on treatment. Individuals with a history of depression- or anxiety-related hospitalization also had more inconsistent sleep patterns, as measured by a higher CV for daily sleep, than those who had not been hospitalized. Comparing individuals based on anxiety symptoms (Method 2) did not yield any statistically significant differences between the two subgroups.
Table 5. Behavioral variables by classification method (Methods 1 and 2).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Method 1</th>
<th>Method 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimal depressive symptoms</td>
<td>Depressive symptoms</td>
</tr>
<tr>
<td>Walk metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, n</td>
<td>617</td>
<td>451</td>
</tr>
</tbody>
</table>
| Daily steps, mean (SD)  | 7782 (3759) | 7179 (3882)
| CV<sup>b</sup> daily steps | 0.48      | 0.50      | 0.48       | 0.50          |
| Steps intensity, %      | 35.2     | 41.1     | 36.6      | 39.4          |
| Low step days, %        | 2.1      | 2.8      | 2.3       | 2.6           |
| High step days, %       | 28.5     | 24.2<sup>a</sup> | 27.7      | 25.1          |
| Sleep metrics           |          |          |
| Participants, n         | 501      | 373      | 526       | 348           |
| Daily sleep, mean (SD)  | 6.97 (1.61) | 6.86 (1.60)| 6.93 (1.60) | 6.91 (1.69) |
| CV daily sleep          | 0.23     | 0.26<sup>a</sup> | 0.24      | 0.25          |
| Daily sleep intensity, %| 14.4     | 16.4<sup>a</sup> | 15.5      | 14.8          |
| Low sleep days, %       | 4.1      | 5.4<sup>a</sup> | 4.4       | 5.1           |
| High sleep days, %      | 8.3      | 9.3      | 8.2       | 9.6           |

<sup>a</sup>P<.001, false discovery rate–corrected P value for multiple comparisons.
<sup>b</sup>CV: coefficient of variation.

Table 6. Behavioral variables by classification method (Methods 3 and 4).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Method 3</th>
<th>Method 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No history of hospitalization</td>
<td>History of hospitalization</td>
</tr>
<tr>
<td>Walk metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, n</td>
<td>1055</td>
<td>13</td>
</tr>
<tr>
<td>Daily steps, mean (SD)</td>
<td>7515 (3788)</td>
<td>8540 (6118)</td>
</tr>
<tr>
<td>CV&lt;sup&gt;b&lt;/sup&gt; daily steps</td>
<td>0.49</td>
<td>0.48</td>
</tr>
<tr>
<td>Steps intensity, %</td>
<td>37.6</td>
<td>45.7</td>
</tr>
<tr>
<td>Low step days, %</td>
<td>2.4</td>
<td>2.1</td>
</tr>
<tr>
<td>High step days, %</td>
<td>26.7</td>
<td>29.3</td>
</tr>
<tr>
<td>Sleep metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, n</td>
<td>863</td>
<td>11</td>
</tr>
<tr>
<td>Daily sleep, mean (SD)</td>
<td>6.93 (1.63)</td>
<td>6.59 (1.71)</td>
</tr>
<tr>
<td>CV daily sleep</td>
<td>0.25</td>
<td>0.36&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Daily sleep intensity, %</td>
<td>15.2</td>
<td>18.0</td>
</tr>
<tr>
<td>Low sleep days, %</td>
<td>4.6</td>
<td>10.4</td>
</tr>
<tr>
<td>High sleep days, %</td>
<td>8.7</td>
<td>12.0</td>
</tr>
</tbody>
</table>

<sup>a</sup>P<.001, false discovery rate–corrected P value for multiple comparisons.
<sup>b</sup>CV: coefficient of variation.
Discussion

Principal Findings

This virtual 1-year observational study was designed to create a longitudinal data set of validated patient reported outcomes; health care utilization and treatment; and behavioral data for individuals with anxiety or depression to understand how passively collected behavioral data can help provide insights into an individual’s overall health.

This analysis found that certain passively tracked behavioral traits are associated with more severe forms of anxiety or depression, as indicated by validated disease severity scales, health care utilization, and medication usage. In particular, severe forms of depression, as measured by PHQ-9, were significantly associated with inconsistent sleep patterns and more disordered sleep. Individuals who were taking anxiety- or depression-related medications slept directionally more but also had more inconsistent sleep patterns than individuals not on medication. Inconsistent sleep patterns were also a trait associated with individuals who had been hospitalized for their anxiety or depression. Further analyses should be conducted to understand whether sleep outcomes are associated with medication use (eg, side effects) or with the severity of the disease.

Our findings on associations between mental health severity and health care utilization were mixed. The baseline analysis found no significant difference in self-reported history of mental health–related hospitalizations among individuals with different levels of anxiety and depression severity, as measured by GAD-7 and PHQ-9, respectively. Given that the frequency of mental health hospitalizations per year was relatively low, we may not have had a large enough sample size to show statistical significance. Furthermore, while we found that a larger proportion of individuals with depressive symptoms were on medication at baseline than individuals with minimal depressive symptoms, other studies have found a trend of increasing medication usage in people with minimal depressive symptoms [13,14]. The proportion of individuals with anxiety symptoms who were on medication at baseline was directionally more than the proportion of individuals with minimal anxiety who were on medication at baseline, although this was not statistically significant. One potential explanation of this finding is that those with anxiety use medication as treatment less often than those with depression as nonpharmacological alternatives are effective (eg, cognitive behavioral therapy, meditation, exercise) [15-18]. Further analyses of the collected longitudinal data may be useful for examining the association between changes in disease severity over time and participants starting and stopping medications over time.

Strengths and Limitations

The design of this study has strengths as well as some limitations. This study was conducted completely virtually, which allowed for a geographically diverse population to enroll and participate in the study; this may increase the overall generalizability of the analyses and findings to a broader US population. Furthermore, about 90% of participants completed the online questionnaires at months 3, 6, 9, and 12, suggesting that it is feasible to engage large, digital populations in virtual studies to better understand health behaviors and outcomes. All behavioral data were passively collected via activity trackers and fitness and health apps, allowing us to capture everyday health behaviors (eg, step count) that may not otherwise be captured in traditional health care settings (eg, routine visits to a doctor’s office). Participants could complete their online assessments in the privacy of their own homes with minimal effort and disruption; they did not have to travel to clinics or have any in-person interactions when providing study data. This allowed us to capture truly real-world data; we were able to analyze this data combined with self-reported health outcomes to better understand the impact of anxiety and depression on individuals’ daily lives and behaviors. This suggests that passively collected digital data can help us characterize mental health illnesses like anxiety and depression beyond what is already captured in clinical measures (eg, GAD-7 and PHQ-9). Another strength is the 1-year duration of the study, which will allow us to examine how changes in behavioral data are associated with changes in disease severity (ie, worsening and improvement of symptoms) over time.

One of the limitations of this study is that it lacked a healthy comparison control group, which may limit findings in future analyses. However, as a first step to understand the associations between passively collected behavioral data and health outcomes, the observational nature of this study is likely sufficient. Although the study population was geographically diverse, the majority of participants were young, female, and Caucasian. However, our results are consistent with the epidemiology of anxiety and depression in the general population, showing a higher prevalence of anxiety and depression among younger age groups, women, and people who identify as White [19-22].

Conclusions

These promising initial findings suggest that longitudinal behavioral and health outcomes data may be useful for developing digital measures of health for mental health symptom severity and progression. In future analyses, we will aim to understand how longitudinal changes in behavioral data can be mapped to changes in disease severity and health care utilization over a 12-month period.

Acknowledgments

The authors would like to thank Leslie Oley, Julie Black, Peter Stradinger, Lauren Vucovich, and Joseph Ganz for product and engineering support; Jaspreet Uppal for clinical research support; and Mai Ka Vang for assistance with preparing the manuscript.
Conflicts of Interest
Evidation Health Inc owns the online study platform that was used for this study. SK and JLAT were employees of Evidation Health at the time the manuscript was written, and ER, LF, and JLJ are currently employed by Evidation Health.

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

Abbreviations
CV: coefficient of variation
GAD-7: Generalized Anxiety Disorder Questionnaire
PHQ-9: Patient Health Questionnaire
Development of an Emotion-Sensitive mHealth Approach for Mood-State Recognition in Bipolar Disorder

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Abstract

Internet- and mobile-based approaches have become increasingly significant to psychological research in the field of bipolar disorders. While research suggests that emotional aspects of bipolar disorders are substantially related to the social and global functioning or the suicidality of patients, these aspects have so far not sufficiently been considered within the context of mobile-based disease management approaches. As a multiprofessional research team, we have developed a new and emotion-sensitive assistance system, which we have adapted to the needs of patients with bipolar disorder. Next to the analysis of self-assessments, third-party assessments, and sensor data, the new assistance system analyzes audio and video data of these patients regarding their emotional content or the presence of emotional cues. In this viewpoint, we describe the theoretical and technological basis of our emotion-sensitive approach and do not present empirical data or a proof of concept. To our knowledge, the new assistance system incorporates the first mobile-based approach to analyze emotional expressions of patients with bipolar disorder. As a next step, the validity and feasibility of our emotion-sensitive approach must be evaluated. In the future, it might benefit diagnostic, prognostic, or even therapeutic purposes and complement existing systems with the help of new and intuitive interaction models.

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KEYWORDS
bipolar disorder; mood recognition; emotion recognition; monitoring; mobile apps; assistance system; mHealth

Introduction

With a prevalence of more than 1%, bipolar disorder is one of the most common mental disorders worldwide [1]. The disease is associated with the suffering of the affected people and their relatives and poses great challenges to them in their everyday lives [2,3]. The depressive and (hypo) manic episodes can have extensive social and economic consequences for patients with bipolar disorder and their families [3]. In particular, the high relapse rates within bipolar disorder are unsettling for all parties concerned: Even with pharmacological treatment [4] and different psychological approaches [5,6], these relapses cannot completely be prevented in many cases.

Because of the frequently severe and chronic course and the individual and social consequences, additional strategies and
support options within patient care are necessary [6,7]. With the proceeding technological development and the digitalization of the health care system, increasing attention has recently been paid to internet- and mobile-based interventions in the field of bipolar disorders [8-10]. Internet-based interventions, such as psychoeducational tutorials, can help to reach a great number of patients. Mobile-based approaches often assess real-time information about illness activity or deliver time-sensitive messages to patients in an ambulatory setting. To achieve this, most systems use smartphone technology, external sensor systems, or wearable devices (portable computer systems that assess and analyze psychophysiological data). In our research project, we developed a new mobile-based assistance system for bipolar disorder. In this viewpoint, we describe the theoretical and technological basis of our approach.

Over the past years, the use of smartphone apps or mobile programs has been investigated with samples of patients with bipolar disorder with an often good feasibility [11-16]. Because of the mobility of digital systems, for example, ambulatory self-assessments can easily be integrated in the patients’ daily routines. This benefits a better availability and can increase the adherence compared with nondigital approaches [11,12,17-19]. Furthermore, the self-assessment approach can be expanded by additional assessments of sensor data: wearable devices or internal smartphone sensors can be used to trace a patient’s mood state [20-22]. Thus, sensor data can aid in automatic recognition of mood-state changes and can support relapse prevention [23-27]. In order to improve disease management as well as treatment compliance and medication adherence in patients with bipolar disorder, self-assessments of patients can be combined with automatic feedback within certain situations [13,14,16,28]. Even simple SMS text message reminders two times per week can improve medication adherence of these patients and help them to create a more positive attitude toward their medication [29]. Interestingly enough, smartphone apps can also support the biological and social rhythms of patients with bipolar disorder. This might lead to a smaller degree of rhythmic disbalances in the long-term course of their disease [30-32]. Beyond that, several studies indicate that mobile-based approaches can reduce the symptom severity in bipolar or other mood disorders [13,14,33-36].

However, the existing approaches neglect the emotional aspects of bipolar disorders. For example, during mood episodes there are typical patterns of experienced emotions: whereas manic states are often characterized by increased happiness or anger and fear, depressive states often show patterns of elevated sadness and disgust [37]. Bipolar disorders are further associated with a generally amplified emotionality [38,39] and difficulties in emotion processing and regulation [40-44], in emotion recognition [45-47], and in the expression of emotions [48,49]. These deficits might partially be related to the current mood state of patients [41,46,47]. Yet, they strongly affect their social and global functioning and are related to severe outcome variables such as suicidality [39,40,42-45,48]. Consequently, emotional aspects have a great impact on the patients’ everyday lives and the long-term course of bipolar disorder.

So far, mobile-based approaches have analyzed the keyboard activity of patients with bipolar disorder [22] or even ambient sound samples [31,32,50] or voice features during phone calls [23,51]. However, to our knowledge, none of the referenced approaches have analyzed the emotional content of audio data or social interactions. Moreover, psychological research has so far focused on emotional responses of fully or partially remitted patients with bipolar disorder by analyzing their facial expressions during standardized tasks [48,49]. Yet, there does not exist any mobile-based approach that analyzes facial expressions of these patients regarding their emotional cues. In reference to the importance of emotional aspects in bipolar disorder, they should play a more important role in the design of mobile Health (mHealth) approaches too. Compared with other behavioral measures, the emotional expressions of patients with bipolar disorder could reflect their emotional reactivity more sensitively [49]. Beyond that, the ambulatory setting would allow to monitor individual changes over time and mood states in real life [52,53]. Thus, emotion-sensitive mHealth systems for bipolar disorder might even increase our understanding of the experienced and expressed emotions of patients or of their impact on the patients’ social and global functioning.

The EmAsIn Project

Within the EmAsIn project (Emotion-sensitive Assistance systems for the reactive psychological Interaction with people) we developed the first emotion-sensitive, technical assistance system for patients with bipolar disorder. Because self-assessments of symptoms are the well-established basis of mood monitoring in bipolar disorder [11,12,17-19], our system also includes regular self-assessments of patients. It further analyzes automatically assessed sensor data, because physiological or behavioral data have been shown to be useful in mood-recognition approaches [23-27] and sleep data have been in the focus of bipolar research for a certain period now [54]. In addition, we incorporated third-party assessments of relatives or related parties, because some patients themselves emphasize the importance of an external point of view regarding their current condition [55]. As a consequence, some of the pressure might be taken off the constant self-monitoring of patients with bipolar disorder. The additionally assessed data could also help in individual cases or during certain periods (e.g., during severe mood episodes) with less reliable or accurate self-assessments [56,57]. The importance of emotional aspects of bipolar disorders [37-49] motivated us to develop the key component of our system, the emotion-sensitive Story of the Day module. It analyzes audio and video data to explore the emotional experiences and expressions of patients. While many apps in this field are poorly investigated [58], we emphasized the importance of an empirically validated basis of our emotion-sensitive approach [59-61]. To consider the patients’ point of view, we initially started a dialogue with patients with bipolar disorder, which indicated their overall positive attitudes toward our innovative ideas [55].

System Concept and Features

Our assistance system includes an Android smartphone app and a connected wearable device, which can be both code protected and password protected. It uses multichannel data acquisition
to realize an early recognition of mood-state changes in bipolar disorder. It further intends to complement the rather technical exchange of information between systems and patients with new and intuitive interaction models. Therefore, it aims to recognize socioemotional cues in human communication behavior and hereby infer conclusions about emotional and mental states. To this end, the emotion-sensitive Story of the Day module analyzes the verbal and facial expressions of patients in short and actively user-triggered recordings with respect to their emotional content or the presence of emotional cues. Consequently, this module collects active and passive emotion-related data of patients with bipolar disorder and relies on its regular use (see “Story of the Day” section). If all the features of the assistance system are activated, it can gather information about mood states and the course of bipolar disorders with the aid of the following resources:

- daily self-assessments of patients regarding their mood, activity level, and other relevant symptoms;
- regular third-party assessments by relatives or other related parties regarding the most important symptoms;
- automatic assessments of (psycho-) physiological parameters such as heart rate or resting heart rate;
- automatic assessments of sleep duration and quality;
- automatic assessments of several behavioral parameters such as recognized activities, movement/acceleration, steps per day, range of motion, or smartphone usage behavior (eg, used apps, number of calls per day);
- assessments of auditive information (eg, voice, emotional content, speech duration, or breaks) as emotional cues and indicators of mood states;
- assessments of visual information (facial expressions) as emotional cues and indicators of mood states.

All data resources are presented in Table 1, which also indicates their mandatory or optional usage within the assistance system. Users can switch between different features and tasks by opening the menu of the app. If this feature is activated, the app reminds them of their tasks by using push notifications at a predefined time of the day. Daily self-assessments consist of six 7-point items (from −3 to 3) about symptoms that are relevant to depressive as well as to (hypo-) manic mood states. Negative values are predominantly associated with depressive symptoms, whereas positive values should reflect (hypo) manic states. In addition, as in earlier approaches [19], each user can choose from a given list of potential early warning signs (like mixed emotions or increased caffeine intake) or can create new items. These items are then incorporated into the daily self-assessments, where they are evaluated with yes or no. The third-party assessments are very similar to the self-assessments, but they are realized by using a separate and individually secured web application.

The assistance system uses smartphone sensors to assess several of the behavioral aspects, for instance, with regard to movement or social interaction (without analyzing content information). Information about sleeping behavior and (psycho-) physiological data is continuously collected with the help of the connected wearable device, which users wear on their wrists (see Multimedia Appendix 1 for more detailed information). Whereas most of the sensor data are automatically assessed, users are asked to use the Story of the Day module on a regular basis (eg, once per day). Once information is gathered through the different sources, the assistance system integrates all data with the aid of an external server and visualizes the accessed information in the form of graphic representations over time. In addition, users can implement a digital version of their own, personal crisis plan with individual strategies for different mood states and locally stored contact information. They can also enter information about their actual medication to use the medication reminder of the system. To facilitate the handling, users can use their own and secured web application to insert and manage information.

The system is supposed to recognize mood-state changes in patients with bipolar and to react by sending warning signals or, like other approaches [13,14,28,30], by proposing recommendations (eg, to consult a doctor) and self-management strategies. All system components are fully developed; only the interventions that depend on the automatic mood-state recognition have not been implemented at the actual stage of development. Apart from long-term analyses using big data approaches, neural networks, and machine learning approaches [62], we are pursuing rule-based evaluation models to allow for an increasing accuracy of the state recognition. To this end, patients can adjust the importance of certain parameters for their own mood-recognition approach. For example, they can assign values between 1 and 3 to each relevant factor (self-assessments, third-party assessments, behavioral, physiological and sleep data, or emotional expressions) to implicate their individual importance (with 1 being less important, 2 moderately important, and 3 very important). The system then includes the individual assignments when integrating and analyzing the assessed data. Beyond that, patients may also assign these values to the warning signs, which are then analyzed as separate factors. Figure 1 illustrates the concept of the assistance system.
Table 1. Data resources of the assistance system.

<table>
<thead>
<tr>
<th>Information source and its components</th>
<th>Parameters</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensor data</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Smartphone</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td>Range of motion&lt;sup&gt;a&lt;/sup&gt;, visited locations&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Activity and behavior</td>
</tr>
<tr>
<td>Accelerometer</td>
<td>Movements/acceleration&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Activity and behavior</td>
</tr>
<tr>
<td>Smartphone usage</td>
<td>Usage duration&lt;sup&gt;a&lt;/sup&gt;, number of calls&lt;sup&gt;a&lt;/sup&gt;, click rate&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Activity and behavior</td>
</tr>
<tr>
<td>Social interaction</td>
<td>Usage of social apps&lt;sup&gt;a&lt;/sup&gt;, number of messages (SMS text messages, emails, instant messengers)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Social behavior</td>
</tr>
<tr>
<td><strong>Wearable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital</td>
<td>Heart rate&lt;sup&gt;a&lt;/sup&gt;, resting heart rate&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Physiological data</td>
</tr>
<tr>
<td>Movement patterns</td>
<td>Steps/distance per day&lt;sup&gt;a&lt;/sup&gt;, recognized activities&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Activity and behavior</td>
</tr>
<tr>
<td>Sleep</td>
<td>Sleeping/wake up time&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Sleep duration</td>
</tr>
<tr>
<td></td>
<td>Bedtime/getting out of bed&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Sleep efficiency</td>
</tr>
<tr>
<td></td>
<td>Wake phases&lt;sup&gt;b&lt;/sup&gt;, activity at night&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Sleep quality</td>
</tr>
<tr>
<td><strong>Self-assessments</strong></td>
<td></td>
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<tr>
<td><strong>Smartphone</strong></td>
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<tr>
<td>Diary</td>
<td>Self-assessments&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Self-image</td>
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<tr>
<td><strong>Third-party assessments</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Web application</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diary</td>
<td>Third-party assessments&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Perception by others</td>
</tr>
<tr>
<td><strong>Story of the Day</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Smartphone</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microphone</td>
<td>Speech duration&lt;sup&gt;b&lt;/sup&gt;, breaks&lt;sup&gt;b&lt;/sup&gt;, words per minute&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Activity/urge to speak</td>
</tr>
<tr>
<td>Camera</td>
<td>Emotional words&lt;sup&gt;b&lt;/sup&gt;, color of the voice&lt;sup&gt;b&lt;/sup&gt;, loudness&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Emotional expression</td>
</tr>
<tr>
<td></td>
<td>Facial expressions&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Emotional expression</td>
</tr>
</tbody>
</table>

<sup>a</sup>Optional.  
<sup>b</sup>Mandatory.
Story of the Day

As opposed to earlier approaches, which analyzed ambient sound samples or voice features without processing emotional information [23,31,32,50,51], our emotion-sensitive module analyzes intentionally recorded sequences regarding the contained auditive and visual emotional cues. When a recording is initiated on the start screen of the Story of the Day module, the app uses the smartphone camera to capture video data. In order to secure a sufficient recording quality, the users mount their smartphones in well-positioned holders before activating this feature. Furthermore, external microphones are attached to the smartphones to improve the audio quality of the recordings. At the beginning of each recording sequence, the users are asked to describe an important event of their day. After telling their story the recording must actively be ended and the users are asked if they want to save the recording. If the microphone and camera do not record any information (ie, no recognized voice or face), the recording is automatically discontinued.

The app analyzes the assessed auditive and visual information separately. The verbal information is analyzed regarding the use of emotional words, the color of the voice, its energy level (ie, loudness), the verbal fluency, and the speech rate as well as the extent to which the story is narrated. The count of emotional words in automatic transcriptions of the used language of each recording is based on the Linguistic Inquiry and Word Count (LIWC) program [59] and includes the emotional categories of positive emotions, negative emotions, sadness, anxiety, or anger. The voice analysis follows the EmoVoice approach [60], a framework that uses acoustic signals as emotional classification units and recognizes emotional or mental states on the basis of these signals. For each audio file, the system analyzes segments of 250 ms and assigns values between 0 and 1 to the categories anger, boredom, disgust, fear, happiness, and sadness. The automatic recognition of emotions in facial expressions during the Story of the Day recordings is based on the Facial Action Coding System (FACS) [61]. In short intervals of 1 frame/second, facial expressions are examined evaluating the 4 emotions, namely, happiness, sadness, anger, and anxiety. For each emotion, the percentage frequency of its coding is calculated.

Discussion

Internet- and mobile-based approaches have become increasingly important to psychological research in the field of bipolar disorders. In particular, the aspiring mHealth approach benefits a consistent self-monitoring of patients with bipolar disorder [11,12,17-19] and allows for mood-recognition approaches based on automatically assessed sensor data [20,21,23-27]. Our new assistance system incorporates some of the well-known components of mHealth systems for bipolar disorder and combines them with the innovative features of third-party assessments and the analysis of emotional expressions.

While the self-perception of patients with bipolar disorder is certainly the most important factor in mood monitoring, self-assessments can be less reliable in specific cases or during severe episodes [56,57]. Beyond that, some patients trust the assessments of relatives or related parties more than their own perception, when it comes to their mood states [55]. Thus, our third-party assessments could help to gain a more comprehensive
view regarding the patients’ mood states. In reference to the great burden, which bipolar disorders are putting on the relationships of patients [63], the third-party assessments might even reduce some of the tension: They can shift the external feedback from possibly strained direct interactions to regular web-based assessments.

Our Story of the Day module, as far as we know, is the first mobile-based approach to analyze the emotional expressions of patients with bipolar disorder. As opposed to the analysis of ambient sound samples or voice features during phone calls [23,31,32,50,51], the actively user-triggered Story of the Day recordings allow us to analyze visual and auditive information as well as the emotional content of the spoken language. The well-established FACS [61], LIWC [59], and EmoVoice approach [60] should provide the technical implementation of our emotion-recognition approach with some helpful framework. This development is especially promising when the effects of emotional deficits on the social and global functioning of patients are considered [39,40,42-45,48]. Consequently, our emotion-sensitive approach is not only interesting in the context of mood-state recognition but might also increase our understanding of experienced and expressed emotions of patients with bipolar disorder. The received feedback in regard to their emotional expressions might be especially informative to patients without regular or with strained social interactions. Moreover, the emotional and narrative character of our Story of the Day module might aid a less technical or distant usage experience and might motivate patients to reflect upon their daily (social) experiences and interactions.

Of course, our new assistance system comes with its limitations. Most importantly, the predictive value of our approach concerning its mood-state recognition and its efficacy and effectiveness with respect to relapse prevention has to be addressed in empirical studies with patients with bipolar disorder. In addition, not all patients approve of the involvement of relatives or related parties in their mood-monitoring approach [55]. Our Story of the Day module must also be used on a regular basis to enable its automatic analysis of emotional expressions. Thus, like self-monitoring systems, our emotion-sensitive approach may depend on the patients’ mood state and motivation. However, as a consequence, the Story of the Day module does not automatically assess audio or video data and thus does not interfere with the patients’ privacy or personal space. Beyond that, our assistance system allows patients to activate or deactivate certain features (eg, the third-party assessments) and meets the patients’ expectations of flexible systems [55,64]. Furthermore, based on our preliminary findings, we estimate that the Story of the Day recordings should not take up more than 2 minutes per day. In the future, our Story of the Day approach might be even less effortful as it could possibly be realized in a more natural setting without smartphone holders or external microphones.

Whereas the EmoVoice approach [60] and, in part, the LIWC approach [59] incorporate the analysis of verbally expressed disgust into our emotion-sensitive module, the Story of the Day module does not recognize this emotion in the facial expressions of patients. Because disgust is one of the more frequently experienced emotions in bipolar disorder [37], subsequent mobile-based FACS approaches [61] should possibly be programmed to include this emotion as well. Finally, our Story of the Day module does not react to suicidal statements and suicidality is not assessed during the self-assessments. The monitoring of suicidal tendencies or even time-sensitive interventions in case of severe suicidal crises with technological help comes with extensive ethical or legal considerations and can have unexpected effects [65]. Accordingly, before implementing such features into mobile-based approaches for bipolar disorder, their feasibility and effects should be examined thoroughly.

With this in mind, there are still some issues to be dealt with in the further development of our assistance system and more research is needed to examine the clinical value of our system. However, our assistance system and its new and innovative features might improve the understanding of the patients’ mood state and could provide important information about the patients’ expressed emotions as well as their (social) interaction behavior. Considering the strong association between emotional aspects and the social and global functioning of patients with bipolar disorder, in the future, emotion-sensitive systems might be even useful during emotion-based treatment approaches in bipolar disorder [66-68].

Conclusion

The mHealth approach offers many opportunities to support patients with bipolar disorder in their everyday struggle with their disease. However, the existing mobile-based approaches do not consider the importance of emotional aspects in bipolar disorder and their implications regarding the social and global functioning of patients. With our assistance system, we aim to address this issue and have therefore implemented the emotion-sensitive Story of the Day module. With the help of this module, our system analyzes the emotional experiences and expressions of patients besides regular self-assessments and third-party assessments as well as the analysis of further sensor data. In the future, emotion-sensitive approaches might not only benefit a better understanding of the patients’ emotional states, but they might also be used to complement the technical exchange of information between systems and patients with more intuitive interaction models. Moreover, they might even support emotion-based interventions in bipolar disorder.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Assessment and analysis of sleep data.

[DOCX File, 13 KB - mental_v7i4e14267_app1.docx ]

References


Abbreviations

FACS: Facial Action Coding System
LIWC: Linguistic Inquiry and Word Count

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Methodological Challenges in Web-Based Trials: Update and Insights From the Relatives Education and Coping Toolkit Trial

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Abstract

There has been a growth in the number of web-based trials of web-based interventions, adding to an increasing evidence base for their feasibility and effectiveness. However, there are challenges associated with such trials, which researchers must address. This discussion paper follows the structure of the Down Your Drink trial methodology paper, providing an update from the literature for each key trial parameter (recruitment, registration eligibility checks, consent and participant withdrawal, randomization, engagement with a web-based intervention, retention, data quality and analysis, spamming, cybersquatting, patient and public involvement, and risk management and adverse events), along with our own recommendations based on designing the Relatives Education and Coping Toolkit randomized controlled trial for relatives of people with psychosis or bipolar disorder. The key recommendations outlined here are relevant for future web-based and hybrid trials and studies using iterative development and test models such as the Accelerated Creation-to-Sustainment model, both within general health research and specifically within mental health research for relatives. Researchers should continue to share lessons learned from conducting web-based trials of web-based interventions to benefit future studies.

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KEYWORDS
randomized controlled trial; research design; methods; internet; web; mental health; relatives; carers

Introduction

Background

There has been rapid growth in the development of digital interventions [1]. One of the many challenges for researchers is testing the effectiveness of web-based interventions, whether through a web-based or hybrid (web-based and offline) trial, or a more iterative process such as the Accelerated Creation-to-Sustainment (ACTS) model [2], to meet the National Institute for Health and Care Excellence (NICE) standards for evidence-based web-based interventions. Other challenges include developing digital intervention theories, methods for detailed economic evaluation, assessing the generalizability of
results to determine what works for whom in what context [3], and finding systems and approaches that can be easily adopted by the UK National Health Service (NHS) or other health care providers.

Murray et al [4] explored the methodological challenges associated with web-based trials of web-based interventions (recruitment, randomization, fidelity of the intervention, retention, and data quality), drawing upon learning from the Down Your Drink (DYD) web-based trial. The main challenges they faced were the risk of participants undermining randomization by reregistering with different details, difficulties in collecting any objectively measured data, and the high rate of attrition.

Since then, there have been a number of reviews of the methodological challenges associated with evaluating digital interventions [5-7], and many studies have focused on specific challenges such as recruitment [8-11], retention [12-19], and intervention engagement [17,18,20-26].

This paper updates Murray et al’s [4] analysis by sharing learning from a national web-based randomized controlled trial (RCT) of an intervention aimed at reducing distress in relatives of people with psychosis or bipolar disorder (Textbox 1).

Textbox 1. Case study: Relatives Education and Coping Toolkit randomized controlled trial.

- **Aim**: To evaluate the clinical- and cost-effectiveness of a web-based, peer-supported–self-management intervention, the Relatives Education and Coping Toolkit (REACT), for relatives of people with psychosis or bipolar disorder.

- **Methods**:
  - **Design**: A primarily web-based, two-arm, pragmatic, observer-blind, randomized controlled superiority trial.
  - **Setting**: The World Wide Web.
  - **Participants**: Based in the United Kingdom, English speaking, currently distressed, and help-seeking relatives of people with psychosis or bipolar disorder, aged ≥16 years, with access to the internet.
  - **Intervention**: The REACT toolkit providing National Institute for Health and Care Excellence recommended information and support through digital, peer-supported, self-management for relatives. REACT included 12 psychoeducation modules, a peer-supported group forum, private messaging to a trained relative (REACT supporter), and a resource directory (RD), ie, a comprehensive list of existing support for relatives. Relatives also received treatment as usual (TAU).
  - **Comparator**: RD only, plus TAU.
  - **Primary outcome**: Relatives’ distress at 24 weeks, measured by the General Health Questionnaire-28 [38].
  - **Procedures**: Recruitment took place through mental health services in the United Kingdom, charities, media, social media, and web-based advertisements. Consent, baseline data collection, and randomization were undertaken on the web through a secure system hosted at Liverpool Clinical Trials Research Centre. Follow-up was conducted primarily using web-based reminder emails, supplemented by additional offline phone calls, texts, and posts. Participants received £10 (US $1.24) on follow-up completion at 12 weeks, and either £10 (US $1.24) or £20 (US $2.48), upfront or on follow-up completion at 24 weeks.

**Design**

This study consists of a discussion paper based on a case study of a web-based RCT of a web-based intervention aimed at relatives of people with psychosis or bipolar disorder (Textbox 1). We have followed the structure of the original Murray et al paper [4] for each key trial parameter and present a brief update from the literature (called past work), including recommendations from the Murray paper. This literature update is based on a nonsystematic scoping search of the literature since the Murray paper (using the search term online randomized controlled trial). The literature update is followed by discussing our own experiences, using the REACT trial approach and results (REACT). Finally, we provide implications for future trials with regard to each key trial parameter (future work).

**Updates and Insights**

**Recruitment**

**Past Work**

Murray et al [4] recommend having a well-planned recruitment strategy which is piloted, advertised on well-known sites, includes patient and public involvement (PPI) input on the recruitment material, and ensures a balance between the ease of recruitment material and sufficient hurdles to ensure
participants are aware of what they are agreeing to, for example, follow-ups.

Study promotion and recruitment approaches have been identified as important determinants of successful recruitment [39]. A combination of web-based and offline strategies has worked well to recruit participants into web-based trials in health research [19,40]. Despite some challenges, such as cost, the potential for misrepresentation, and potentially low trial recruitment rates [11], Facebook has proved to be a highly successful web-based recruitment strategy [19,41].

Previous studies have found a difference in demographics depending on whether participants were recruited on the web or offline [19,38,39], but not all studies have identified the same differences. There is some agreement that more females than males come into research through web-based strategies, such as Facebook [19,42], and evidence that more highly educated participants are more likely to be recruited offline [19]. Some studies have found that older participants are more likely to be recruited through web-based strategies [19,40], whereas others have found that younger people are more likely to be recruited on the web [11,39]. Differences in the demographic characteristics of participants by recruitment strategy suggest that increasing the breadth of recruitment sources may increase sample diversity and, therefore, the generalizability of trial findings. Continually reviewing the success of recruitment strategies during a trial may increase the likelihood of meeting recruitment targets [19].

**Relatives Education and Coping Toolkit**

In line with Murray et al’s [4] recommendations, the REACT trial used a well-planned recruitment strategy combining web-based (Twitter, Facebook, online forums, Google Ads, web-based newspaper article, and NHS and mental health charity websites) and offline (mental health teams, general practitioners (GPs), universities, radio, NHS, and service user and caregiver support groups) recruitment strategies between April 22, 2016, and September 30, 2017. Strategies and materials were coproduced with REACT supporters (trained relatives employed on the trial team), who also supported recruitment. Participants were asked how they had heard about REACT (using a drop-down menu) as part of the trial registration.

The recruitment target of 666 relatives was exceeded within the recruitment period (N=800). Participants were typically middle-aged (40-60 years; 422/800, 52.8%), white British (727/800, 90.9%), female (648/800, 81.0%), and educated to university graduate level (437/800, 54.6%). Similar demographic characteristics have been found in web-based trials of web-based smoking cessation interventions [9,19]. The highest proportion of participants were mothers (387/800, 48.3%), supporting a young adult aged ≤35 years (485/800, 60.6%) with more than half of these supporting someone with bipolar disorder (462/800, 57.8%). Most were supporting only 1 person with a mental health problem, but some (209/800, 26.1%) reported supporting two or more people, and many (457/800, 57.1%) had other dependents. Over half (485/800, 60.6%) were married or in a civil partnership. Most relatives were working: some were in full-time work (301/800, 37.6%), some were in part-time employment (188/800, 23.5%), whereas others undertook voluntary work (23/800, 2.9%). A small group (66/800, 8.3%) were unable to work because of their caregiving commitments. The vast majority had good quality home internet access (795/800, 99.4%). The population recruited was similar to that recruited in face-to-face trials of caregiver interventions [43]; therefore, although the sample was biased in terms of demographics (eg, most participants being white British, female, and mothers), there is no clear evidence that this bias was related to the trial being based on the web.

As part of a post hoc analysis, we explored the relationship between key demographic variables and web-based versus offline recruitment. There was no pattern regarding who came into the trial through web-based versus offline strategies in terms of age (N=800; $\chi^2=5.5; \ P=.36$) or education level (N=800; $\chi^2=1.9; \ P=.40$). However, in line with previous research [19,42], more females were recruited through web-based strategies compared with males (N=800; $\chi^2=16.7; \ P<.001$).

The success of each recruitment strategy used was indicated by the number of randomized participants who were recruited via each strategy (Table 1). Of the randomized participants, more than half (421/800, 52.6%) were recruited through 5 primary web-based strategies, and less than half (379/800, 47.4%) were recruited through 10 primary offline strategies. The most successful strategies (Facebook and mental health teams or other professionals) were also two of the most expensive. The costs associated with Facebook related to outsourcing Facebook advertisements to an information technology company for development and maintenance. Over 13 months, 873,096 individuals were reached; 53,216 people engaged with an advertisement (liking, commenting, or sharing), and there were 71,026 clicks on the REACT website. The costs associated with mental health teams/professionals were related to service support costs for staff time, trial manager and REACT supporter time, and promotional material. We decided to use the available data on costs incurred, in line with our in-trial analytical approach, rather than hypothetical data on costs of an NHS model of referral to the intervention. Recruitment costs for the trial were calculated over the total trial period and divided by 3287, the number of people who completed eligibility screening for the trial. Cost included an average per participant in both arms of the trial, as both required recruitments. Recruitment costs for each strategy were divided by the number of participants who were recruited (and randomized) via that strategy. The components and total cost of recruitment are outlined in Table 2.
Table 1. Recruitment strategies for randomized participants.

<table>
<thead>
<tr>
<th>Recruitment strategies for randomized participants</th>
<th>Web-based/offline</th>
<th>Values, n (%)</th>
<th>Approximate cost per participant (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facebook</td>
<td>Web-based</td>
<td>206 (25.8)</td>
<td>93 (US $115.39)</td>
</tr>
<tr>
<td>Mental health teams/professionals</td>
<td>Offline</td>
<td>151 (18.9)</td>
<td>107 (US $132.77)</td>
</tr>
<tr>
<td>Internet search</td>
<td>Web-based</td>
<td>121 (15.1)</td>
<td>28 (US $34.74)</td>
</tr>
<tr>
<td>Mental health charities(^a)</td>
<td>Web-based</td>
<td>77 (9.6)</td>
<td>38 (US $47.15)</td>
</tr>
<tr>
<td>Recommended by a friend/family</td>
<td>Offline</td>
<td>74 (9.3)</td>
<td>0</td>
</tr>
<tr>
<td>GP(^b)</td>
<td>Offline</td>
<td>59 (7.4)</td>
<td>170 (US $210.94)</td>
</tr>
<tr>
<td>Caregiver or service-user support group</td>
<td>Offline</td>
<td>42 (5.3)</td>
<td>4 (US $4.96)</td>
</tr>
<tr>
<td>NHS(^c) contacts</td>
<td>Offline</td>
<td>25 (3.1)</td>
<td>()(^d)</td>
</tr>
<tr>
<td>Twitter</td>
<td>Web-based</td>
<td>15 (1.9)</td>
<td>2 (US $2.48)</td>
</tr>
<tr>
<td>Employer</td>
<td>Offline</td>
<td>8 (1.0)</td>
<td>32 (US $412.51)</td>
</tr>
<tr>
<td>Other third sector organization</td>
<td>Offline</td>
<td>8 (1.0)</td>
<td>()</td>
</tr>
<tr>
<td>Not classifiable</td>
<td>Offline</td>
<td>6 (0.8)</td>
<td>()</td>
</tr>
<tr>
<td>Other public adverts (excluding NHS adverts)</td>
<td>Offline</td>
<td>4 (0.5)</td>
<td>()</td>
</tr>
<tr>
<td>Local newspaper</td>
<td>Web-based</td>
<td>2 (0.3)</td>
<td>65.4 (US $81.15)</td>
</tr>
<tr>
<td>Research team</td>
<td>Offline</td>
<td>2 (0.3)</td>
<td>()</td>
</tr>
</tbody>
</table>

\(^a\)Mental health charities used a combination of web-based and offline strategies; however, most were web-based, and by far, the biggest recruiter was Bipolar UK, and their main means of recruitment were email-newsletters.

\(^b\)GP: general practitioner.

\(^c\)NHS: National Health Service.

\(^d\)Value unknown.

Table 2. Recruitment costs.

<table>
<thead>
<tr>
<th>Recruitment strategy</th>
<th>Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisements (Facebook, Google, and Bipolar UK)</td>
<td>11,059.56 (US $13722.70)</td>
</tr>
<tr>
<td>Printing</td>
<td>1526.00 (US $652.66)</td>
</tr>
<tr>
<td>Flyers and postage</td>
<td>50.00 (US $62.04)</td>
</tr>
<tr>
<td>Total recruitment costs</td>
<td>12,635.56 (US $15678.20)</td>
</tr>
</tbody>
</table>

Despite designing a broad (throughout the United Kingdom) recruitment strategy incorporating a wide range of both web-based and offline methods, our sample predominantly comprised middle-aged, highly educated, white British females, who cared for an individual with bipolar disorder. It is possible that the predominance of highly educated individuals reflects the interest of this group in research and self-education. Moreover, the predominance of female participants could partially reflect the continuing burden of care falling to women. The lack of relatives from ethnic minority groups could result from both bias in the referral process of offline recruitment strategies and from lack of cultural adaptation in content and language, both of which were beyond the scope of this study, but is also a persistent failure across mental health services more widely.

**Future Work**

A combination of web-based and offline strategies worked well to recruit relatives of people with psychosis/bipolar disorder. Although mental health teams/professionals proved a successful recruitment avenue, recruitment targets would not have been met if this had been the only strategy used. NHS trusts and GP practices rarely have an accurate, up-to-date method of identifying relatives. Therefore, recruitment is often through the patient, who may forget or not wish to pass the information on. Bolstering offline NHS recruitment with web-based strategies such as social media is effective, with Facebook proving most successful. That said, expert knowledge of how to target Facebook adverts and test the effectiveness of different ones may be required for cost-effective advertisement.

Monitoring of recruitment strategy success is important to adapt and refocus time, money, and effort. For example, we stopped relatively unsuccessful and costly Google Ads (classified under Advertisements in Table 1) and concentrated on successful (yet still costly) Facebook advertisements.

Despite the extensive recruitment strategy applied in the REACT trial, predominantly highly educated, white British female participants, who cared for an individual with bipolar disorder were recruited, which creates a problem with generalizability.
NHS research and development departments need to ensure better availability of caregiver data so that offline recruitment methods can be made more effective, and clinical trials (both offline and web-based) can be made more accessible. Moreover, cultural adaptation should be a key focus of future work in this area to ensure that digital health interventions do not exacerbate existing inequalities in access to health care.

Registration Eligibility Checks

Past Work

Murray et al [4] did not specifically review registration and eligibility checks. Buis et al [8] analyzed help tickets (provided by 38% of participants) logged in a database during enrolment into a web-based RCT of a walking program and found that the most common issue was related to the study process. Being older, female, and having a lower self-rated internet ability increased the likelihood of reporting an issue during enrolment.

As with all trials, randomized participants must meet strict eligibility criteria to adhere to the protocol. In web-based trials, there is an increased risk of not detecting participants who may have misrepresented their eligibility to take part, perhaps because of seeking payment or potential access to treatment [10]. Kramer at al [10] suggested procedural (eg, not advertising payment), technical (eg, tracking internet protocol [IP] addresses to identify multiple registrations), and data analytic strategies (eg, sensitivity analyses) to address sample validity in studies using the internet for recruitment.

Relatives Education and Coping Toolkit

The registration process aimed to check eligibility (using web-based checkboxes), ensure consent was fully informed, avoid participants registering more than once, and encourage completion of baseline questionnaires before randomization. On the basis of PPI feedback, the landing page had limited text, included videos, and highlighted the required commitment to follow-ups (as recommended by Murray et al [4]). Strategies were also employed beyond the landing page to encourage trial registration—the inclusion of lay language to explain processes and encourage continuation, a progress bar, phone number activation (participants verified their phone number by inputting a code sent to their mobile/landline into the registration system), automated reminder emails 24 hours after consent and 7 days after baseline questionnaires were started, and the option to have direct contact with the trial manager on the web or by telephone.

Overall, 43% of those who completed the eligibility checks failed on at least one item, most commonly (81% of those failing) on the requirement to report being strung up and nervous all the time, rather more than usual, or much more than usual (Table 3). This item was included in the screening process to avoid a floor effect at baseline. It showed the highest item-total correlation with the total General Health Questionnaire-28 (GHQ-28) [38] scores in our feasibility study [44]. However, relatives who had been distressed for longer periods and so responded no more than usual were ineligible. Following contact from ineligible participants highlighting their frustration at being excluded from this item, lay language pop-ups were included to explain why certain criteria were important and had not been met. These pop-ups did not enable potential participants to change their answers, but there was nothing to stop the participant attempting to progress by reaccessing the eligibility process. This information helped participants to understand why they were not eligible and alleviated frustration (we did not receive any further contact from participants regarding issues with eligibility after the introduction of these pop-ups).

Table 3. Eligibility details.

<table>
<thead>
<tr>
<th>Question</th>
<th>Number of participants failing eligibility for the question, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am 16 years old or over</td>
<td>10 (1)</td>
</tr>
<tr>
<td>I am a relative (or close friend providing regular support) of someone with psychosis or bipolar disorder</td>
<td>88 (6)</td>
</tr>
<tr>
<td>Have you recently been feeling nervous and strung up all the time?</td>
<td>1146 (80.9)</td>
</tr>
<tr>
<td>I would like to receive help for my distress through an online toolkit</td>
<td>118 (8.3)</td>
</tr>
<tr>
<td>I have regular access to a computer which is connected to the internet</td>
<td>28 (2)</td>
</tr>
<tr>
<td>I have a good working knowledge of written and spoken English language</td>
<td>13 (1)</td>
</tr>
<tr>
<td>I live in the UKa</td>
<td>13 (1)</td>
</tr>
<tr>
<td>To the best of my knowledge, I am the only relative/close friend of the person I support taking part in the REACTb study</td>
<td>67 (5)</td>
</tr>
</tbody>
</table>

*aUK: United Kingdom.

bREACT: Relatives Education and Coping Toolkit.

Future Work

Our Relatives Advisory Group (RAG) recommended the following strategies for the REACT trial: limiting text, adding videos highlighting trial commitment, using lay language to explain the process, progress bars, reminder emails, and personal contact. Feedback from users of the site agreed with these recommendations. Therefore, similar strategies should be employed and could potentially encourage continued engagement with the registration process. Future trials should consider recording reasons why people ask for help during the
registration process to provide personalized feedback and improve the design of the process.

Careful consideration is needed regarding eligibility questions to avoid being too inclusive or exclusive of participants. Providing lay language pop-ups to explain ineligibility and including suggestions for other relevant studies or sources of support is particularly recommended to reduce participant frustration.

PPI feedback is essential for all recruitment materials and for designing trial landing and registration pages.

Consent and Participant Withdrawal

Past Work

Consent was not specifically reviewed in Murray et al’s paper [4]. Valid informed consent must be obtained for all trial participants in line with ethical standards, including the General Data Protection Regulation (GDPR) [45]. The British Psychological Society (BPS) [46] recommends that internet-mediated research fully informs participants regarding times at which, and ways in which they can withdraw from a study.

Despite the guidelines and recommendations on internet-mediated research, there is a general lack of guidance on assessing the capacity to consent and the practicalities of the withdrawal process for web-based trials.

In line with the Privacy and Electronic Communications Regulations (PECR) [47], Murray et al [4] suggest that all emails include information on the withdrawal process.

Relatives Education and Coping Toolkit

With regard to consent, the BPS and Health Research Authority (HRA) guidelines for internet-mediated research were adhered to [46, 48]. These include providing checkboxes, limiting the length of the consent form, and providing participants with sufficient detail about the study, their participation, and potential risks in the participant information sheet (PIS). The PIS was available on the web and presented as part of the registration process before the web-based consent form. NHS ethical approval was obtained from the Lancaster National Research Ethics Service Committee (15/NW/0732).

As suggested by Murray et al [4], information regarding the withdrawal process was included in the PIS, and a link to allow withdrawal was contained in all follow-up reminder emails. Participants could withdraw at 3 different levels (from 12-week follow-up but not 24-week follow-up; from all follow-ups but continue use of REACT or the resource directory [RD]; or from all follow-ups and REACT or RD) and were asked to provide a reason for their withdrawal from a drop-down menu with the following options: I don’t have time due to other commitments; I didn’t like the website I was given; I don’t like filling in the questionnaires; I don’t feel well enough to take part; or Other (please specify). Participants could withdraw on the web or via contact with the trial manager, who would then add the relevant information to the web-based dashboard, including the level of withdrawal and reason if given.

A total of 800 participants completed the web-based consent procedures and entered the trial. Of these, 5.8% (46/800) of participants withdrew from the trial (6 from 12-week follow-up only, 26 from all remaining follow-ups, and 14 from all remaining follow-ups and intervention). A total of 7 participants reported that their withdrawal was because of lack of time due to other commitments; 4 reported they did not like the website they were given; 4 reported they did not like filling in the questionnaires; 4 reported that they did not feel well enough to take part; and 31 gave a combination of other reasons (not categorized).

Future Work

Researchers should follow guidelines (eg, GDPR, BPS, and HRA) for gaining web-based consent, as outlined earlier. Despite following guidelines for internet-mediated research, the big challenge that we were unable to address was the ethical issue of assumed capacity in web-based trials. There is a lack of face-to-face contact between researchers and participants, which results in missing dialogue and interaction required to establish the capacity to consent. Future research would benefit from reviewing the current range of web-based interventions and the types of risk they present, including the assumed capacity to consent.

Participants must be given the option to withdraw from the trial at any time, and it is important for researchers, especially those conducting a web-based trial where contact is remote, to work out exactly what participants wish to withdraw from. This can be done by offering participants options to withdraw from different levels of the trial, for example, the research versus the intervention. Identifying and sharing reasons for withdrawal may help to reduce attrition in future web-based trials of web-based interventions.

Randomization

Past Work

The biggest risk to the validity of the randomization process in web-based trials is the reregistration of participants who were not allocated to the trial arm they hoped for. Murray et al [4] took steps to reduce the risk of reregistration—email validation, removal of incentive to reregister, and monitoring of potential reregistrations (through offline contact details and IP addresses). Although not infallible strategies, there was no evidence to suggest that reregistration was a significant issue. Therefore, the steps implemented may have been adequate, and more draconian approaches may put people off registering at all.

Relatives Education and Coping Toolkit

Recommendations from the DYD trial were followed in the REACT RCT. Specifically, a validated email address and phone number (mobile or landline) were a requirement for registration and checked for prior use. The advantages of the comparator (RD) were highlighted, and it was made clear in the PIS that the RD group would be given access to the content of the REACT modules at the end of the trial; financial incentives were provided to both arms only after baseline was complete and for follow-up (further details in the section Retention); and participant contact details were verified as unique (ie, did not...
match any already registered) by automated univariate monitoring of data fields for email, mobile number, landline number, postcode, and address. We chose not to use IP address checks to monitor registration because of the risk of the ease with which a participant can access a website from a different IP address, or the risk that we could block participants using a shared external IP address (eg, where an organization has 1 external facing IP address but many internal addresses).

It was also made clear in the PIS that only 1 relative per service user should register for the trial because people who are caring for the same individual are likely to have related levels of distress, and that log-in details should not be shared. We could not explicitly check whether only 1 person per service user registered because we did not collect any data about the service user. However, based on the assumption that many caregivers would be immediate relatives and immediate relatives are more likely to live with the person they care for, we checked that relatives’ addresses were unique.

There was no evidence that multiple registrations were an issue, based on system checks for duplicate email addresses, phone numbers, and postal addresses.

**Future Work**

Although there was no evidence that multiple registrations were an issue in the DYD or REACT trials, this was possibly because of the steps followed to reduce this risk. Researchers should aim to validate contact details, remove incentives to reregister, and collect and monitor offline contact details as precautionary measures.

**Engagement With Web-Based Interventions**

**Past Work**

To ensure fidelity of the intervention (ie, how much a participant uses the intervention and which modules/sections), a detailed description of the development of the DYD intervention was published [49], and participant use of the intervention was automatically monitored. The authors suggest that considerable preparatory work is required to understand how and why the intervention is likely to work.

Studies have suggested an association between greater engagement (higher intervention use) and improved outcomes [22,50]; however, for some, 1 visit can be enough to elicit a positive change [18]. The problem with measuring intervention use in all trials is knowing what meaningful engagement is—more engagement does not necessarily mean more effective engagement [26]. Understanding how and how much participants use web-based interventions is particularly challenging as participants are free to use the intervention when and how they wish (unlike if they were receiving face-to-face therapy in an offline trial).

**Relatives Education and Coping Toolkit**

To ensure that the REACT intervention was engaging for users, PPI was an important part of the development of the resource and running the REACT trial. Relatives were involved in the development of the initial content for the toolkit [51] and in subsequent iterations to develop a web-based version of REACT [52].

Moreover, we chose to employ peer workers—relatives with lived experience of supporting someone with a mental health problem—to support the website. The benefits of employing peer workers were highlighted in the design workshops that we conducted to develop the web-based version of REACT [52], and have been evidenced by research showing benefits both for those receiving support and for the peers themselves [53-56]. Furthermore, our perception was that relatives (peer workers) would be highly knowledgeable, empathetic, and motivated to support other relatives, making the intervention more engaging. Developing the peer worker/REACT supporter role as part of the NHS workforce was also consistent with recommendations from NICE in 2016.

Relatives were also involved in advisory/consultant roles to ensure that their input was recognized in the delivery and steering of the trial, including all main trial parameters. This included an advisory panel to consult with about trial processes and the content of the REACT toolkit and RD and the Trial Management Group and Trial Steering Committee (TSC), enabling them to influence key decision making relevant to the REACT trial and engaging users.

Although a description of REACT has been published [52,56], we did not specify to relatives how much or how often they should engage with REACT. Web use was measured by data showing activity on webpages (page downloads, number of log-ins, and time spent on a page), but none of these were completely accurate measures of user behavior and did not tell us anything about how this information was being processed or used. To allow for prolonged periods of inactivity when participants did not actively log off from the intervention, inactivity time on a given page was capped at 20 min. These capped values were replaced with the mean total time spent on the given page by REACT participants.

The most popular module (visited by 52% of REACT participants) was the REACT group forum, where relatives could share experiences with each other in a safe, online community facilitated by REACT supporters.

There was no statistically significant causal impact of intervention use (in terms of the number of webpage downloads \(P=.30; Z=-1.1\), number of log-ins \(P=.30; Z=-1.0\), and time spent on REACT \(P=.30; Z=-1.1\), assessed using instrumental variable regression) on the outcome (in terms of a reduction in distress at 24 weeks according to the GHQ-28).

**Future Work**

On the basis of our findings, the most popular section of the intervention was the interactive forum [28]. Therefore, including an interactive forum in web-based interventions may attract more participants; however, care should be taken to adequately facilitate such modules to manage risk (see section Risk Management and Adverse Events).

Although we were able to measure intervention use, we were unable to specify what an ideal level or pattern of use was likely to be. This is particularly challenging to do where the exact
mechanism of action is unknown, and the intervention sites link out to other sites, for example, the RD in the REACT intervention, which appeared to be used for a very small amount of time, but may have led to participants using the information to access other relevant resources that we did not monitor. It may be informative to track user traffic to other sites in these circumstances, to understand what information and support participants are getting, and qualitatively explore how they are using this information. Patterns of use alone could helpfully be supplemented by prespecified process evaluations to understand in a deeper context, the implementation, and mechanisms of impact.

Retention

Past Work

The primary method of follow-up in the DYD trial was email (an initial email followed by up to 3 reminders) containing a link to follow-up questionnaires. A subsample of nonresponders was studied at 3 months (final follow-up) to see if offline (postal or phone) reminders were helpful. Murray and colleagues found that offline follow-up was poor, possibly because of participants' desire for anonymity, which resulted in less than one-third of participants providing offline contact details [4]. The authors suggest careful consideration of offline follow-up, given the additional expense and time needed compared with web-based follow-up.

The loss to follow-up is still one of the biggest challenges for web-based trials [6], jeopardizing statistical power, and therefore the generalizability, reliability, and validity of results [57]. Previous research suggests that being female, older, and better educated predicts greater response to follow-up [23,58], as well as being white and having good internet skills [59,60]. Reminding participants of the importance of completing follow-ups and providing them with incentives may reduce follow-up attrition [13]. Research suggests that providing a higher financial reward increases retention to follow-up [12,15,18].

Relatives Education and Coping Toolkit

Drawing on recommendations from the DYD trial and other previous studies [12,15,61,62], we used several strategies to maximize follow-up. First, participants were only randomized once baseline assessment measures were completed (also crucial to the integrity of the trial in general). Second, detailed explanations about why data completion at follow-up was so important were included in our recruitment materials. Third, participants in the comparator arm were informed that they would be able to access toolkit modules after the final follow-up. Finally, multiple contact details were collected at registration, which allowed the research team to send multiple reminders by different methods (email, post, SMS, and phone) and with different options for completing data (based on PPI feedback), striking a balance between cost, data, and burden on participants. Finally, participants were offered a financial incentive for baseline and follow-up. The effectiveness of £10 (US $12.41) versus £20 (US $24.82) and conditional versus unconditional financial incentives at 24 weeks was tested in a study within a trial.

The REACT RCT achieved a 72.8% (582/800) retention rate at the primary outcome point (24 weeks), surpassing our minimum threshold for adequate study power (70%) and that achieved in the DYD trial (48%). As part of a post hoc analysis, we explored the relationship between key demographic, recruitment, and intervention use variables, and retention. There was a statistically significant association between age and retention at 24 weeks follow-up (older participants were more likely to provide data at 24 weeks; N=800; $\chi^2 = 15.31; P<.009$), but not for gender (N=800; $\chi^2 = 3.52; P<.06$), or education level (N=800; $\chi^2 = 4.06; P>.10$). There was no statistically significant relationship between whether participants had been recruited on the web or offline and retention at 24 weeks follow-up (N=800; $\chi^2 = 2.79; P<.10$). In line with previous research [17,22], higher intervention use (in terms of time spent on the website, number of webpage downloads, and number of log-ins) was significantly associated with greater retention at 24 weeks ($P<.001$).

The highest proportion of participants completed follow-up on the web after the initial email request to do so; however, there was a cumulative effect of additional reminders (Table 4). There was no effect of higher versus lower or conditional versus unconditional incentives on follow-up completion.
Table 4. Participant completion of the primary questionnaire after each reminder.

<table>
<thead>
<tr>
<th>Reminder</th>
<th>Web-based or offline retention strategy</th>
<th>Participants who completed the questionnaire at 12 weeks (n=594), n (%)</th>
<th>Participants who completed the questionnaire at 24 weeks (n=599), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed on the web after first reminder email</td>
<td>Web-based</td>
<td>177^2 (30.0)</td>
<td>162 (27.0)</td>
</tr>
<tr>
<td>Completed on the web after second reminder email</td>
<td>Web-based</td>
<td>114 (19.1)</td>
<td>71 (11.9)</td>
</tr>
<tr>
<td>Completed on the web after third reminder email</td>
<td>Web-based</td>
<td>61 (10.2)</td>
<td>93 (15.5)</td>
</tr>
<tr>
<td>Completed on the web after manual text message</td>
<td>Offline</td>
<td>80 (13.5)</td>
<td>94 (15.7)</td>
</tr>
<tr>
<td>Completed GHQ-28^b over the phone or on the web after phone call</td>
<td>Offline</td>
<td>68 (11.4)</td>
<td>81 (13.5)</td>
</tr>
<tr>
<td>Completed GHQ-28 via post or on the web after receiving a postal pack</td>
<td>Offline</td>
<td>84 (14.1)</td>
<td>76 (12.7)</td>
</tr>
<tr>
<td>Completed GHQ-28 via auto text</td>
<td>Web-based</td>
<td>10 (1.7)</td>
<td>22 (3.7)</td>
</tr>
</tbody>
</table>

^aFive patients were not sent a 12-week reminder email, 2 of these were because of issues with the reminder system, and 3 patients completed the 12-week follow-up at 11 weeks postrandomization, that is, before the first reminder was sent.

^bGHQ-28: General Health Questionnaire-28.

**Future Work**

Despite additional offline forms of contact (SMS, phone call, and postal) being time consuming in the REACT RCT, it is unlikely that people who completed these strategies would have done so otherwise. Therefore, with careful consideration, a combination of web-based and offline retention strategies is likely to be most effective for retention to follow-up.

In line with previous research [19], there was no statistically significant relationship between whether participants had been recruited on the web or offline and retention, providing support for the use of both web-based and offline recruitment strategies (see Recruitment section).

In contrast to previous research [12,15,18], we found no effect of higher versus lower and conditional versus unconditional incentives on follow-up completion, which might reflect differences in the populations and therefore highlight the importance of understanding the motivations of the population being recruited (for which PPI involvement is crucial). For example, it is possible that older relatives in a caring role in REACT are more motivated to take part in the study by having access to the intervention and the opportunity to improve care for other relatives, whereas younger people recruited to a sexual health or smoking cessation study [12,18] may have less disposable income and be more motivated by the financial reward. However, this remains speculative and is an important area for future research. Care should be taken to avoid ineffective strategies or strategies that could undermine pre-existing motivations, such as altruism.

**Data Quality and Analysis**

**Past Work**

Potential bias because of constraints on how data are collected, independent verification of data, missing data, and low follow-up rates are important considerations for web-based trials [4]. In the DYD trial, data quality at baseline and follow-up was good in terms of useable data. To maximize data quality, Murray et al [4] collected baseline data before randomization, maximized the credibility of the comparator, used a primary outcome measure developed for web use, and checked reliability and validity. They also minimized the use of free text in data collection by using drop-down menus or forced choice, required participants to complete mandatory questions, did not allow participants to provide unusable data, and piloted questionnaires. The authors recommended an active PPI group to provide feedback on data quality and collaboration between statisticians and programmers to ensure data are collected and stored in a useable format.

Murray et al [4] also suggested that researchers address some of the challenges with web-based trials during analysis, for example, through intention-to-treat and sensitivity analyses.

We are not aware of any updates from the literature.

**Relatives Education and Coping Toolkit**

The REACT RCT followed the procedures and recommendations from the DYD trial, and also reviewed the response rates and completeness of the primary outcome regularly.

In the REACT trial, both intention-to-treat and sensitivity analysis were used along with mean imputation to replace capped inactivity for website use.

Intention-to-treat (ie, analysis according to the randomized group, regardless of whether the participant engaged with their randomized intervention) was the primary analysis approach. This was supplemented by causal analyses of the primary outcome, using instrumental variable regression with continuous measures of web usage (total number of webpage downloads from the REACT intervention website, total time spent logged on the REACT intervention website, and the total number of
log-ins to the REACT intervention website) to assess the impact of actual intervention use on the outcome.

A joint modeling approach (using baseline, 12-week, and 24-week outcome data) was used to assess the impact of missing data at 24 weeks on the conclusions drawn from the analysis of each primary and secondary efficacy outcome. This analysis assessed whether there was any difference in outcome (here the longitudinal outcome rather than the outcome at 24 weeks alone) between the randomized arms adjusted for missingness by inherently allowing for the correlation between patterns in missingness and outcome.

Sensitivity analyses were employed to assess the impact of late data completions on the primary outcome (eg, excluding results received beyond 27 weeks for the 24-week primary outcome). Participants scoring higher on the GHQ-28 at baseline were more likely to drop out at follow-up; therefore, data were not missing at random. Accounting for this was important as analyses appeared to show some statistically significant benefit of REACT over RD only at follow-up on how supported relatives felt, which did not remain after accounting for missing data.

Despite relatively good quality effectiveness data, some of the health economics (HE) data were poor. For example, because of the lack of quality checks, data on the use of medicines was not usable. These issues were likely because of the health economist not being involved in designing the data collection process, lack of adequate testing at the outset, some items not having mutually exclusive options in drop-down menus, and occasional failure of links to follow-on questions. Unfortunately, HE evaluation was not conducted as part of the feasibility study for REACT, which would have identified issues with the HE data earlier.

Future Work

Extensive testing of data collection procedures and quality is recommended. Data should be reviewed early in the trial to check whether they are being collected correctly and to check for missing data. Future web-based trials would benefit from including a health economist in designing the data collection process and, when possible, conducting an economic evaluation at the feasibility trial stage.

Spamming

Past Work

For mass mailings to be legal, they must have an unsubscribe option [4]. One participant in the DYD trial suggested repeat follow-up reminder emails verged on being spam because of no obvious way to withdraw permission. Emails were amended to remind participants that they could withdraw at any time.

We are not aware of any updates from the literature.

Relative Education and Coping Toolkit

As per PECR [47] rules and legislation around clinical trials, in the REACT trial, we included the following on all follow-up emails: “P.S. Please remember that you can choose not to complete this follow-up without giving a reason. However, if you feel you cannot (or do not want to) complete this follow-up, it would be really helpful for the future if you could tell us why. Please click here [link to withdraw included].” There was no evidence that spamming was an issue.

Future Work

Participants must be contacted several times during a longitudinal study such as a trial; in web-based trials of web-based interventions, this is often via email and may be a combination of reminders to complete follow-up and reminders to visit the intervention website, creating a lot of email traffic. Working closely with PPI groups and ethics committees, it is important to find a way to contact participants repeatedly, without being intrusive. Participants should be given control over the number of emails received regarding the use of the intervention, as there is likely to be individual variation in what is felt to be useful. It must be clear on all emails that participants can withdraw from the trial at any time. Making email titles factual and academic rather than friendly, avoiding the use of phrases such as free online support, and considering where the email appears to have been sent from may help to avoid emails going into spam folders.

Cybersquatting

Past Work

Cyber squatters (fake domain names based on the intervention website name) may put people off further searching if they think they have come across the original website [4]. By the end of the DYD pilot study, there were at least three cyber squatters making money from advertising other websites. The authors advise other researchers to buy all related domain names before starting research.

Quick response (QR) codes have been used on offline recruitment materials to take potential participants directly to the correct trial website [63], but can only be used on mobile phones or tablets.

Relative Education and Coping Toolkit

Although the REACT website address was visible on all written recruitment materials, and all participant emails contained a direct link to the website, many participants also used web search engines. This was initially a problem because many found the website from the REACT feasibility study [44], which had a similar domain name; therefore, the feasibility website was taken down. However, a more challenging issue was that during the trial, a parallel implementation study [64] was running at the same time, and also ran from Lancaster University. This study took place in 6 trusts across the United Kingdom, each with its own REACT-related domain name. This led to some confusion, which required a complex approach of redirecting participants to ensure they were trying to access the right website.

Future Work

In addition to checking, and potentially buying (depending on cost), related domain names before the commencement of a trial, researchers should use direct links to the trial website on all web-based recruitment material and participant emails, and avoid having multiple, similar domain names for linked studies.
An alternative is a single log-in page that redirects participants to the appropriate version of the website. QR codes can be used on offline recruitment materials to take potential participants directly to the correct trial website through their mobile phones or tablets. The effectiveness of QR codes for reducing the effects of cybersquatting in trials for relatives of people with serious mental illness requires further investigation.

Patient and Public Involvement

Past Work

PPI was not specifically reviewed in the paper by Murray et al [4] on the DYD trial. Although participants appreciate the flexibility and convenience of web-based trials, the lack of connectedness and understanding can pose a challenge for the engagement of patients and the public involved in supporting the study (PPI) if this is also done on the web [65]. PPI in web-based trials may require new strategies to enhance engagement and ensure meaningful involvement.

Relatives Education and Coping Toolkit

To ensure engagement, relatives involved in the clinical delivery of REACT (REACT supporters and supervisors) were physically located with the research team, and consequently had high levels of face-to-face contact with other members of the team. However, the RAG, trial management meetings, TSC, and an independent data monitoring and ethics committee (IDMEC) all met on the web. Participants were located across the United Kingdom and this saved time and offered a cost-efficient approach.

However, feedback from participants suggested that the remote nature of contact in the RAG, TSC, and IDMEC had a detrimental impact on engagement for some members, particularly those with a role of PPI, who felt directly less engaged with the process or the other people involved and found it harder to input. They also found the technical aspects of web-based meetings to be challenging and less engaging.

Future Work

Effort is needed to understand the motivation for people to take part in advisory groups and oversight committees, particularly those contributing from a PPI perspective, and whether a web-based design will be able to meet their expectations. PPI input to support the delivery of the research may best be done using a combination of web-based and offline approaches to facilitate engagement, and training should be provided by the research team in both the technology and format of web-based meetings.

Risk Management and Adverse Events

Past Work

Risk management was not specifically reviewed in Murray et al’s paper [4]. Identifying and responding to risk during a web-based trial needs careful consideration because of the remote nature of contact. Risk is one of the things that NHS trust staff are most concerned about when considering the promotion of web-based interventions to their service users [64], and awareness of how risk is managed is likely to facilitate staff engagement.

Relatives Education and Coping Toolkit

A comprehensive approach to risk was taken to identify and manage potential adverse events. The REACT website had several clear notifications that REACT was not monitored outside of working hours and could not offer crisis support. Clear signposting to places for support (including NHS services and charities such as Bipolar UK and Rethink) were included in places where risk could be picked up on the website. Red flags (low-risk adverse events) were raised by the web-based data capture system in response to answers to questionnaire items that indicated possible risk to self or to the person cared for. This automatically triggered a standardized email to participants, expressing concern, checking if the participant was okay and pointing them to appropriate support, and a notification email to the trial manager. Risk could also be identified by the REACT supporters through direct messaging or the forum, or the trial manager when contact was made for follow-up, resulting in a tailored version of the standardized email being sent. Identified risk events were recorded on a web-based dashboard.

High-risk adverse events (clear evidence of immediate and serious risk to life or to child welfare, leading to immediate contact with police or social services as appropriate) were reported to lead clinical contact, the TSC chair, sponsor, and NHS Research Ethics Committee. Clinical contacts were available within the team for advice on managing risk, and the trial manager and supporters were trained in risk assessment and protocols to respond to this. The supporters also received regular supervision with a clinical psychologist and peer support with each other.

Over the course of the trial, 363 participants were sent low-risk standardized automated emails (185 participants were sent more than one email), 3 low-risk adverse events in the RD were identified by the trial manager, 16 low-risk adverse events (13 from intervention and 3 from RD) were identified by the REACT supporters, and no high-risk adverse events were reported.

Future Work

All staff should be trained in risk management specific to the population they work with, and clear protocols provided. Managing risk on the web is likely to be a new skill for staff, and study-specific protocols are likely to be required, as clinical services may not have appropriate governance in place. It is also important that participants understand how risk will be managed to ensure they feel safe and supported.

Key Recommendations for Designing Web-Based Trials

The key recommendations are as follows:

1. PPI in the design and delivery of all stages of the study is crucial and may be best performed using a combination of web-based and offline approaches to maximize engagement. Ensure PPI input includes cultural diversity, and that this
informs recruitment and retention strategies that increase equality in access for any ethnic or demographic populations.

2. Ensure participants are directed to the right website by buying all related domain names and directing them, and considering the use of QR codes.

3. Combine web-based and offline recruitment strategies and monitor the success of each recruitment strategy during the study to inform flexible adaptation throughout recruitment.

4. Understand the motivation of participants for taking part in the trial and target incentives accordingly. Greater financial incentives may not always improve retention and could undermine altruistic motivations.

5. Where exclusion criteria are applied, explain clearly why these are necessary and signpost people who are not eligible to take part in alternative sources of help where possible to reduce frustration.

6. Reduce the risk of reregistration by those who do not meet the inclusion criteria or are not allocated their preferred intervention by requesting web-based and offline details and checking personal details for before use, offering access to both interventions at the end of the study, and ensuring financial reward is equal in both study groups and is given after baseline measures are completed.

7. Ensure all design complies with ethical and data protection guidelines, including clear instructions on how to withdraw from any elements of the process in all correspondence.

8. Carefully test data collection procedures and data quality before trial launch and throughout trial implementation. Maximize data quality by ensuring data capture is designed to: only allow valid responses, using forced-choice drop-down options where possible and systems are fully tested at the outset and regular points throughout the study.

9. Consider giving expectations for levels of use to participants and/or including a peer forum to increase levels of engagement.

10. Maximize retention by highlighting why retention is so important in both study groups, incentivizing each data collection point, using a combination of web-based and offline follow-up strategies, and offering all participants access to both interventions at the end of the study.

11. Where relevant, ensure that clear risk protocols are in place, and staff are adequately trained.

Conclusions

Web-based trials are increasingly being used to test web-based interventions. Researchers are sharing lessons learned from conducting such trials, which is of great benefit to future studies. This paper has provided recommendations based on key considerations for web-based trials of web-based interventions (recruitment, registration eligibility checks, consent and participant withdrawal, randomization, engagement with a web-based intervention, retention, data quality and analysis, spamming, cybersquatting, PPI, and risk management and adverse events) adding to this growing literature base. The development considerations and solutions outlined here are relevant for future web-based and hybrid trials and ACTS studies, both within general health research and specifically within mental health research for relatives. The structure of what we did is also relevant for future face-to-face trials.

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Authors' Contributions

The first author (HR) was the trial manager and led the writing of this paper. The last author (FL) is the chief investigator. All other authors are listed alphabetically, and their roles are described. S Jones, EM, PW, and S Johnson were coapplicants and designed and managed the study, including securing funding. SD led the design of the statistical analysis and oversaw the work of AR-H and NR to carry out data management and analysis. S Jones supervised the REACT supporters during the trial. SF worked as a REACT supporter during the trial and was involved in the recruitment process. DA and AW designed and maintained IT systems for the trial, including the delivery of REACT and collection of data on the web. BM supported administration and trial management. CM developed and carried out the HE analysis for the trial. All authors contributed to the writing of the paper and approved the final version.

Conflicts of Interest

Professor FL and S Jones were part of the team that developed the REACT intervention, and so this is not an independent evaluation. There are no other conflicts of interest to declare.

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Abbreviations

ACTS: Accelerated Creation-to-Sustainment  
BPS: British Psychological Society  
DYD: Down Your Drink  
GDPR: General Data Protection Regulation  
GHQ-28: General Health Questionnaire-28  
GP: general practitioner  
HE: health economics  
HRA: Health Research Authority  
IDMEC: independent data monitoring and ethics committee  
IP: internet protocol  
NHS: National Health Service  
NICE: National Institute for Health and Care Excellence  
PECR: Privacy and Electronic Communications Regulations  
PIS: participant information sheet  
PPI: patient and public involvement  
QR: quick response  
RAG: Relatives Advisory Group  
RCT: randomized controlled trial  
RD: resource directory  
REACT: Relatives Education and Coping Toolkit  
TAU: treatment as usual  
TSC: Trial Steering Committee

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Assessment of Population Well-Being With the Mental Health Quotient (MHQ): Development and Usability Study

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Abstract

Background: Existing mental health assessment tools provide an incomplete picture of symptom experience and create ambiguity, bias, and inconsistency in mental health outcomes. Furthermore, by focusing on disorders and dysfunction, they do not allow a view of mental health and well-being across a general population.

Objective: This study aims to demonstrate the outcomes and validity of a new web-based assessment tool called the Mental Health Quotient (MHQ), which is designed for the general population. The MHQ covers the complete breadth of clinical mental health symptoms and also captures healthy mental functioning to provide a complete profile of an individual’s mental health from clinical to thriving.

Methods: The MHQ was developed based on the coding of symptoms assessed in 126 existing Diagnostic and Statistical Manual of Mental Disorders (DSM)-based psychiatric assessment tools as well as neuroscientific criteria laid out by Research Domain Criteria to arrive at a comprehensive set of semantically distinct mental health symptoms and attributes. These were formulated into questions on a 9-point scale with both positive and negative dimensions and developed into a web-based tool that takes approximately 14 min to complete. As its output, the assessment provides overall MHQ scores as well as subscores for 6 categories of mental health that distinguish clinical and at-risk groups from healthy populations based on a nonlinear scoring algorithm. MHQ items were also mapped to the DSM fifth edition (DSM-5), and clinical diagnostic criteria for 10 disorders were applied to the MHQ outcomes to cross-validate scores labeled at-risk and clinical. Initial data were collected from 1665 adult respondents to test the tool.

Results: Scores in the normal healthy range spanned from 0 to 200 for the overall MHQ, with an average score of approximately 100 (SD 45), and from 0 to 100 with average scores between 48 (SD 21) and 55 (SD 22) for subscores in each of the 6 mental health subcategories. Overall, 2.46% (41/1665) and 13.09% (218/1665) of respondents were classified as clinical and at-risk, respectively, with negative scores. Validation against DSM-5 diagnostic criteria showed that 95% (39/41) of those designated clinical were positive for at least one DSM-5–based disorder, whereas only 1.14% (16/1406) of those with a positive MHQ score met the diagnostic criteria for a mental health disorder.

Conclusions: The MHQ provides a fast, easy, and comprehensive way to assess population mental health and well-being; identify at-risk individuals and subgroups; and provide diagnosis-relevant information across 10 disorders.

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KEYWORDS
psychiatry; public health; methods; mental health; population health; social determinants of health; global health; behavioral symptoms; diagnosis; symptom assessment; psychopathology; mental disorders; mhealth; depression; anxiety; attention deficit disorder with hyperactivity; autistic disorder; internet
Introduction

Background

According to the World Health Organization, mental health is “a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community” [1]. According to this definition, any framework of mental health assessment should therefore not only reflect the presence of dysfunction but also provide insight into positive aspects of mental well-being, ensuring it is applicable not only for clinical groups but also for the wider population [2]. In addition, although personalized approaches to mental health are essential in ensuring effective treatment outcomes at the individual level [3-5], population-level approaches provide an understanding of the broader geographical, cultural, and experiential factors that influence mental health on a macroscale [6,7]. This latter perspective provides an opportunity to develop interventions that induce large-scale shifts in population well-being and is becoming increasingly important for understanding how to improve mental health outcomes [8,9]. However, current approaches to mental health assessment pose considerable challenges to these goals and ideals.

Challenges in Mental Health Assessment

One major challenge is that the clinical heritage of mental health assessment means that most tools are not designed for the general population but are instead built around specific psychiatric disorder categories based on the clinical classification systems of the Diagnostic and Statistical Manual of Mental Disorders (DSM) [10] or the International Classification of Diseases (ICD) [11]. In this way, an assessment can identify whether an individual exhibits symptoms pertaining to a specific mental health disorder such as depression, attention-deficit/hyperactivity disorder (ADHD), or alcohol addiction but does not readily provide a perspective of their overall mental health. In contrast, the general population falls along a continuum ranging from disordered to thriving and therefore having a system that is predominantly focused on disorders and dysfunction, without an equivalent understanding of well-being, presents a challenge to advancing the understanding of the borders between normal mental health and clinical disorder [12-15], especially because many mental health symptoms such as sadness, anxiety, and risk-taking also fall within the spectrum of normal mental functioning in the general population. Understanding when such normal mental functions cross the boundary to become symptoms requires an assessment approach that is designed for the general population and that encompasses the range from clinical dysfunction to positive mental assets.

A second challenge is that existing mental health assessment tools, despite being broadly based on symptom criteria defined by DSM or ICD classification systems, are highly heterogeneous. Our recent analysis of 126 commonly used mental health screening assessments revealed considerable inconsistency in symptom assessment across different tools focusing on the same disorder and substantial overlap between disorders [16]. Consequently, two assessments that target the same population group, but which used different tools to assess their experience of mental health problems, may deliver different results because they are assessing a different set of symptoms (see also the study by Fried [17]). This creates ambiguity, bias, and inconsistency in mental health determination and confuses the development of effective treatments and interventions to promote well-being within the general population. Moreover, when examining assessment tools that span multiple disorders and therefore aim to provide a broader perspective on mental health, Newson et al [16] found that none of the 16 cross-disorder assessment tools that were analyzed covered the complete breadth of mental health symptoms and few considered positive mental assets (see also the study by Allsopp et al [18]). This suggests that existing cross-disorder tools fail to provide a complete picture of mental health symptoms and positive assets that would apply to both clinical and normal healthy populations.

The Mental Health Quotient

To address these challenges, we have developed a new web-based assessment tool called the Mental Health Quotient (MHQ) [19], which is designed for the general population and covers the complete breadth of clinical mental health symptoms as well as positive mental assets. It has been developed based on an extensive review of the way mental health is assessed in clinical and research fields [16], and its purpose is to provide a comprehensive assessment of an individual’s mental health profile ranging from clinical to thriving, which is suitable for both clinical and population-based assessments. Here, we describe the development of the MHQ and provide preliminary data from a cross-section of the population to illustrate its output.

Methods

Design and Development of the MHQ

Key Design Criteria

The key design criteria of the MHQ were that it had to be fast and easy to complete by the general population (take ≤15 min) and administered such that respondents felt confident in providing honest responses that were reflective of the current perception of the respondent’s mental health. The MHQ was therefore designed to provide a view of respondent perception within their individual life context, which is not absolute, that is, what one person means by a severity rating of 8 could be different from what someone else means in actual life outcomes and can change over time. This is in line with how the majority of mental health symptoms are typically assessed. In addition, as an output, it would have to provide an overall score of mental health as well as scores along key macro dimensions. Taking these requirements into consideration, the standard version of the MHQ was developed to be taken on the web anonymously and provide a score and full individual report that encourages honest self-report.

http://mental.jmir.org/2020/7/e17935/
Developing a Complete Inventory of Mental Health and Well-Being Elements

The MHQ was developed based on a comprehensive review of symptoms assessed across 126 commonly used psychiatric assessment tools (Figure 1), spanning disorders of depression, anxiety, bipolar disorder, ADHD, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), addiction, schizophrenia, eating disorder, and autism spectrum disorder (ASD), and cross-disorder tools (see the study by Newson et al [16] for a complete list of assessment tools).

A total of 10,154 questions, taken from these 126 assessment tools, were identified and coded based on a judgment of their semantic content and consolidated into a set of 43 symptom categories by grouping similar preliminary symptom codings (see the study by Newson et al [16] for a more detailed description). This approach was selected because diagnoses are determined from self-reported symptoms that are based on a semantic description, rather than underlying biological factors. Therefore, the objective was not to reduce the scale down into independent items in terms of occurrence but to cover the breadth of symptoms of mental health assessment based on their semantic description (as an example of this approach, fever and fatigue are semantically distinct but often co-occur). This set of symptom categories was then reviewed in the context of the Research Domain Criteria (RDoC) constructs and subconstructs put forward by the National Institute of Mental Health [20-22], and a few additions were made to ensure that the list of items reflected the components within this non-DSM framework. Next, we ensured that there were items within the MHQ that reflected symptoms of neurological disorders (eg, dementia) that were not covered in the original review [16]. The resulting categories were then restructured as follows. First, categories that reflected purely physical symptoms (eg, urination problems) were consolidated under the generalized item of Physical health issues. Second, categories that reflected items that a naive respondent might find difficult to differentiate (eg, delusions and unwanted thoughts) were also consolidated. Third, where a category reflected multiple symptoms or functions, it was split into 2 (or 3) independent items to make it clear to the respondent which function or symptom was being assessed (eg, sleep quality vs nightmares). This resulted in 47 semantically distinct items (Textbox 1).

The resultant items from this review and reorganization were then split into 2 formats: those mental functions that could manifest as a spectrum from positive to negative, which we called spectrum items (27 questions in all), and those symptoms that purely represented detractions from overall mental health, which we called problem items (20 questions in all).

Figure 1. Diagram illustrating the method of development of the Mental Health Quotient. A total of 126 commonly used psychiatric assessment tools covering 10 disorders (as well as those taking a cross-disorder approach) were reviewed and consolidated into 43 symptom categories. These categories, together with additional symptom categories taken from a review of Research Domain Criteria constructs as well as dementia elements, were reorganized into a final set of 47 items that were divided into spectrum and problem items for inclusion in the Mental Health Quotient. ADHD: attention-deficit/hyperactivity disorder; ASD: autism spectrum disorder; DSM: Diagnostic and Statistical Manual of Mental Disorders; OCD: obsessive-compulsive disorder; PTSD: post-traumatic stress disorder; RDoC: Research Domain Criteria.
Textbox 1. List of spectrum and problem items.

**Spectrum questions**
- Adaptability to change
- Self-worth and confidence
- Creativity and problem solving
- Drive and motivation
- Stability and calmness
- Sleep quality
- Self-control and impulsivity
- Ability to learn
- Coordination
- Relationships with others
- Emotional resilience
- Planning and organization
- Physical intimacy
- Speech and language
- Memory
- Social interactions and co-operation
- Decision making and risk-taking
- Curiosity, interest, and enthusiasm
- Energy level
- Emotional control
- Focus and concentration
- Appetite regulation
- Empathy
- Sensory sensitivity
- Self-image
- Outlook and optimism
- Selective attention

**Problem questions**
- Restlessness and hyperactivity
- Fear and anxiety
- Susceptibility to infection
- Aggression toward others
- Avoidance and withdrawal
- Unwanted, strange, or obsessive thoughts
- Mood swings
- Sense of being detached from reality
- Nightmares
- Addictions
- Anger and irritability
- Suicidal thoughts or intentions
- Experience of pain
• Guilt and blame
• Hallucinations
• Traumatic flashbacks
• Repetitive or compulsive actions
• Feelings of sadness, distress, and hopelessness
• Physical health issues
• Confusion or slowed thinking

**Question Format**

Questions were answered based on the current perception of the respondent (“Please choose your answers based on your current perception of yourself”) and were formulated on a 9-point scale reflecting the consequence on one’s life functioning and performance. Figure 2 shows an example of a spectrum question from the MHQ (on adaptability to change) and an example of a problem question. Each question included a broad category label as well as a one-sentence description of the item for clarity.

The scale of spectrum questions was designed to reflect functions that could be an asset for some individuals but a problem for others. In this way, spectrum questions were developed such that they did not relate to the presence or absence of a function or symptom but instead focused on the impact that the item had on the individual across a range of positive or negative possibilities. In the 9-point scale for spectrum items, 1 referred to “Is a real challenge and impacts my ability to function effectively,” 9 referred to “It is a real asset to my life and my performance,” and 5 referred to “Sometimes I wish it was better, but it’s ok.”

Problem questions were designed to reflect functions or dysfunctions that typically had a negative impact on someone’s life and could rarely be seen as a positive asset. Here, 1 on the 9-point scale referred to “Never causes me any problems,” 9 referred to “Has a constant and severe impact on my ability to function effectively,” and 5 referred to “Sometimes causes me difficulties or distress but I can manage.”

Within the spectrum and problems sections of the assessment tool, questions were presented in a random order so as not to be leading or priming for the subsequent question.
Demographic, Experiential, and Momentary Questions

Questions designed to collect demographic, experiential, and momentary information were also included in the MHQ assessment. These questions aimed to provide insight into the life context and situation of the individual at the time of taking the assessment to understand how they influence mental health. Demographic questions were included to ask about the nature of a person’s daily occupation, geography, age, and gender. Momentary assessments were designed to determine certain aspects of the individual’s situation, as well as their physical and mental state at the time of taking the assessment, including alertness; mood; hours slept the previous night; time since last meal; and any current physical symptoms such as headache, nausea, or pain. Experiential questions were included to ask about life satisfaction, life trauma, whether they had a diagnosed medical disorder, or whether they were currently seeking mental health treatment. These questions were answered using multiple-choice answer options, using 9-point rating scales, or using a text box, depending on the specific question type, and were included to identify how these factors influence mental health and well-being.

Scoring of the MHQ

Computing the MHQ

The MHQ was not computed as a simple average of raw scores, given (1) there are both negative and positive aspects, (2) there are differences in the seriousness of consequences of different symptom types, and (3) consequences do not necessarily increase linearly at higher values on the scale. Therefore, the raw scores were transformed in 2 steps, which included a threshold-based rescaling of the 9-point scale to a positive-negative scale, followed by the application of a differential nonlinear weighting of the negative scores to better distinguish at-risk populations.

For all questions, a value \( N \) was determined as the rescaling threshold to separate the scale into a positive side depicting a...
normal questions, responses on the rating scale were transformed to \( N = \text{(rating response)} \), where \( N \) was a threshold number between 2 and 6 that was selected depending on the seriousness of the particular symptom and determined where the scale split between positive and negative. Thus, if \( N \) was 2, a rating response of 1 (representing the absence of the problem) would be rescaled to a 1, and a rating response of 9 (representing a constant and severe impact on the ability to function effectively) would be rescaled to \(-7\). If \( N \) was 4, a rating response of 1 would be rescaled to 3, and a rating response of 9 would be rescaled to \(-5\). For spectrum questions, the scores were rescaled as \((\text{rating response}) - N\), where \( N \) was a number between 2 and 6. Thus, if \( N \) was 3, a rating response of 1 (representing a constant and severe impact on the ability to function effectively) would be rescaled to a \(-2\), and a rating response of 9 (representing an asset to life and performance) would be rescaled to 6. The specific values of \( N \) form part of a proprietary MHQ algorithm, where lower numbers depict items that have a greater negative consequence either to the individual or those around them when experienced at severe levels (eg, suicidal thoughts or intentions and aggression toward others).

In contrast, higher \( N \) values depict items that were evaluated as having a less negative consequence to the individual or which are often found within a healthy population (eg, guilt and blame and adaptability to change).

After this positive-negative rescaling, a differential nonlinear weighting was applied to negative scores of different symptoms to create greater distinction in the at-risk group. This weighting value also forms part of the proprietary MHQ algorithm and, similar to \( N \), was determined based on an evaluation of the negative consequence of each symptom. For example, a rescaled negative score of \(-7\) for suicidal thoughts or intentions would be weighted more negatively than a \(-7\) for restlessness and hyperactivity and therefore result in a greater negative amplification of the MHQ score. Similarly, a rescaled negative score of \(-2\) for energy levels would be weighted more negatively than a \(-2\) for creativity and problem solving and result in a greater negative amplification of the MHQ score.

The resulting rescaled and nonlinearly weighted scores across all problem and spectrum items were then summed to provide an aggregate intermediate score. This intermediate score could be either a negative or positive score, where negative scores identified those respondents who had or were at risk for a clinical mental health issue and positive scores represented a normal or healthy range of mental health. To compute the MHQ, positive scores were then normalized to a scale between 0 and 200, whereas negative scores were normalized across a smaller window of \(-1\) to \(-100\). The negative scale was chosen to be smaller to provide a mitigated number to minimize any psychological distress that could be induced by receiving a highly negative score. Thus, the overall MHQ score spans a possible range from \(-100\) to \(+200\), where negative scores reflect clinical or clinically at-risk populations and positive scores reflect the distribution of the normal healthy population. This score range was also chosen to be similar to the way that IQ scores are computed, where scores are centralized around 100.

**MHQ Subscores**

Subscores were also computed for 6 broad subcategories of mental health: core cognition, complex cognition, mood and outlook, drive and motivation, social self, and mind-body (Textbox 2).

To compute the subcategory scores, a weighted average of items for each subcategory was calculated by weighting spectrum or problem items core to the subcategory as \( I \) and spectrum or problem items secondary to the subcategory as \( 0.5 \). This weighting algorithm was developed based on a review of cognitive and neuroscience models of brain functioning and forms a part of the proprietary MHQ algorithm. For example, the item **stability and calmness** was coded with a primary \( I \) weighting in the mood and outlook subcategory and a secondary \( 0.5 \) weighting in the mind and body subcategory to reflect its dual components of emotion and physiological response, whereas the item **unwanted, strange, or obsessive thoughts** was dual coded with a primary weighting in the core cognition subcategory and a secondary weighting in the mood and outlook subcategory to reflect both the cognitive and emotional elements of this item. In this regard, an item could be assigned to 2 different subcategories and occasionally to 3 different subcategories. Overall, each subcategory comprised 10 to 24 items. The subcategory scores were then normalized to constrain them to a smaller scale than the overall MHQ to distinguish them from the overall score. Positive scores were normalized to the range of 0 to 100, whereas negative scores were normalized to the range of \(-1\) to \(-50\).
Mapping of the MHQ Against DSM-5 Criteria

Given that the MHQ items were derived from validated DSM-based assessments and span the breadth of symptoms assessed across 10 DSM-derived disorders, they can be readily mapped to DSM criteria. Thus, to determine the diagnostic status in relation to the MHQ score ranges, each of the 47 MHQ question items was first mapped to the diagnostic criteria of 10 mental health disorders (depression, bipolar disorder, anxiety, OCD, PTSD, schizophrenia, eating disorder, addiction, ADHD, and ASD), as defined by the DSM fifth edition (DSM-5). For example, the MHQ items of feelings of sadness, distress, and hopelessness and outlook and optimism were mapped onto the depressed mood criteria for depression, whereas the MHQ items of unwanted, strange, or obsessive thoughts, self-control and impulsivity, and emotional control were mapped onto the obsession criteria for OCD. Those below the negative threshold $N$ on the spectrum rating scale and above the negative threshold $N$ on the problem rating scale were considered to meet the severity criteria of the DSM-5.

To arrive at the diagnostic indication, we then applied the diagnostic criteria of the DSM-5 for these 10 disorders to the MHQ responses. These criteria stated the type of symptom (eg, interest, fear), the number of symptoms required (eg, must have at least three), and whether any specific symptoms must be present (eg, depression must have either a depressed mood or markedly diminished interest) for a diagnosis of a clinical disorder. Together, this provided a view of (1) the percentage of symptoms for a particular disorder that the individual exhibits (ie, the number of severe symptoms associated with that disorder they report divided by the total number of symptoms associated with that disorder), (2) the percentage of an individual’s symptoms associated with each of the 10 DSM-5–based disorder classifications (ie, the number of severe symptoms they exhibit associated with that disorder divided by the total number of severe symptoms they report), and (3) a diagnostic indication for each disorder based on criteria-derived algorithms. An example of the MHQ output for the DSM-5 mapping of symptoms for one individual is shown in Table 1.

We note that the diagnosis is based on criteria of symptom severity but excludes specifics of frequency and duration of symptoms not captured in the MHQ, which are sometimes part of the DSM-5 diagnostic criteria.
Table 1. Example Mental Health Quotient output for Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition mapping across 10 different mental health disorders for one individual.

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Disorder symptoms, n/N (%)</th>
<th>Individual’s symptoms (n=20), n (%)</th>
<th>Diagnostic indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>10/14 (71)</td>
<td>10 (50)</td>
<td>Positive</td>
</tr>
<tr>
<td>Anxiety</td>
<td>6/11 (55)</td>
<td>6 (30)</td>
<td>Negative</td>
</tr>
<tr>
<td>Bipolar</td>
<td>11/15 (73)</td>
<td>11 (55)</td>
<td>Negative</td>
</tr>
<tr>
<td>PTSD(^a)</td>
<td>9/20 (45)</td>
<td>9 (45)</td>
<td>Negative</td>
</tr>
<tr>
<td>OCD(^b)</td>
<td>4/6 (67)</td>
<td>4 (20)</td>
<td>Negative</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>4/7 (57)</td>
<td>4 (20)</td>
<td>Negative</td>
</tr>
<tr>
<td>Eating disorder</td>
<td>3/3 (100)</td>
<td>3 (15)</td>
<td>Positive</td>
</tr>
<tr>
<td>Addiction</td>
<td>1/4 (25)</td>
<td>1 (5)</td>
<td>Negative</td>
</tr>
<tr>
<td>ADHD(^c)</td>
<td>4/8 (50)</td>
<td>4 (20)</td>
<td>Negative</td>
</tr>
<tr>
<td>ASD(^d)</td>
<td>2/9 (22)</td>
<td>2 (10)</td>
<td>Negative</td>
</tr>
</tbody>
</table>

\(^a\) PTSD: post-traumatic stress disorder.
\(^b\) OCD: obsessive-compulsive disorder.
\(^c\) ADHD: attention-deficit/hyperactivity disorder.
\(^d\) ASD: autism spectrum disorder.

**Reporting of the MHQ**

The output of the MHQ was summarized both as scores as well as into an optional detailed report with recommendations for action that could be obtained by the respondent. Providing a detailed report ensured greater interest of the respondent to answer questions thoughtfully and accurately. Figure 3 shows an extract of an example MHQ results report detailing the MHQ score and subscores. The first section offers an overall MHQ score and a recommendation based on that score. The following sections offer scores for each of the 6 subcategories (Textbox 2) and recommendations based on each of those scores.

DSM-5-based mapping (eg, as shown in Table 1) is not included in the current iteration of the individual output report, although it may be included in the future. When the MHQ is used in a clinical setting, for instance, the DSM-5 mapping can be provided to an individual’s physician to provide transdiagnostic insight.
Figure 3. Extract of an example Mental Health Quotient results report. The report details the overall Mental Health Quotient score and recommendations based on that score. It also details each of the 6 subcategory scores as well as descriptions and recommendations based on each of those subcategory scores. MHQ: Mental Health Quotient.

Results

Testing of the MHQ in the General Population

Participant and Protocol for Data Collection

A total of 1961 responses were collected in the study. Respondents were recruited from the websites of Psychology Today and Sapien Labs using a series of blog articles targeted at adults from July 2019 to February 2020 by providing links to the study. The study received ethics approval from the Health Media Lab Institutional Review Board. Respondents took part by accessing the MHQ on the web [19] and completing the assessment. Those aged younger than 18 years were not eligible to participate. On average, the assessment took 14 min to complete, with the typical time taken for completion being between 8 min and 20 min (1315/1961, 67.06% of respondents). In addition, 97.96% (1921/1961) of those taking part said that the assessment was easy to understand.

Data Cleaning and Exclusion Criteria

The following exclusion criteria were applied to the responses for data cleaning purposes. First, the exclusion of all but the first of multiple assessments from the same internet protocol address. Second, those respondents who took under 7 min (an
The positive MHQ scores had an average of 101 (median 105), while negative scores had an average of 81 (median 94 and mode 139), with a peak in the negative range immediately below 0. This arises because of the compression of the negative scores to a smaller scale of 50% of the positive scale, to the left of 0. This reflects the characteristics of the algorithm (negative thresholding and nonlinear weighting), which creates a greater distinction between people who have negative symptoms of mental health disorders, such as the patients who would likely require immediate clinical intervention (labeled clinical). The proportion of respondents reporting negative scores is therefore in line with the annual prevalence rates of mental health disorders reported from other sources.[23-25].

There were certain important characteristics of the MHQ score distribution. First, the scale spanned both positive and negative numbers, and the distribution was more heavily skewed to the left compared with a simple average of the raw scores (Figure 4 in comparison with Figure 5). This reflects the characteristics of the algorithm (negative thresholding and nonlinear weighting, see section Scoring of the MHQ), which creates a greater distinction between people who have negative symptoms of different levels of seriousness and life consequence. Second, there was a peak in the negative range in the bin immediately to the left of 0. This arises because of the compression of the negative scores to a smaller scale of 50% of the positive scale, such that each bin would be double what it would otherwise be. The rationale for this differential was to mitigate stress to the respondent.
**Figure 4.** Distribution of Mental Health Quotient scores across 1665 respondents. Shows the percentage of respondents falling into Mental Health Quotient score windows ranging from −100 to +200 and across each of the 6 MHQ score levels. Gray bars denote negative scores and black bars denote positive scores. MHQ score levels are (from left to right) clinical (score range: −100 to −51), at-risk (−50 to −1), enduring (0-50), managing (51-100), succeeding (101-150), and thriving (151-200). MHQ: Mental Health Quotient.

**Figure 5.** Distribution of raw scores depicting the percentage of respondents falling into different raw score brackets. Raw scores were calculated as the sum of spectrum question rating responses and reverse-scored problem question rating responses (i.e., where 1 is converted to a 9 and vice versa to maintain a consistent positive-negative direction).
Validation of MHQ Score Labels Against DSM-5 Diagnostic Criteria

To determine the validity of the MHQ scoring approach, we applied DSM-5–mapped diagnostic criteria from 10 different mental health disorders to the MHQ responses (see the Methods section). This rule-based algorithm identified respondents who met the criteria for a diagnosis of at least one mental health disorder, out of a possible 10 mental health disorders. We then examined the pattern of diagnoses across the different MHQ levels from clinical to thriving. We found that 95% (39/41) of individuals with an MHQ score in the clinical range met the diagnostic criteria for at least one mental health disorder, and 30.7% (67/218) of those in the at-risk range met the diagnostic criteria for at least one mental health disorder. Those in the clinical and at-risk categories who did not meet the DSM-5 criteria for a disorder diagnosis nonetheless had a large number of severe symptoms that spanned multiple disorders (an average of 6 severe symptoms compared with an average of 1 in the positive MHQ score group).

Within the positive score range (from 0 to 200), only 1.14% (16/1406) of the respondents met the DSM-5 criteria equivalent to a disorder diagnosis, with 88% (14/16) of these being in the enduring category. Thus, MHQ scores exhibit both a low false-positive rate within the clinical score range and a low false-negative rate within the positive score range.

MHQ by Age and Gender

Next, we show the initial results of overall MHQ scores by gender (Figure 6) and age (Figure 7). The distribution for males and females showed that a greater proportion of females reported negative MHQ scores compared with males (177/1018, 17.39% for females compared with 12.6% [77/609] for males; Figure 6), with the greatest difference being in the mood and outlook subcategory (204/1018, 20.04% of the female respondents were at-risk or clinical compared with 92/609, 15.1% of the male respondents), and mind-body (169/1018, 16.60% of the female respondents were at-risk or clinical compared with 44/609, 7.2% of the male respondents) subcategories. Both subcategories contain a large proportion of depressive symptoms; therefore, this finding is in line with the gender differences reported elsewhere [26-28]. In addition, MHQ scores differed substantially by age, with older age brackets having increasingly positive scores overall (Figure 7). MHQ scores of respondents in the 18 to 24 years age range were sharply lower, with 23.7% (58/245) in the negative at-risk or clinical range and only 27.3% (67/245) in the succeeding or thriving range. The proportion of respondents who were at-risk or clinical declined with age from 23.7% (58/245) to just 9.4% (11/117) in the 65+ years age group, and the proportion of those succeeding or thriving (ie, scores above 100) increased with age from 27.3% (67/245) to 69.2% (81/117). This pattern is in line with data from other sources [29]. This view by age and gender was not significantly different between respondents from the United States alone versus respondents from all other countries together. However, at this stage, because of the small representation from other countries (maximum of 149/1665, 8.95% for any individual country), a country-wise comparison was not possible.

Figure 6. Cumulative percentage of respondents across the Mental Health Quotient score range for male and female groups (N values for male and female groups shown in the legend). MHQ: Mental Health Quotient.
Figure 7. Distribution of Mental Health Quotient scores across ages. Shows both the cumulative percentage of respondents across the Mental Health Quotient score range for each age bracket (N values for each age bracket shown in the legend) and the linear increase in the proportion of succeeding or thriving (Mental Health Quotient scores above 100) and the decrease in the proportion of at-risk or clinical (Mental Health Quotient scores below 0) from younger to older age groups. MHQ: Mental Health Quotient.

**MHQ Subcategory Scores**

Next, we show the distribution of MHQ subcategory scores across each of the 6 subcategories of mental health (Figure 8). The distribution structure is highly similar to the overall MHQ across all categories, with a normal distribution in the positive range and a skew in the negative range. The average values across the entire score range for each subcategory were as follows: core cognition 47 (median 54, mode 75); complex cognition 49 (median 53, mode 51); drive and motivation 47 (median 54, mode 74); mood and outlook 39 (median 43, mode −2); social self 39 (median 46, mode −1); and mind-body 40 (median 45, mode 65). Within the positive score range, the average, median, and modal values were as follows: core cognition 54 (median 57, mode 63); complex cognition 54 (median 56, mode 51); drive and motivation 55 (median 57, mode 74); mood and outlook 49 (median 51, mode 80); social self 53 (median 56, mode 75); and mind-body 48 (median 49, mode 65). A few key aspects warrant mention: the social self-subcategory, in particular, had a comparatively large proportion of people in the negative range (374/1665, 22.46% overall and 24/1665, 1.44% in the clinical range) followed by mood and outlook (302/1665, 18.14% overall, and 19/1665, 1.14% in the clinical range), indicating that challenges relating to these aspects of mental health were highly prevalent in the population of respondents (Figure 8). In contrast, the proportion of respondents facing serious challenges in their cognition (core and complex), drive and motivation, and mind-body were comparatively smaller.
**Discussion**

**A New Tool for Assessing Individual and Population Mental Health and Well-Being**

Assessment is the first step in identifying individuals and groups who are most at risk from mental health challenges as well as understanding the overall mental well-being of a population. However, existing mental health assessment tools exhibit several limitations [16] that hinder both effective transdisorder diagnosis and their application to the general population. Here, we present the MHQ, a uniquely designed web-based assessment tool that provides both an individual view of mental health and clinical risk and, when aggregated, a population view of overall mental well-being.

**MHQ as a Unique and Comprehensive View of Both Symptoms and Assets**

The MHQ spans the breadth of mental health symptoms associated with major psychiatric disorders in a standardized and unbiased manner as well as assets and abilities important for overall mental well-being. The fact that 97.96% (1921/1961) of respondents found the MHQ easy to understand, and that it took, on average, only 14 min to complete, indicates that the tool is highly accessible to the general population.

The MHQ was uniquely developed based on an extensive review of symptoms from 126 assessment tools across 10 different mental health disorders as well as taking into account disorder agnostic approaches to mental health, such as RDoC [20-22]. In this regard, it represents the most comprehensive symptom profiling available, overcoming many limitations and biases of existing tools that include only partial lists of symptoms and are often skewed toward feelings or behaviors [16]. The MHQ also goes beyond a disorder-based approach (ie, a focus on negative symptoms alone) with the inclusion of spectrum items that consider a person’s mental abilities and assets. This aspect, rarely considered by existing mental health assessment tools, is critical to existing views of mental well-being [1] and addresses the growing realization that positive aspects of mental health are essential for an integrated view of health [2,30].

Together, this design approach allows respondents, on an individual level, to obtain a holistic picture of both concerns and abilities across their results profile, while at the population level, it ensures that insights are not based on an incomplete or biased picture of reported symptoms and functions.
Insights Into Individual Mental Health

On the one hand, the MHQ can be used to provide personalized insight into an individual’s mental health in a manner that is disorder agnostic and avoids the ambiguity of disorder classification [18]. These insights are accompanied by feedback that is generated based on the individual scoring profile. This allows at-risk individuals to self-identify so that they can seek appropriate support before reaching clinical levels of distress or impairment. For example, in this preliminary data set, 13.09% (218/1665) of the respondents were identified as being at-risk, whereas 2.46% (41/1665) of the respondents likely required immediate clinical intervention, of which 95% (39/41) met the DSM-5 criteria for a mental health disorder. It also provides a mechanism for individuals within a normal healthy range to evaluate dimensions of their mental health and identify challenge areas so that they can take action (eg, make adjustments to their lifestyle) to strengthen and preserve their well-being even if they are not considered clinically at risk. Owing to its close equivalence to diagnostic outcomes based on DSM-5 criteria, the MHQ can also be used as a fast patient screen on admittance to a hospital clinic, where individual scores and mappings to DSM-5 disorder classifications, as shown in Table 1, can provide an initial impression of a patient’s symptoms and diagnosis to guide faster paths to treatment.

Validation of the MHQ Against DSM-5 Diagnostic Criteria and Known Epidemiology

The preliminary data presented here from just 1665 adult respondents demonstrated that overall 15.56% (259/1665) of the respondents were identified as being at-risk (218/1665, 13.09%) or requiring immediate clinical intervention (41/1665, 2.46%). Comparisons of MHQ scores against DSM-5 criteria also revealed a low false-positive rate (2/41, 5%) within the clinical score range, where 95% (39/41) of the respondents met the criteria for a diagnosis of at least one mental health disorder. There was also a low false-negative rate (16/1406, 1.14%) within the positive score range (from enduring to thriving), indicating that 98.86% (1390/1406) of respondents with a positive MHQ score did not meet the criteria for a mental health disorder diagnosis. The close alignment between MHQ scores and the degree to which people meet DSM-5 diagnostic criteria demonstrates its validity as a mental health assessment tool capable of identifying at-risk individuals within a population as well as providing a comprehensive cross-disorder clinical view.

One limitation was that the MHQ mapping to the DSM-5, and the subsequent diagnostic indication, only took into account the severity of symptoms and not the duration or frequency of symptoms required for some disorders, as these aspects do not form part of the MHQ. However, the MHQ is also able to identify those people with a large number of severe clinical symptoms in need of help, whose symptoms do not fall specifically into any particular disorder classification.

At the population level, the proportion of respondents reporting negative scores is in line with annual prevalence rates of mental health disorders reported from other sources [23-25]. In addition, female respondents scored slightly more poorly, especially in the mood and outlook and mind-body subcategories, both subcategories with a large proportion of depressive symptoms, in line with gender differences reported elsewhere [26-28]. Finally, the data showed that individuals within the youngest age bracket (18-24 years) were most at risk of experiencing mental health challenges, which is also in line with data from other sources [29]. Thus, the overall results of the MHQ are in line with other epidemiological estimates along various dimensions, demonstrating its validity as an epidemiological mental health assessment tool.

Potential Applications of the MHQ

The MHQ was designed to be easy to implement in research initiatives using large populations of individuals to obtain insights into the profile of mental health challenges and positive well-being. When used in a large-scale epidemiological context, relating MHQ scores to a range of demographic, experiential, and situational variables can support the development of relevant interventions or policies that could induce larger-scale shifts in population well-being. Furthermore, the MHQ can be used within specific organizations, such as companies or universities, to measure and track the overall mental health and well-being of their workforce or student body, respectively; to support the design of tailored interventions suited to that specific group; to identify at-risk individuals or subgroups; and to assess the impact of any support programs. The MHQ can also be used in a clinical context as a first-line screening tool within both primary care and psychiatric clinics. From a research perspective, the results obtained from the MHQ can also enable a better understanding of the relationship between individual symptoms and symptom profiles and underlying biomarkers and be used to examine the efficacy of new treatment regimes.

Identifying the Borders Between Abnormal and Normal Mental Health

The development of an assessment tool that covers the breadth of mental ill health through to positive functioning, and one that is accessible to the general population, is also relevant for one of the major discussion points pertaining to the diagnosis and classification of mental disorders, namely, the distinction between normal and abnormal mental health [12,14,15]. As most negative mental states, such as sadness, despair, anxiety, fear, agitation, and anger, are not abnormalities per se but normal responses to life’s ups and downs, being able to decipher whether a person is responding normally to difficult circumstances, or experiencing pathological levels of distress or impairment, is not straightforward [13]. One challenge underpinning this debate relates to the fact that, currently, there is a poor understanding of the state and diversity of mental health across a normal population. Thus, if there is a poor understanding of what the continuum of normal mental health looks like, how can we understand when it is starting to slide into abnormal. Such a distinction is necessary not only to prevent false positives in diagnosis, a label that can be unduly associated with stigma but also to ensure that people receive appropriate treatment and that clinical research studies investigating underlying etiologies select from appropriate sample pools. The MHQ assessment tool has been constructed to capture this breadth of function from positive assets to extreme distress to establish these distinctions.
Psychiatric disorders are among the most disabling health conditions worldwide, creating a significant burden on individuals and societies [31]. Assessments of mental health that are accessible to the general population support the early identification of at-risk individuals or subgroups and reveal relevant risk factors. This, in turn, can help reduce the burden by facilitating the development of relevant and effective interventions and policies before symptoms escalate to clinical levels. The importance of population accessible tools is further emphasized by the reported gap between those with severe distress and impairment and those receiving the help and support they need [32]. The MHQ aims to help realize the vital goals of mental health prevention and support by providing a means to measure and track population mental health. Going beyond this, the MHQ ultimately seeks to enable a paradigm that can manage and improve the lives and well-being of all people, and not just those with a clinical disorder.

Acknowledgments

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Authors’ Contributions

JN and TT developed the assessment tool. JN drafted the manuscript. TT and JN revised the manuscript, approved the final version, and agreed to be accountable for all aspects of the work.

Conflicts of Interest

The MHQ is both freely available on the web as well as available as a customizable and fee-for-use research tool from Sapien Labs, which is a 501(c)(3) nonprofit organization. There is no direct financial benefit to the authors.

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Abbreviations
- ADHD: attention-deficit/hyperactivity disorder
- ASD: autism spectrum disorder
- DSM: Diagnostic and Statistical Manual of Mental Disorders
- ICD: International Classification of Diseases
- MHQ: Mental Health Quotient
- OCD: obsessive-compulsive disorder
- PTSD: post-traumatic stress disorder
- RDoC: Research Domain Criteria
Toward a Taxonomy for Analyzing the Heart Rate as a Physiological Indicator of Posttraumatic Stress Disorder: Systematic Review and Development of a Framework

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Abstract

Background: Posttraumatic stress disorder (PTSD) is a prevalent psychiatric condition that is associated with symptoms such as hyperarousal and overreactions. Treatments for PTSD are limited to medications and in-session therapies. Assessing the way the heart responds to PTSD has shown promise in detecting and understanding the onset of symptoms.

Objective: This study aimed to extract statistical and mathematical approaches that researchers can use to analyze heart rate (HR) data to understand PTSD.

Methods: A scoping literature review was conducted to extract HR models. A total of 5 databases including Medical Literature Analysis and Retrieval System Online (Medline) OVID, Medline EBSCO, Cumulative Index to Nursing and Allied Health Literature (CINAHL) EBSCO, Excerpta Medica Database (Embase) Ovid, and Google Scholar were searched. Non–English language studies, as well as studies that did not analyze human data, were excluded. A total of 54 studies that met the inclusion criteria were included in this review.

Results: We identified 4 categories of models: descriptive time-independent output, descriptive and time-dependent output, predictive and time-independent output, and predictive and time-dependent output. Descriptive and time-independent output models include analysis of variance and first-order exponential; the descriptive time-dependent output model includes a classical time series analysis and mixed regression. Predictive time-independent output models include machine learning methods and analysis of the HR-based fluctuation-dissipation method. Finally, predictive time-dependent output models include the time-variant method and nonlinear dynamic modeling.

Conclusions: All of the identified modeling categories have relevance in PTSD, although the modeling selection is dependent on the specific goals of the study. Descriptive models are well-founded for the inference of PTSD. However, there is a need for additional studies in this area that explore a broader set of predictive models and other factors (eg, activity level) that have not been analyzed with descriptive models.

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KEYWORDS

heart rate; statistics; PTSD; mental health; physiology
Introduction

Background

Posttraumatic stress disorder (PTSD) is a psychiatric condition that develops as a result of experiencing injury, severe psychological shock, and other trauma [1]. Individuals with PTSD are affected by the recall of traumatic experiences and often develop depression, anxiety, emotional instabilities, and suicidal thoughts [2]. Recent reports suggest that individuals with PTSD are about 5 times more likely to commit suicide than individuals without PTSD [3]. Approximately 10% of American women and 4% of American men experience PTSD in their lifetime [4]. PTSD is an endemic among veterans as well, affecting between 17% and 24% of veterans from recent conflicts [5].

Although an alarming number of individuals are afflicted with PTSD, there are significant barriers to care delivery [6,7]. These barriers include a shortage of qualified clinicians and understaffed mental health clinics, geographical constraints to accessing mental health facilities, financial obstacles, and cultural factors such as social stigma, and limited capabilities in objective diagnosis (currently limited to self-reported measures such as the PTSD checklist [PCL-5]) [8]. Studies have shown that self-management and factors such as positivity directly affect PTSD symptoms and ease in dealing with them [9]. Mobile health (mHealth) apps have shown promise in facilitating self-management (eg, education, mindfulness, and self-assessment) and have the potential to facilitate direct communication between people who have PTSD and their health care providers [10]. mHealth apps deployed on wearable devices (eg, smartwatches) that are equipped with an array of physiological sensors (eg, heart rate [HR]) may also enable continuous remote monitoring of signs and symptoms of PTSD. Indeed, recent efforts have shown promising applications of watch-based HR sensors to detect the onset of PTSD hyperarousal events [11].

Objectives

Despite recent work, the extent of knowledge on the physiological reactions to PTSD and, in particular, HR is limited, and research is needed to better understand the changes in HR associated with PTSD. Few models (eg, analysis of variance [ANOVA], regression analysis) have been developed to relate changes in heart activity to disorder states. In particular, given the opportunity to collect HR data nonintrusively, it is important to use appropriate mathematical and statistical methods to ensure the accumulation of convergent knowledge in this field and to characterize and understand HR in terms of PTSD. In this paper, we document the findings from a review of the current literature on measures and models used in various domains to analyze HR data. In addition to summarizing and synthesizing the HR analysis methods, we provide an evaluation of methods for applications relevant to PTSD detection and diagnosis.

Methods

Search Strategy

A scoping review was conducted using the strategies outlined in the preferred reporting items for systematic reviews and meta-analyses (PRISMA) methodology [12]. The scoping review approach was selected because it is effective for knowledge evaluation and gap identification [13]. The review spanned 5 main databases: (1) Medical Literature Analysis and Retrieval System Online (Medline) OVID, (2) Medline EBSCO, (3) Cumulative Index to Nursing and Allied Health Literature (CINAHL) EBSCO, (4) Excerpta Medica Database (Embase) Ovid, and (5) Google Scholar. Search terms included heart*, pulse*, heart rate*, model*, heart beat*, and analysis*. All studies published in or after the year 2000 were included. This search was supplemented by a secondary search of cited articles in the results. The search was completed on January 15, 2020.

Study Selection, Inclusion, and Exclusion Criteria

Abstracts were reviewed for relevance, and articles that did not discuss HR-related measures in detail and did not provide or use quantitative methods for analysis were excluded. Other exclusion criteria were non–English language articles and articles that assessed non–heart-based physiological measures such as skin conductance and blood pressure. Furthermore, studies that did not analyze human physiology were excluded. The inclusion criteria were all articles that discussed human HR analysis. Our initial search yielded 1905 results. After removing duplicate articles and checking for eligibility using Rayyan QCRI (a web app for assisting literature reviews), 270 articles were further reviewed. Out of the 270, 138 were exclusively about non–heart-based measures reactions, 67 did not focus on human physiology, and 11 had duplicated content. Of these, 54 articles from the search were included in this review based on their relevance to the topic.

Furthermore, the bibliography of references in each research paper was investigated thoroughly (backward search) to identify pertinent articles, and then Google Scholar searches (forward search) were conducted to find the full text. Figure 1 shows the PRISMA flow chart for the article selection process.
Results

We listed the articles identified by the search process into 2 categories based on our synthesis: studies of the effects of PTSD on heart physiology and quantitative modeling techniques for heart data. We further partitioned studies of PTSD effects into 2 types: (1) studies that investigate the effect of PTSD on heart rate variability (HRV) and (2) studies that explore the effect of PTSD on HR. The literature on models can be further classified by the model’s focus on describing versus predicting data and the model output. These categories and subdivisions are discussed in the following sections.

Effects of Posttraumatic Stress Disorder on Heart Rate Variability

HRV measures variations in heartbeats and is related to the electrical activity of the heart [14]. Common frequency domain analysis metrics for HRV include high frequency power (HF), low frequency power (LF), the ratio of LF to HF, coherence score (COH), root mean square of successive differences between normal heartbeats (RMSSD), and the SD of the interbeat interval of normal sinus beats (SDNN) [15-18]. LF and HF are frequency bands of HRV that tend to correlate with parasympathetic nervous system activity. LF is the frequency activity in the range of 0.04 to 0.15 Hz, and HF is the activity in the range of 0.15 to 0.4 Hz. The quantified relative intensity of these measures is referred to as power [1], and such power is obtained by applying power spectral and frequency domain analyses [19].

The reviewed articles found that PTSD causes sustained changes in the autonomic nervous system (ANS; the part of the nervous system that is responsible for regulating automated functions in the body, such as heart activity) [20]. The ANS consists of the parasympathetic nervous system (PNS), which regulates blood pressure and breathing rate during rest, and the sympathetic nervous system (SNS), which adjusts blood pressure and HR during activity. Heart activity is representative of the performance of these systems [21]. Various effects of PTSD on ANS have also been documented. Higher HR levels indicate lower HRV and are linked to increased rates of mental stress and physical activity [22,23]. PTSD, as a particular type of
anxiety disorder, also disturbs HR and HRV. HRV has been studied widely in the literature to assess PTSD [18,24-26]. Evidence suggests that individuals with PTSD have lower resting HRV than individuals without PTSD when other factors (age, gender, and health level) are controlled [27]. According to the meta-review Nagpal et al [1], HF, a measure for the parasympathetic activity of ANS, is significantly lower in individuals with PTSD than in individuals without PTSD (approximately 0.6 ms²). However, LF, which assesses both the sympathetic and parasympathetic activity of the ANS, is slightly reduced in individuals with PTSD (approximately 0.2 ms²). This results in a significant increase in LF divided by HF of individuals with PTSD [1,28-30].

RMSSD and SDNN are time-domain measures of HRV. SDNN is an index of SNS activity [24]. SDNN is decreased in individuals with PTSD compared with healthy individuals (approximately 6.7 ms), showing an increase in sympathetic activity [1,31]. In addition, decreased levels of RMSSD was observed among individuals with PTSD (approximately 7.5 ms), suggesting lower vagal activity in this population [1,31].

Although an HRV analysis is common among studies of anxiety [32], some factors need to be considered when HRV measures are used. First, studies show that HRV is dependent on HR and cannot be analyzed independently to represent ANS activity [32,33]. In addition, previous research has linked high HRV to pathological conditions related to heart deficiencies [32]. For instance, diseases such as atrial fibrillation increase HRV and HR are associated with higher mortality rates [34]. Hence, higher rates of HRV do not always indicate an abnormal mental state. Ideally, measurements should take into account patient’s comorbidities such as heart deficiencies in addition to subjective (eg, self-reported scales) and objective (eg, HRV, ECG) methods [35]. Gender, health, age, and HR also affect HRV, and they need to be considered as covariates when HRV measures are used [24]. Aging decreases HRV time-domain features such as SDNN [36,37]. HRV time-domain features increase with improved health conditions [38,39]. LF and SDNN are also lower in females than in males; however, the HF parameter of HRV is greater in women than in men [40]. Higher HR levels are also associated with decreased HRV [41] because when the heart beats faster, the beat-to-beat intervals are smaller. Other factors such as climate, job satisfaction, lifestyle, and medications can also affect HRV and should be considered as an influential factor when HRV is analyzed [42].

**Effect of Posttraumatic Stress Disorder on Heart Rate**

HR is the number of heartbeats per 60 seconds. Normal HR differs among individuals based on age and gender, health level, and respiratory activity [43]. Both HR and HRV are modulated by the ANS [44]. As the SNS activates, PNS activity is suppressed; therefore, HR increases and HRV decreases [45]. As a result, there is an inverse relationship between HR and HRV [33].

PTSD can affect HR in 2 modalities: resting and fluctuation [1,46-48]. Studies suggest that resting HR can be between 5 and 6.6 beats per minute in individuals with PTSD than in individuals without PTSD depending on the type of population (eg, veteran, civilian) [49-51]. For example, resting HR is roughly higher than 5 beats per minute in civilians with PTSD than in civilians without PTSD, and this number increases to 6.6 beats per minute in the veteran population [51,52]. In the nonresting state, evidence suggests that HR increases with exposure to PTSD stressors [1].

Another HR measure that has been investigated in terms of PTSD is HR fluctuations (changes in HR levels) in the presence of stimuli [53]. There are conflicting findings on the comparison of this measure between individuals with and without PTSD. Although a study by Roy et al [54] showed that HR changes are higher in people with PTSD than in people without PTSD, a study by Halligan et al [55] claims the opposite.

**Heart Rate Models**

On the basis of our synthesis of the existing literature, we categorized mathematical models of HR into descriptive and predictive models, both of which could provide insight relevant to understanding the psychophysiological responses to PTSD. Descriptive methods can be used to describe and make inferences about a data set, whereas predictive methods can be applied to forecast trends and patterns in the data. Predictive and descriptive models can be further characterized by their type of output—time-independent or time-dependent (Figure 2). Time-dependent outputs use time as one of the descriptive variables to analyze the dependent variable(s) or output(s). Time-independent output, however, does not depend on time and does not change over time. Although the models reviewed below are summarized and synthesized for relevance to PTSD-related analysis, these methods are not limited to PTSD and anxiety disorder domains.
**Descriptive Models**

**Time-Independent Output**

**Analysis of Variance**

Linear regression, and in particular ANOVA, is a statistical model used for the analysis of HR in several articles (Table 1). ANOVA can be used to compare HR trends and group means in experimental studies [56,57]. Studies have used ANOVA to account for the effectiveness of treatments in individuals with PTSD, as measured by HR [58]. Some studies chose ANOVA as their method of analysis to show that resting HR is higher in individuals with PTSD than in individuals without PTSD [57]. For example, the study by Gelpin et al [59] compared the resting HR in individuals pre-and posttreatment to measure the success of therapy sessions. Buckley et al [52] used ANOVA to compare resting HR in patients with PTSD with that of healthy controls, finding that patients with PTSD, in general, have significantly higher resting HR levels (approximately a 6 beats-per-minute difference). Although using ANOVA for the analysis of time-independent HR data is highly common, ANOVA is limited in several respects. ANOVA has strong assumptions and is ill-suited to model-dependent measures with strong temporal correlations. For instance, the independency of observations is one of the main assumptions of ANOVA; however, consecutive HR real-time-based data are a highly correlative type of data. Thus, ANOVA should not be used to make time-based HR predictions [60].

**First-Order Exponential Model**

A first-order exponential model provides a function with a sustained growth or decay rate [61]. In terms of HR analysis, first-order exponential models have been used to generate a nonlinear regression model for HR based on heart rate recovery (HRR) [62]. HRR is an indicator of vagal reactivation and SNS deactivation [63].

Bartels-Ferreira et al [63] used the first-order exponential method to measure postexercise time-independent HRR based on HR decay curves. Recovering from the onset of PTSD symptoms is associated with activation of vagal tone and withdrawal of SNS activity, both of which are correlated with HRR [64]. Although this method shows promise in the assessment of HR fluctuations associated with PTSD, the reviewed literature (Table 1) examined ANS in the context of physical activity, and HR decay after activity was curve fitted by a first-order exponential function [63]. In this case, the goodness of fit was moderate ($R^2$ was approximately 0.65), which warrants additional research. Another limitation associated with this method is that the exponential functions show erroneous patterns for very small (30-second) and very large (600-second) time windows [61]. For instance, Bartels-Ferreira et al [63] found that the least goodness of fit was for the smallest time window, which was 30 seconds ($R^2=0.42$). Conversely, when the length of the window of time was a moderate number (approximately 360 seconds), a relatively better goodness of fit was obtained (approximately 0.69). This shows that the HRR curve fitted by first-order exponential models performs better (higher $R^2$) when windows of times are neither too big nor too small. Table 1 shows a summary of articles that studied descriptive models with time-independent output. In this table, domain is the field of the study. Independent variables are factors that are controlled by researchers, and dependent variables are dependent on them. Independent variables are used to describe or classify dependent variable.
### Time-Dependent Output

#### Classical Time Series Analysis

Classical time series analysis is a common statistical method that can analyze time-dependent data trends by looking into linear relationships. Classical time series analysis is also a promising method for analyzing HR and HR fluctuations as these measures are time-based [69,70].

Peng et al [70] applied time series analysis to examine the long-term correlation within HR data and its relation to heart diseases such as cogestive heart failure. Using this method, the authors showed that there is some independency between beat-to-beat HR fluctuations in healthy people that does not exist in patients with cardiovascular disease. The findings further suggest that classical time series analysis is a promising direction for PTSD hyperarousal analysis because similar HR changes have been documented in patients with PTSD compared with healthy people in the presence of stimuli [71].

Beyond the analogous use case, the classical time series has several benefits compared with ANOVA. As the model explicitly considers autocorrelation, it does not require the assumption of independence of observations [72]. The models also have predictive capability and are well validated for illustrating trends and forecasting [73]. However, 1 drawback of this method is the stationary assumption (constant mean value of the series), which is not always reasonable in HR data (eg, when data are collected before and during exercise).

#### Mixed Regression Model

Mixed regression analysis has been used in the literature to evaluate physiological responses to energy expenditure [74]. This type of modeling can be applied with correlated observations. Thus, it is beneficial for psychophysiology analyses that need to account for individual similarities such as gender [60]. Multiple regression typically proceeds in a stepwise process with a focus on identifying 2 main effects: the population fixed effect and the random effect. The population-fixed effect explains similarities in the dataset (for instance HR), whereas the random effect represents the differences among observations (the error term). For instance, Gee et al [75] used respiration as a random effect to estimate HR and ultimately predict episodes of bradycardia in infants. Using a mixed regression method and accounting for respiration as a covariate, in this case, has increased the accuracy of the measured HR by 11%.

The ability of mixed regression models to account for individual differences makes them an advantageous choice for modeling PTSD. Several studies have identified significant individual differences in people with PTSD [1,57,76,77]. Specifically, HR and HRV levels are significantly affected by individual differences such as age, general health, and gender [24]. This type of modeling might produce similar results to ANOVA in many cases. However, in comparison with ANOVA, mixed regression models are more effective for data sets with missing values and multiple random effects [78]. This is important as in real-world and naturalistic studies, data sets with high rates of missing values are common and can be challenging to deal with [79]. Table 2 shows a comparison of time-dependent output methods.

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**ANOV**

<table>
<thead>
<tr>
<th>Method and authors</th>
<th>Domain</th>
<th>Independent variables</th>
<th>Dependent variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shalev et al [57]</td>
<td>PTSD</td>
<td>Gender, age, HR&lt;sup&gt;c&lt;/sup&gt;, trauma history, event security&lt;sup&gt;b&lt;/sup&gt;</td>
<td>HR</td>
</tr>
<tr>
<td>Strath et al [65]</td>
<td>Physical activity</td>
<td>HR, oxygen intake, age, fitness</td>
<td>HR</td>
</tr>
<tr>
<td>Romero-Ugalde et al [66]</td>
<td>Physical activity</td>
<td>Accelerometer, energy expenditure, HR</td>
<td>HR</td>
</tr>
<tr>
<td>Khoueiry et al [67]</td>
<td>Medical</td>
<td>HR, hospitalization duration, age</td>
<td>HR</td>
</tr>
<tr>
<td>Tonhajzerova et al [68]</td>
<td>Physiology</td>
<td>Resting HR, major depressive disorder</td>
<td>HR</td>
</tr>
</tbody>
</table>

<sup>a</sup> ANOVA: analysis of variance.

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

<sup>c</sup> HR: heart rate.

<sup>d</sup> HRR: heart rate recovery.
The success of applying machine learning methods depends on the data used to train and evaluate the algorithm. Machine learning algorithms typically require large training sets—several thousand observations—and they implicitly assume that the data and associated labels are of equal quality. In cases where the data are noisy, or labels are unreliable, machine learning training algorithms may fail to converge to a generalizable solution. Furthermore, if the training data examples are biased (eg, nonrepresentative population samples), the machine learning algorithms trained on the data may also be similarly biased. It is often difficult to identify these issues through standard training and testing processes of machine learning algorithms; thus, machine learning analyses should be accompanied by descriptive analyses to obtain a better understanding of the data and potential errors or bias [83].

Most of the reviewed studies used HRV, along with machine learning algorithms to predict stress levels in individuals [84-86]. Machine learning studies evaluating HR have primarily focused on energy expenditure [87,88]. An exception is McDonald et al [11] who evaluated several machine learning algorithms—neural networks, decision trees, support vector machines, convolutional neural networks, and random forests—to predict the onset of PTSD symptoms in the veteran population. This study used HR data with a 1 Hz frequency (1 observation per second) as the input of these algorithms. Although the raw 1 Hz data were used to train the neural network–based models, additional feature generation and selection was performed before training the decision tree, support vector machine, and random forest algorithms. This feature generation identified linear trends, Fourier transforms, and change quantiles as relevant features for the detection of the onset of PTSD symptoms. Among all machine learning methods, support vector machines, and random forest algorithms performed best (ie, had the highest area under the receiver operating characteristic curve (ROC) 0.67). Although machine learning shows promise for the inferential analysis of HR data for PTSD research, explaining the purpose of machine learning components may be difficult, and often predictive results have a limited rational explanation [89].

**Fluctuation-Dissipation Theory**

The fluctuation-dissipation theory (FDT) is a common approach in thermodynamics that is used to predict system behavior by breaking the system responses into small forces [90]. This theorem, which follows thermodynamic rules, can model the HRR after stress moments.

Chen et al [91] used FDT to predict patients’ HR reactions to presupontaneous and postspontaneous breathing trial treatment. They used this method to divide the system (in this case, the treatment process) into different phases, including pretreatment, midtreatment, and posttreatment. After breaking the entire treatment process to these small phases, each phase was modeled separately. The reactions to treatments in each phase were modeled using HRR measures. All models were then combined to create the final comprehensive model. Chen et al [91] found that thermodynamic rules can also model the HR response after stress moments. This is because of the similar effect of stress and spontaneous breathing trials on organs (a common clinical procedure used to assess the ventilation performance of patients). These researchers suggest dividing the system into prestress and poststress moments, modeling each phase, and finally assembling a model for final prediction. They further suggest
that the HRR extracted from this type of modeling can be used to personalize care as HR can be remotely monitored through noninvasive hospital devices.

In terms of mathematical concepts, this type of modeling has a powerful predictive capability by grouping individuals and therefore minimizing the error rate [91]. This approach requires significantly less data than other methods, such as time-variant modeling of HR. Hence, it enables researchers to include more variables in their model. Moreover, Chen et al [91] claim that although models that use Gaussian functions have around 65% error rate to predict patients’ response to spontaneous breathing trial, implementing FDT decreases this error rate by over 10%. Therefore, this approach provides more accurate results than methods that use Gaussian functions, such as some machine learning algorithms (eg, adaptive neuro-fuzzy inference system [ANFIS]). A potential reason for this could be that the system is broken down into smaller pieces, where each part has its own specific and defining features. However, in ANFIS, the system was considered as a whole, and a set of features was defined for the entire system overlooking dissimilarities within the system. In addition, unlike most statistical approaches that make assumptions about the data, this method is assumption-free and is considered more robust to assumptions (eg, normality of residuals, independency of measurements). Despite its promising application to the analysis of HR and the lack of restrictive assumptions, FDT is computationally intense. This means that the model needs a high level of proficiency in understanding the mathematics and statistics behind FDT. Especially, in comparison with approaches such as ANOVA, classical time series, and mixed regression, using this approach requires higher levels of domain knowledge, for example, studies in machine learning and FDT methods (Table 3).

Table 3. Results from example studies that used predictive models with time-independent output.

<table>
<thead>
<tr>
<th>Method and authors</th>
<th>Domain</th>
<th>Independent variables</th>
<th>Dependent variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolus et al [87]</td>
<td>Biomedical (energy expenditure)</td>
<td>HA, oxygen consumption, work rate</td>
<td>Work rate</td>
</tr>
<tr>
<td>McDonald et al [11]</td>
<td>PTSDa</td>
<td>HR, subjective stress moments</td>
<td>Stress moment</td>
</tr>
<tr>
<td>Healey et al [86]</td>
<td>Driving</td>
<td>HR, HRVc, skin conductance, muscle activity, muscle tension, breathing rate</td>
<td>To detect stress</td>
</tr>
<tr>
<td>Kolus et al [88]</td>
<td>Physical activity</td>
<td>HR, maximum HR, oxygen consumption, body type, work rate</td>
<td>Work rate</td>
</tr>
<tr>
<td>Zhang et al [92]</td>
<td>Physical activity</td>
<td>HR, body attitude information, body movement</td>
<td>HR</td>
</tr>
</tbody>
</table>

aHR: heart rate.
bPTSD: posttraumatic stress disorder.
cHRV: heart rate variability.

**Time-Dependent Output**

**Time-Variant Modeling**

Time-variant modeling is a mathematical approach used to analyze time-dependent data sets and provide a time-dependent output. Time-variant models of HR can generate HRR measures in real time. Some studies suggest that measuring HRR in real time can especially help assess arousals and arousability in different individuals in response to mental stressors [93]. This shows promise for PTSD research given its potential to enable the comparison between the effect of internal stimuli (stressors generated through memory) and external stimuli (stressors generated from the environment) on the arousability of patients with PTSD.

Although time-variant modeling has been replicated in the literature and has shown promise in analyzing HR data [33,94], it is computationally intense. The process of solving the equations within the model includes defining multiplex matrices for each variable, which is time and space consuming. Moreover, time-variant modeling requires large data sets of HF (eg, 100 Hz) HR data, which is often not feasible for real-time data collection instruments such as wearable devices that record continuous data for large windows of time (eg, more than 30 min).

**Nonlinear Dynamic Modeling**

Nonlinear dynamic modeling of HR consists of depicting HR as the output of a nonlinear dynamic system [95].

Nonlinear dynamic modeling of HR can be a promising method to assess arousal patterns by measuring SNS activity [96]. Hence, this approach may be useful for analyzing PTSD hyperarousal patterns as they are associated with SNS activity. Despite the advantages of this model, it requires high-frequency HR data (eg, 100 Hz) or even instantaneous HR [96]. Instantaneous HR is an HR measure derived from HRV, which is different from raw HR measured by wearable devices. Instantaneous HR can be extracted by multiplying RR intervals (the time between two consecutive R waves of the HRV signal) by 60 and needs to be measured at an HF (>250 Hz), whereas smartwatches collect HR data with a much lower frequency (<5 Hz) [96].

This model accounts for the natural nonlinearity and time-dependent features of HR data. In addition, the learnability
and predictability of this method can help detect the onset of symptoms in patients with PTSD. A limitation of this method for characterizing PTSD aspects is the assumption of invertibility [97]. This assumption indicates that all the variable matrices used in equations are required to be invertible. In many cases, and mainly in nonlaboratory settings, this assumption cannot be met [97]. Moreover, these methods are relatively slow and more computationally intense compared with other methods such as machine learning (for both training and testing the model) because they involve solving multiple complex mathematical equations [66]. Table 4 shows examples of predictive models with time-dependent output.

**Table 4.** Results from studies that used predictive models with time-dependent output.

<table>
<thead>
<tr>
<th>Method and authors</th>
<th>Domain</th>
<th>Independent variables</th>
<th>Dependent variable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time variant</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lefever et al [94]</td>
<td>Sports science—biomedical</td>
<td>HR(^a), participants’ input power, road gradient,</td>
<td>HRV(^b)</td>
</tr>
<tr>
<td>Olufsen et al [98]</td>
<td>Biology, health care</td>
<td>HR, resting HR, blood pressure</td>
<td></td>
</tr>
<tr>
<td><strong>Nonlinear dynamic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chen et al [69]</td>
<td>Health care (patient data)</td>
<td>Resting HR, arterial blood pressure, HR, HRV</td>
<td>Heart beat</td>
</tr>
<tr>
<td>Kazmi et al [33]</td>
<td>Biophysics</td>
<td>Human normal sinus rhythm, human congestive heart rate failure</td>
<td>HRV (they look at the correlation)</td>
</tr>
</tbody>
</table>

\(^a\)HR: heart rate.  
\(^b\)HRV: heart rate variability.

**Discussion**

**Descriptive Framework Based on the Summary of Findings**

We categorized the methods used to analyze HR data into 2 categories: descriptive and predictive. In the context of PTSD, descriptive models may be used to characterize PTSD triggers and the factors that affect their occurrence, whereas predictive models may be useful to predict PTSD onset to facilitate timely intervention. The extracted models provide methods for evaluating, describing, comparing, interpreting, and understanding patterns in the HR data. However, interpreting the data in a meaningful way depends on the specific objectives of the study. The data at hand can be analyzed with one or many of the reviewed models based on the goal of the study and the assumptions of the models. Each model corresponds to a distinct type of output and different interpretations of the data with different assumptions. On the basis of the process of data collection, the number of observations, and variables in the data, researchers might choose one or a combination of models provided. Table 5 provides a framework for choosing a model based on the limitations, assumptions, and features of each model and the data at hand. Furthermore, Table 5 presents the articles that used a specific method.
Table 5. Descriptive framework for heart rate–related analysis methods extracted from the literature.

<table>
<thead>
<tr>
<th>Model</th>
<th>Assumptions</th>
<th>Features</th>
<th>Limitations</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Descriptive, time-independent output</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **ANOVA**
| - Normal distribution of residuals         | • Capable of comparing groups and looking at trends                          | • Restrictive assumptions                                                | [47, 52-54, 57-59, 65-68, 99-102]                                         |
|    | - Constant variance of populations         | • Computationally simple                                                    | • Type I error                                                           |                                                                      |
|    | - Independence and identically distributed observations |                                                                              | • Just applicable to linear analysis                                      |                                                                      |
| **A first-order exponential model**        | • Continuous observations                                                   | • Not repeated in studies                                                | [63]                                                                    |
|    | - Observations should be identical (eg, no age, gender difference)           | • Gives higher weights to recent observations                              |                                                                             |                                                                      |
|    | - Environmental effects are constant      |                                                                              | • Higher error rates than classical time series and mixed regression     |                                                                      |
| **Descriptive, time-dependent output**     |                                                                              |                                                                          |                                                                            |                                                                      |
| Classical time series analysis              | • Stationary observations (constant mean values of series)                  | • Advantageous for analyzing time-based trends                          | Requires stationary data sets                                           | [33, 69, 70, 80]                                                      |
| **Mixed regression model**                 | • Normality of residuals distribution                                       | • Does not require independence of data points                          |                                                                             |                                                                      |
|    |                                                                              | • Used in the literature to analyze cardiovascular disease                   |                                                                             |                                                                      |
|    |                                                                              | • Includes linear and non-linear analysis                                   |                                                                             |                                                                      |
| **Predictive, time-independent output**    |                                                                              |                                                                          |                                                                            |                                                                      |
| Machine learning methods                   | • Limited dependencies of the observations (each machine learning algorithm has its assumptions that need to be checked) | • Proactive algorithm (can be used for action-reaction type of data sets) | Can over fit or under fit data                                          | [11, 86-88, 92, 108-110]                                             |
|    |                                                                              | • Powerful predictive method                                                | Cannot be applied to data sets with highly dependent variables          |                                                                      |
|    |                                                                              | • Rapid analysis prediction, and processing                                | The process has little rational explanation                               |                                                                      |
|    |                                                                              | • Simplifies time-intensive computations                                    |                                                                             |                                                                      |
| **Fluctuation-dissipation theory**         | • Equilibrium system (the system and observations are not changing)         | • Powerful predictive capability                                          | Computationally intense Time consuming                                  | [70, 91, 111]                                                        |
|    |                                                                              | • Does not have restrictive assumptions such as normality of residuals      |                                                                             |                                                                      |
|    |                                                                              | • Significantly less data needed compared with a general data fitting approach |                                                                             |                                                                      |
| **Predictive, time-dependent output**      |                                                                              |                                                                          |                                                                            |                                                                      |
| Time-variant modeling                      | • Requires big data sets with high-frequency data points (more than 60 Hz)   | • Can be used to describe data as well as forecasting the future         | Computationally intense Slow process                                     | [33, 93, 94, 96, 98, 112-116]                                        |
Athletes have lower HR levels than sedentary people decreases with age. Females have higher HR levels than men. The maximum HR typically by individual characteristics including age, sex, health, resting HR, respiration, and lifestyle [24]. The maximum HR typically decreases with age. Females have higher HR levels than men [126]. Athletes have lower HR levels than sedentary people [127]. Resting HR is lower in more active people, and lower resting HRs result in lower HR levels [128]. As the respiratory system affects heart activity, studies suggest that incorporating respiration as a factor in HR models improves HR estimation significantly [78]. Lifestyle such as smoking habits affects HR as well; people who smoke have a higher HR than nonsmokers [129]. Beyond these general characteristics, it is important to consider the type of physical activity in the analysis. Physical activity

<table>
<thead>
<tr>
<th>Model</th>
<th>Assumptions</th>
<th>Features</th>
<th>Limitations</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonlinear dynamic modeling</td>
<td>• Invertible matrices</td>
<td>• Very accurate</td>
<td>• Computationally intense</td>
<td>[33, 66, 96, 98, 104, 112, 113, 116-121]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Replicated multiple times in studies</td>
<td>• Slow process</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Requires invertible matrices that is not always feasible in naturalistic settings</td>
<td></td>
</tr>
</tbody>
</table>

*ANOVA: analysis of variance.

**Fit Assessment**

Fit assessment can be conducted to examine the efficiency of each method in modeling a specific dataset. Fit assessment is especially promising for comparing different methods if they are applied to the same data set. However, considering the wide range of applicable fit indices, researchers might struggle to compare them. In the category of descriptive models, $R^2$ and adjusted $R^2$ are the main indices of fit assessment. $R^2$ indicates the degree of variation in the dependent variable caused by the independent variable(s). Adjusted $R^2$ is a revised version of $R^2$ that accounts for the number of independent variables in a model [122]. Generally, adjusted $R^2$ is more promising than $R^2$ as it is more robust to overfitting [122]. In the prediction methods category, a variety of measures other than $R^2$ and adjusted $R^2$ were used to assess the quality of fit. Some of these measures include sensitivity, specificity, accuracy, and area under the ROC curve (AUC)-ROC. Sensitivity is the number of true-positives divided by the total number of observations, and specificity is the number of true-negatives divided by the total number of observations [123]. Accuracy is the number of true predictions divided by the total number of predictions. The error rate is 1 minus the accuracy or the number of wrong detections divided by the total number of observations [124]. Finally, AUC-ROC is a curve that plots the true-positive rate (Y axis) versus the false-positive rate (X axis) to measure the performance of the model. It is important to bear in mind that fit indices are data dependent; therefore, comparisons are the best made by fitting multiple models to the same data set.

In the statistical analysis of data in the PTSD domain, fit assessments have been used to show the efficiency of the results. For instance, McDonald et al [11] used ROC curves along with accuracy to show that random forest works better than other machine learning methods to predict hyperarousal moments in people with PTSD. Shalev et al [125] used sensitivity and specificity to predict the development of PTSD based on their instant responses to trauma. Bartels et al [63] applied adjusted $R^2$ to assess the goodness of fit for their proposed exponential model. Examples of fit adjustments are summarized in Table 6.

**Table 6. Examples of fit assessment for different methods used in studies.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Variables</th>
<th>Fit measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strath et al [65]</td>
<td>ANOVA</td>
<td>HR, oxygen intake, age, fitness</td>
<td>$R^2$=0.87</td>
</tr>
<tr>
<td>Zakier et al [80]</td>
<td>Classical time series</td>
<td>HR, energy expenditure, accelerometer, age</td>
<td>$R^2$=0.84</td>
</tr>
<tr>
<td>McDonald et al [11]</td>
<td>Machine learning</td>
<td>HR, subjective stress moments</td>
<td>Area under receiver operating characteristics curve=0.67</td>
</tr>
<tr>
<td>Healey et al [86]</td>
<td>Machine learning</td>
<td>HR, HRV, skin conductance, muscle activity, muscle tension, breathing rate</td>
<td>Accuracy=97%</td>
</tr>
<tr>
<td>Chen et al [91]</td>
<td>Fluctuation-dissipation theory</td>
<td>HR recovery, blood pressure, instantaneous HR</td>
<td>Error rate=25%</td>
</tr>
<tr>
<td>Chen et al [66]</td>
<td>Nonlinear dynamic</td>
<td>Resting HR, arterial blood pressure, HR, HRV</td>
<td>Sensitivity=0.941; predictability=0.988</td>
</tr>
</tbody>
</table>

*aANOVA: analysis of variance.

*HR: heart rate.

*HRV: heart rate variability.

**Methodological Considerations for Heart Rate Assessments**

The models identified in this review represent several promising directions for future exploration, but they also illustrate a hidden complexity in the use of HR data as model input. HR is impacted by individual characteristics including age, sex, health, resting HR, respiration, and lifestyle [24]. The maximum HR typically decreases with age. Females have higher HR levels than men [126]. Athletes have lower HR levels than sedentary people [127]. Resting HR is lower in more active people, and lower resting HRs result in lower HR levels [128]. As the respiratory system affects heart activity, studies suggest that incorporating respiration as a factor in HR models improves HR estimation significantly [78]. Lifestyle such as smoking habits affects HR as well; people who smoke have a higher HR than nonsmokers [129]. Beyond these general characteristics, it is important to consider the type of physical activity in the analysis. Physical activity
Heart Rate Assessments in Anxiety Domains

HR data have been widely investigated in the domains of physical activity and energy expenditure. Although there are some differences between the effects of mental stress on HR and the effects of physical activity on HR, there are many similarities that make these domains connected. Physical activity affects SNS performance in the short term and PNS performance in the long term. As a result, HR increases during physical activities (due to SNS activation), and resting HR is lower in athletes who have higher rates of physical activity (because of PNS performance).

Similarly, in terms of mental stress, whereas acute stress or immediate response to stressors activates SNS, chronic stress increases vagal and parasympathetic activity. These similarities enable researchers in mental stress domains to employ models and pathways that are extracted in physical activity domains. For instance, one main measure that is used broadly to examine energy expenditure is HRR. This measure is an accepted indicator of SNS deactivation and PNS activation. Recovering from acute stress and arousability is also associated with the withdrawal of SNS and activation of PNS. As a result, HRR can be a proper measure to be considered in studies that examine acute stress.

Limitations

This scoping review attempted to include all articles that analyzed HR; however, it is still likely that some were overlooked. Furthermore, the authors categorized the HR models based on their own synthesis of the literature and relevance to PTSD. These models can be listed and categorized in a variety of ways, such as deterministic versus stochastic.

Another limitation of this review is that although the identified models have been applied across various domains (eg, energy expenditure and general stress prediction), to our knowledge, only 2 papers directly applied these methods to data from patients diagnosed with PTSD. In particular, only 1 study used a predictive approach in the PTSD domain. Other studies were primarily limited to linear descriptive statistics such as the t test or ANOVA. These methods are valid for making inferences about PTSD and comparing their effects on HR among different groups. However, there is a need for additional studies in this area that explore a broader set of predictive models and other factors (eg, activity level) that have not been analyzed with descriptive models.

Beyond the specific application of these models to PTSD, there are several more general challenges. The reviewed research often proceeded independently, with few links between the various studies. This diversity makes comparisons across studies difficult. Studies have used different data sets with different variables based on individual goals. Furthermore, the reviewed work often focused on testing 1 specific model rather than a broad comparison. Often critical details, such as the model and parameter selection process, were not reported in the articles. Another critical detail often not addressed in the reviewed studies was the mismatch between the model requirements and the sampling rates, which may result in conditions such as overfitting.

Collectively, these limitations suggest a need for substantial additional work in modeling the relationship between HR and PTSD. Future studies should consider comparisons between several models, analyze or explicitly discuss decisions made throughout the modeling process, and comprehensively document their HR data collection. As future studies are conducted that enact these criteria, the utility of the modeling approaches identified here will become clearer, and the path to more effective PTSD treatments will become more attainable.

Conclusions

The goals of this review were to identify and characterize quantitative HR models for relevant applications in PTSD. One of the gaps in this area is the absence of a framework that researchers can use before, during, and after their data collection to choose a method to analyze HR data. In this regard, we developed a descriptive framework that can be used to determine the method to apply to HR data to achieve more efficient results. We identified 4 broad categories of methods: descriptive time-independent output, descriptive time-dependent output, predictive time-independent output, and predictive time-dependent output. Descriptive time-independent output models include ANOVA and first-order exponential, whereas descriptive time-dependent output models include classical time series analysis and mixed regression. Predictive time-independent output models include machine learning methods and analysis of HR-based FDT. Finally, predictive time-independent output models include the time-variant method and nonlinear dynamic modeling.

All of the identified modeling categories have relevance in PTSD, although modeling selection is highly dependent on the specific goals of the modeler. For instance, one might use ANOVA to examine the differences in resting HR in individuals with PTSD versus without PTSD.

Acknowledgments

The authors would like to acknowledge Ms Margaret Foster, a systematic review expert librarian at the Texas A&M University system, who helped to develop the search strategy.
Conflicts of Interest

None declared.

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**Abbreviations**

ANFIS: adaptive neuro-fuzzy inference system
ANOVA: analysis of variance
ANS: autonomic nervous system
AUC-ROC: area under the receiver operating characteristics curve
COH: coherence score
FDT: fluctuation-dissipation theory
HF: high frequency power
HR: heart rate
HRR: heart rate response
HRV: heart rate variability
LF: low frequency power
mHealth: mobile health
PNS: parasympathetic nervous system
PRISMA: preferred reporting items for systematic reviews and meta-analyses
PTSD: posttraumatic stress disorder
RMSSD: root mean square of successive differences between normal heart beats
SDNN: SD of the interbeat interval of normal sinus beats
SNS: sympathetic nervous system

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Assessing Digital Risk in Psychiatric Patients: Mixed Methods Study of Psychiatry Trainees’ Experiences, Views, and Understanding

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Abstract

Background: The use of digital technology can help people access information and provide support for their mental health problems, but it can also expose them to risk, such as bullying or prosuicide websites. It may be important to consider internet-related risk behavior (digital risk) within a generic psychiatric risk assessment, but no studies have explored the practice or acceptability of this among psychiatrists.

Objective: This study aimed to explore psychiatry trainees’ experiences, views, and understanding of digital risk in psychiatry. We predicted that clinician awareness would be highest among trainees who work in child and adolescent mental health services.

Methods: We conducted a cross-sectional survey of psychiatry trainees attending a UK regional trainees’ conference to investigate how they routinely assess patients’ internet use and related risk of harm and their experience and confidence in assessing these risks. We conducted focus groups to further explore trainees’ understandings and experiences of digital risk assessment. Descriptive statistics and chi-squared tests were used to present the quantitative data. A thematic analysis was used to identify the key themes in the qualitative data set.

Results: The cross-sectional survey was completed by 113 out of 312 psychiatry trainees (response rate 36.2%), from a range of subspecialties and experience levels. Half of the trainees (57/113, 50.4%) reported treating patients exposed to digital risk, particularly trainees subspecializing in child and adolescent psychiatry (17/22, 77% vs 40/91, 44%; P=.02). However, 67.3% (76/113) reported not feeling competent to assess digital risk. Child and adolescent psychiatrists were more likely than others to ask patients routinely about specific digital risk domains, including reckless web-based behavior (18/20, 90% vs 54/82, 66%; P=.03), prosuicide websites (20/21, 95% vs 57/81, 70%; P=.01), and online sexual behavior (17/21, 81% vs 44/81, 54%; P=.02). Although 84.1% (95/113) of the participants reported using a proforma to record general risk assessment, only 5% (5/95) of these participants prompted an assessment of internet use. Only 9.7% (11/113) of the trainees had received digital risk training, and 73.5% (83/113) reported that they would value this. Our thematic analysis of transcripts from 3 focus groups (comprising 11 trainees) identified 2 main themes: barriers to assessment and management of digital risk, and the double-edged sword of web use. Barriers reported included the novelty and complexity of the internet, a lack of confidence and guidance in addressing internet use directly, and ongoing tension between assessment and privacy.
Conclusions: Although it is common for psychiatrists to encounter patients subject to digital risk, trainee psychiatrists lack competence and confidence in their assessment. Training in digital risk and the inclusion of prompts in standardized risk pro formas would promote good clinical practice and prevent a potential blind spot in general risk assessment.

(KEYWORDS: risk assessment; internet; suicide; self-injurious behavior; mental health; psychiatrists; mixed methods; mobile phone)

Introduction

Background

The use of digital technology continues to rise, with an estimated 4.13 billion internet users worldwide [1]. The United Kingdom has the second highest number of internet users in Europe [2], and most people in the United Kingdom own a smartphone, with over 95% of 16- to 24-year-olds owning one [3]. The use of web-based social networks is also increasing rapidly; Facebook had 1.62 billion daily active users by the end of 2019 [4,5]. The rising use of digital technology poses new risks for patients and thus is a complex challenge for psychiatrists. Although it has benefits in terms of social communication, peer support, self-management, and dissemination of knowledge, it can also expose people to adverse novel activities, which are harmful to themselves and others.

Harms related to internet-related behaviors (which we refer to as digital risk) have not yet been quantified in the general population or for those with mental health problems. A classification system has been proposed for digital risk in children and families and includes commercial, aggressive, and sexual risks and corruption of values. These are further subclassified by 3 modes of web-based communication: person as recipient, person as participant, and person as initiator [6]. Although this classification system was developed for children and families, it is also relevant to both young people and adults who can be vulnerable to risk in similar domains. The classification of digital risk (adapted from the European research on children’s internet use [6]) has been described in Table 1.

Table 1. Classification of digital risk.

<table>
<thead>
<tr>
<th>Risks</th>
<th>Content (person as recipient)</th>
<th>Contact (person as participant)</th>
<th>Conduct (person as initiator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>Advertising, spam</td>
<td>Tracking/harvesting personal information</td>
<td>Gambling, illegal downloads, hacking</td>
</tr>
<tr>
<td>Aggressive</td>
<td>Violent/gruesome/hateful content</td>
<td>Being bullied, harassed, or stalked</td>
<td>Bullying or harassing another</td>
</tr>
<tr>
<td>Sexual</td>
<td>Pornographic/harmful sexual content</td>
<td>Meeting strangers, being groomed</td>
<td>Creating/uploading pornographic material</td>
</tr>
<tr>
<td>Values</td>
<td>Racist, biased information/advice (eg, drugs)</td>
<td>Self-harm, unwelcome persuasion/coercion</td>
<td>Providing advice (eg, suicide/proanorexia)</td>
</tr>
</tbody>
</table>

Increasing internet use has been accompanied by a rise in discriminatory or criminal activity on social media platforms, such as grooming, cyberbullying, and harassment, with over 32,000 Facebook crimes reported to the police in the United Kingdom in 2019 [7]. Approximately one-fifth of US adolescents report experiences of cyberbullying (bullying or harassment using electronic forms of contact) [8], most frequently via a social media site [9]. The frequency of cyberbullying is associated with self-harm, depression, anxiety, suicidality, and drug and alcohol problems [8,10-12]. A multicenter interview study of 11- to 16-year-olds across 25 European countries used weighted estimates to suggest that 17% of children have been exposed to sexual images on the web (ie, images or video of someone naked, of their genitals, of someone having sex, and showing sex in a violent way and other sexual images), 13% to proanorexia websites, and 20% to websites that publish hate messages [13].

Other internet-related risks include pro suicide websites containing advice and a discussion of lethal methods. A UK cross-sectional study of young adults found that suicide-/self-harm–related internet use was reported by 22.5% of participants, with both prosuicide and suicide prevention sites being accessed [14]. Another study in both children and adults found that self-harm related to internet use was associated with high suicidal intent [15]. The widespread availability of prescriptions and illicit medication on the web is also concerning. There are reports of web-based pharmacies that employ no restrictions on the age of consumers, where products can be bought in large quantities without a prescription and some preparations could contain hidden toxic compounds [16]. With increasing numbers of people obtaining medication and other products on the web, the risk of intentional or unintentional toxicity is potentially increased [17].

People with mental illness have been shown to have higher levels of internet addiction, and there are positive and significant associations with attention deficit hyperactivity disorder, depression, and anxiety [14]. They may also be more vulnerable to prosuicide and other potentially harmful websites [18].

These risks also apply to the elderly, who are relatively technologically naive, and to children, who as digital natives [19] have been brought up with much greater exposure to the internet via computers and mobile devices during a vulnerable stage in their development. Both are vulnerable to exploitation; the former because they may not be aware of scammers’ techniques, and the latter because they are less likely to have emotional resources or experience to counter exploitation or other risks. Of particular concern are those in each age group...
who have mental health problems, who are already vulnerable to exploitation offline and for whom this risk is amplified in their online life. Young people who are vulnerable offline in relation to social disadvantage are more likely to report high-risk web experiences relating to inappropriate content, conduct, contacts, and cyber scams [20]. Young people are also more susceptible than adults to the effects of social modeling of suicidal behavior, including in relation to the media [21,22].

Health care professionals working in children’s services are likely to encounter patients with exposure to such risks and may therefore have more awareness and expertise in assessment and management.

At present, there is no accepted protocol for assessing digital risk and no existing validated questionnaire for assessing digital risk. To our knowledge, there has been no research internationally exploring the practice of digital risk assessment among mental health professionals. Consequently, this study was designed by psychiatry trainees to investigate the practice of assessment and management of online risk.

**Objectives**

This study aimed to explore experiences, views, and understanding of patients’ digital risk among trainee psychiatrists (doctors specializing in psychiatry training with up to 6 years of experience in working in psychiatric services) in the United Kingdom. We predicted that clinician awareness would be low but highest among trainees who work in child and adolescent mental health services (CAMHS), as these psychiatrists care for patients with more active digital engagement. We also aimed to examine experiences of training in digital risk and existing risk assessment practices.

**Methods**

We conducted a sequential mixed methods study of psychiatry trainees’ views and experiences, using a cross-sectional survey followed by a series of focus groups to generate in-depth qualitative understanding.

**Cross-Sectional Survey**

**Survey Instrument**

We developed a survey tool for this study in 3 stages. First, we reviewed the literature on digital risk, including the EU Kids online report [23] and media reports of digital risk, to generate a theoretical framework for digital risk. We then drafted a questionnaire with input from clinicians and specialists from the UK National Health Service (NHS) mental health service and the Tavistock and Portman NHS Trust. We presented our draft survey to the London Digital Safety Network meeting, a forum of mental health professionals who are leading experts in digital risk in psychiatry, to assess face validity and revise it in response to their feedback. Finally, the questionnaire was piloted in 2 stages, initially as a paper survey with a group of 20 trainee psychiatrists and then, following revisions, a larger pilot of 120 mental health professionals (on paper or via a website address). We again amended the questionnaire based on their feedback.

The final draft of the questionnaire included specific questions about trainees’ clinical experience of, and training in, digital risk (Multimedia Appendix 1). It obtained demographic information and occupational history, including training grade (core trainee [up to 3 years of psychiatry experience rotating across a broad range of specialties within psychiatry], higher trainee [more than 3 years of psychiatry experience with specialization in their patient group, eg, general adults or children and adolescents], or others [other training grades]); duration of experience in psychiatry; psychiatry specialty (children and adolescents [aged 18 years and below]; working age adults [aged 18 to 64 years], older adults [aged 65 years and above], forensic patients, or others [eg, intellectual disability psychiatry or specialist psychotherapy services]); and the respondent’s own frequency of internet use and ownership of specific devices and relevant technology.

**Data Collection**

Using this questionnaire, we conducted a cross-sectional survey of trainee psychiatrists attending a conference in London, United Kingdom, in November 2013. All London-based psychiatry trainees were expected to attend. We distributed paper copies of the survey, which could be completed anonymously, and provided access to a web-based version to every attendee. There were no financial incentives for completing the survey. We provided written information at the start of the survey including the length of the survey, and completion of the survey indicated informed consent. We sent reminders after 2 and 4 weeks to all of the attendees at the conference to prompt those who had not yet completed the survey.

Ethical approval was not required by the psychiatry training committee, as the survey was regarded as a service improvement project.

**Statistical Analysis**

We used descriptive statistics to describe demographic data, occupational history, digital technology use and nature, extent of digital risk assessment experience, and reported confidence and competence in digital risk assessment. We compared trainees specializing in child and adolescent psychiatry with those from other subspecialties (general adult, forensic, learning disability, older adults, substance misuse, psychotherapy, academic, and liaison) using chi-square tests and Mantel-Haenszel tests. A P value of .05 was used as the threshold for statistical significance. We conducted all analyses using SPSS for Windows, version 22.

**Focus Groups**

**Setting and Participants**

We conducted focus groups with London-based trainee psychiatrists from January 2015 to June 2016. The participants were purposively sampled from 2 training programs within the London area. This was not a nested sample from those who had taken part in the earlier regional conference, but participation in both was not precluded.

We sent emails to all potential participants via the training program’s administrators inviting them to contact us if interested in taking part. We included participants who are training in
We anticipated reaching data saturation once 10 to 20 trainee psychiatrists had participated in focus groups and aimed to conduct 3 focus groups with 3 to 6 participants per group. To encourage disclosure among less experienced trainees, we grouped participants by training, so that 1 focus group comprised core trainees (1-3 years of psychiatry experience), 1 comprised higher trainees in general adult psychiatry (more than 4 years of psychiatry experience specializing in working age patients), and 1 comprised higher trainees in CAMHS (4-7 years of psychiatry experience with specialization in children aged under 18 years).

Focus groups were conducted at times adjacent to regular teaching commitments, or during lunch breaks, for participants’ convenience. Each focus group lasted approximately 50 min and was facilitated by 2 researchers, who were themselves psychiatric trainees (1 in general adult psychiatry [GA] and 1 in older adult psychiatry [AS]). The focus groups were audio recorded and transcribed verbatim by the first author. All participants provided written informed consent.

Focus groups were guided by a semistructured topic guide devised using the results of the cross-sectional survey. This guide aimed to probe trainees’ clinical experiences of digital risk, assessment, and training in more depth. We discussed our draft topic guide with clinicians working with the London Digital Safety Network and made revisions based on their feedback. The final topic guide (Multimedia Appendix 2) elicited views on what participants believed online digital risk was, whether they had observed this in their clinical practice, and how they routinely managed this clinically. Prompts also explored whether participants had training in digital risk and if not, whether they would value this.

Analysis
Two researchers (ME and GA; both psychiatrists with mental health research experience and only one of whom had collected data) conducted an independent thematic analysis of focus group data [24,25]. An initial coding frame was developed and adjusted as themes emerged from data, generating higher order and subthemes. Any coding disagreements were discussed together with a wider research team to clarify and refine understandings.

To encourage personal reflexivity [26] and reduce the influence of theoretical or individual biases, we ensured that our research team consisted of a range of backgrounds. GA is an adult psychiatrist and an academic with interest in digital mental health. GL and RG are child and adolescent psychiatrists. RG is an expert in digital risk and is part of the board of the UK Council for Child Internet Safety and cochairs the Digital Resilience Working Group. ME is an academic adult psychiatrist with an undergraduate degree in social sciences. AP and SJ are psychiatrists and academics with an interest in sociology and social psychology. DO is an academic general adult psychiatrist and the integrated academic training lead for psychiatry, whereas AS is an older adult academic psychiatrist. NM is a social psychologist and a specialist in qualitative research methods in mental health.

Results
Cross-Sectional Survey
Of the 312 psychiatry trainees attending the conference, 133 (42.6%) completed the survey although only 113 (36.2%) provided their demographic and clinical information, and we included only these respondents in our analysis to allow us to compare responses by demographic characteristics. There was an approximately equal balance of men and women and of core and higher trainees (Table 2), and our sample covered a range of training grades. Trainees worked in a variety of areas across inner and suburban London (Table 2). There was a high level of digital literacy, with 92.9% (105/113) possessing a smartphone and 61.9% (70/113) reporting use of a computer or smartphone for more than an hour per day.
Table 2. Summary of demographic, professional backgrounds, and digital technology use.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>53 (46.9)</td>
</tr>
<tr>
<td>Female</td>
<td>60 (53.0)</td>
</tr>
<tr>
<td><strong>Training grade</strong></td>
<td></td>
</tr>
<tr>
<td>Core trainee</td>
<td>60 (53.0)</td>
</tr>
<tr>
<td>Higher trainee</td>
<td>48 (42.5)</td>
</tr>
<tr>
<td>Others</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td><strong>Experience as psychiatrist (years)</strong></td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>64 (56.6)</td>
</tr>
<tr>
<td>5-10</td>
<td>40 (35.4)</td>
</tr>
<tr>
<td>≥11</td>
<td>9 (8.0)</td>
</tr>
<tr>
<td><strong>Psychiatry specialty</strong></td>
<td></td>
</tr>
<tr>
<td>Children and adolescents</td>
<td>22 (19.5)</td>
</tr>
<tr>
<td>Working age adults</td>
<td>63 (55.8)</td>
</tr>
<tr>
<td>Older adults</td>
<td>11 (9.7)</td>
</tr>
<tr>
<td>Forensic patients</td>
<td>11 (9.7)</td>
</tr>
<tr>
<td>Others</td>
<td>7 (6.2)</td>
</tr>
<tr>
<td><strong>Digital literacy</strong></td>
<td></td>
</tr>
<tr>
<td>Possesses a smartphone</td>
<td>105 (92.9)</td>
</tr>
<tr>
<td>Possesses a tablet</td>
<td>59 (52.2)</td>
</tr>
<tr>
<td>Possesses a personal computer or laptop</td>
<td>92 (81.4)</td>
</tr>
<tr>
<td>Uses a phone/computer for more than an hour per day</td>
<td>70 (61.9)</td>
</tr>
</tbody>
</table>

**Digital Risk Assessment**

In total, 50.4% (57/113) of the respondents reported having treated patients who had been exposed to risk related to web-based activity (Table 3). A total of 23.0% (26/113) said they had never considered the impact of patients’ digital life on their mental health, as part of their assessments. CAMHS trainees were not more likely to inquire about the impact of their patients’ digital lives (20/22, 91% vs 67/91, 74%; \( P = .10 \)), despite being more likely than other specialty trainees to have previously treated patients affected by digital risk (17/22, 77% vs 40/91, 44%; \( P = .02 \)).

Trainees most commonly reported assessing whether patients sought web-based information about their mental health problems (99/113, 87.6%) and whether they had purchased drugs or medication on the web (83/102, 81.4%). CAMHS trainees were more likely to report asking patients about specific risk domains, including reckless web behavior (18/20, 90% vs 54/82, 66%; \( P = .03 \), prosuicide websites (20/21, 95% vs 57/81, 70%; \( P = .01 \)), and sexual web behavior (17/21, 81% vs 44/81, 54%; \( P = .02 \)).
Table 3. Clinical experience and practice in relation to digital risk.

<table>
<thead>
<tr>
<th>Question asked, responses</th>
<th>All trainees (n=113), n (%)</th>
<th>CAMHS&lt;sup&gt;a&lt;/sup&gt; trainees (n=22), n (%)</th>
<th>Other trainees (n=91), n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your clinical work, have you treated any patients who have been exposed to risk relating to web-based activities?</td>
<td></td>
<td></td>
<td></td>
<td>8.2 (2)</td>
<td>.02</td>
</tr>
<tr>
<td>Yes</td>
<td>57 (50.4)</td>
<td>17 (77)</td>
<td>40 (44)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>32 (28.3)</td>
<td>2 (9)</td>
<td>30 (33)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsure</td>
<td>24 (21.2)</td>
<td>3 (14)</td>
<td>21 (23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In your usual clinical practice, do you ask patients about:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The impact of their digital life</td>
<td></td>
<td></td>
<td></td>
<td>2.9 (1)</td>
<td>.10</td>
</tr>
<tr>
<td>Yes</td>
<td>87 (76.9)</td>
<td>20 (91)</td>
<td>67 (74)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>26 (23.0)</td>
<td>2 (9)</td>
<td>24 (26)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they access web information about mental health</td>
<td></td>
<td></td>
<td></td>
<td>1.5 (1)</td>
<td>.30</td>
</tr>
<tr>
<td>Yes</td>
<td>99 (87.6)</td>
<td>21 (95)</td>
<td>78 (86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14 (12.4)</td>
<td>1 (5)</td>
<td>13 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much time they spend on the web&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>4.2 (1)</td>
<td>.05</td>
</tr>
<tr>
<td>Yes</td>
<td>75 (72.8)</td>
<td>19 (90)</td>
<td>56 (68)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>28 (27.2)</td>
<td>2 (10)</td>
<td>26 (32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they engage in reckless web behavior&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>4.5 (1)</td>
<td>.03</td>
</tr>
<tr>
<td>Yes</td>
<td>72 (70.6)</td>
<td>18 (90)</td>
<td>54 (66)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>30 (29.4)</td>
<td>2 (10)</td>
<td>28 (34)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they access prosuicide websites&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>5.6 (1)</td>
<td>.01</td>
</tr>
<tr>
<td>Yes</td>
<td>77 (75.5)</td>
<td>20 (95)</td>
<td>57 (70)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>25 (24.5)</td>
<td>1 (5)</td>
<td>24 (30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they have been a victim of cyberbullying&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>3.1 (1)</td>
<td>.06</td>
</tr>
<tr>
<td>Yes</td>
<td>78 (75.7)</td>
<td>19 (90)</td>
<td>59 (72)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>25 (24.3)</td>
<td>2 (10)</td>
<td>23 (28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they engage in sexual web behavior&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>4.9 (1)</td>
<td>.02</td>
</tr>
<tr>
<td>Yes</td>
<td>61 (59.8)</td>
<td>17 (81)</td>
<td>44 (54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>41 (40.2)</td>
<td>4 (19)</td>
<td>37 (46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether they buy drugs/medication on the web&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>0.3 (1)</td>
<td>.42</td>
</tr>
<tr>
<td>Yes</td>
<td>83 (81.4)</td>
<td>18 (86)</td>
<td>65 (80)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19 (18.6)</td>
<td>3 (14)</td>
<td>16 (20)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> CAMHS: child and adolescent mental health services.
<sup>b</sup> On the basis of survey responses from 103 participants.
<sup>c</sup> On the basis of survey responses from 102 participants.

**Trainee Competence**

Approximately two-third (76/113) of the trainees stated that they did not consider themselves competent in assessing online risk behavior; 90.3% (102/113) had not received training in digital risk assessment, and overall, 73.4% (83/113) reported that they would value this (Table 4). The majority of trainees reported using a proforma from their local hospital trust to record risk assessment (95/113, 84.1%), but only 5% (5/95) said it contained a prompt about internet use.

The trainees who had received training in assessing online risk were more likely to rate themselves as competent to assess online risk (OR 6.7, 95% CI 1.7-27.1; P=.01), although there was no difference in whether they reported asking patients about the impact of their digital life than those who had not been trained (OR 1.4, 95% CI 0.3-6.9; P=.69).
Table 4. Confidence and training in relation to digital risk.

<table>
<thead>
<tr>
<th>Question asked, responses</th>
<th>All trainees (n=113), n (%)</th>
<th>CAMHS trainees (n=22), n (%)</th>
<th>All other trainees (n=91), n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you consider yourself competent to assess web risk?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>37 (32.7)</td>
<td>9 (41)</td>
<td>28 (31)</td>
<td>0.8 (1)</td>
<td>.25</td>
</tr>
<tr>
<td>No</td>
<td>76 (67.3)</td>
<td>13 (59)</td>
<td>63 (69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had any training in assessing web risk?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11 (9.7)</td>
<td>4 (18)</td>
<td>7 (8)</td>
<td>2.2 (1)</td>
<td>.14</td>
</tr>
<tr>
<td>No</td>
<td>102 (90.3)</td>
<td>18 (82)</td>
<td>84 (92)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would you value this training if it were offered?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>83 (73.5)</td>
<td>16 (73)</td>
<td>67 (74)</td>
<td>0.86 (2)</td>
<td>.65</td>
</tr>
<tr>
<td>No</td>
<td>6 (5.3)</td>
<td>2 (9)</td>
<td>4 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsure</td>
<td>24 (21.2)</td>
<td>4 (18)</td>
<td>20 (22)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CAMHS: child and adolescent mental health services.

Qualitative Focus Groups

There were 11 trainees who participated in 3 focus groups. Ages ranged from 25 to 35 years, participants were all born in the United Kingdom but identified as a variety of ethnic backgrounds, and most were female. The first group comprised 5 core trainees, the second included 3 higher trainees working in general adult psychiatry, and the third included 3 higher trainees specializing in child and adolescent psychiatry.

From the analysis of transcripts, we identified 2 main themes: barriers to assessment and management of digital risk and the double-edged sword of web use.

The findings of these key themes and their subthemes are discussed as follows.

Barriers to Assessment and Management

Most focus group participants reported that they rarely assessed digital risk when carrying out standard psychiatric risk assessments, and the first theme concerned the implied barriers to this assessment. These involved both reluctance to ask about risk and conceptual difficulties in understanding and measuring that risk.

Migration of the Social World

One explanation for not assessing digital risk was that their practice had not yet adapted to a recent shift of patient’s social lives to a new digital space. This was conceptualized by the CAMHS trainees as a new and distinct third world, which was not merely a new social space but also a thinking space for their patients. Participants were struck by how this migration of the patient’s social world into a more public space led to greater exposure of patients’ private thinking, blurring previous distinctions. This migration was observed particularly by the CAMHS trainees, reflecting that children and adolescents may be more likely to share private information on the web:

...the thinking space, the social world of children and adolescents has migrated. [Respondent 1 (R1) CAMHS trainee]

As Child Psychiatrists we instinctively start talking to young people about school and home life, so they are the two worlds we think of... It's almost kind of getting hang of the idea that actually there's this third world. [R4 CAMHS]

Novelty

The complexity, novelty, and pace of change of the internet and available digital tools impacted all participants’ confidence in assessing digital risk, either through a lack of technical understanding or the fear of appearing out of touch to their patients. All groups identified that age discrepancies between themselves and their patients created an additional challenge because of a gap in knowledge and experience. This impeded assessment as trainees felt that if they did not have firsthand experience of the digital platforms themselves, then they were less able to quantify and manage the associated risks. This was particularly marked in the CAMHS focus group but was raised to a lesser extent by the younger trainees, who were more familiar with a range of different digital tools and apps and considered that their older senior colleagues would be even less aware of new technological developments and risks:

I think it's just a fact that some of the older clinicians just don’t know about some of these apps and websites--And things that are there. So if you don’t know about it, how do you ask? [R2 CAMHS]

All groups described their patients’ online interactions as having a hidden quality, which made the assessment of the extent or nature of the risk particularly challenging when contrasted with more easily quantifiable risks in the physical world, such as drug and alcohol intake or social isolation. Therefore, trainees were less likely to ask about a risk unless they felt confident that they could understand, measure, and manage that risk in an informed way:

It's always difficult these days trying to ascertain someone’s level of social support because normally you’d say how many friends do you see in an average month? But of course now it’s impossible to work that out, or to really make a valid judgement of how
genuine those relationships are. [R3 general adult psychiatry trainee (general)]

**Lack of Training**

Participants in all groups reported a scarcity of training on how to approach digital risk assessment. None of the prompts they had embedded into their risk assessments from the start of their training included questions on digital use. Core trainees also noted the absence among colleagues of any consensus on how to ask about these risks:

...clinicians were just told in the team meeting, oh you’ve just got to ask about online risk, or something like that. So actually I don’t know how individual clinicians asked about it...I don’t know. It wasn’t a “set question” kind of thing, it was just a “do it your own way.” [R1 CAMHS]

Despite being identified as digitally literate, core trainees expressed the most anxiety about how to word their questions and the degree to which it was appropriate to probe directly into patients’ private online worlds. This lack of training impacted the confidence of all participants in asking direct questions about the patient’s internet use, preferring to ask indirectly or more commonly to let patients raise it themselves:

I think if it’s something that they bring up then I’d feel comfortable exploring that...But it's not something that I would consciously bring up just, you know, without them already inputting it to be honest. [R2 general]

However, the intentions behind indirect questions differed slightly by years of experience. The higher clinicians reported vague questions to carefully tease out more information, whereas the younger and less-experienced trainees were anxious about causing harm through suggestions. Their fear was that by assessing risk, they might paradoxically increase it:

I felt like, what if I put ideas in their head? What if they’re not doing that? [R1 core trainee (core)]

There is that worry...am I putting ideas into their head? But so long as it’s open, so I’ll never name a specific website...I think I’ve approached it in quite a round-about way rather than being quite direct. [R5 core]

All participants wanted more formal support and guidance in both assessing and managing any risks identified. They felt the need to adapt their existing generic risk assessments to include digital risk prompts to encourage habitual assessment. The core trainees suggested that training should also include advice about how to manage the risk, and not merely assess it. All 3 groups felt that training in the form of specific digital risk assessment workshops, vignettes, and role plays (which are teaching approaches embedded in the psychiatry curriculum for general risk assessment) would be necessary to improve confidence in assessment and management:

I think just embedding it in our training framework is a good start. When we learn how to conduct assessments in psychiatry, we have these headings.

And when we learnt there was nothing around this kind of stuff, but even bringing this into part of the social history that you take. Even that as a starter will make them more conscious of it right from when they start training. [R3 general]

All 3 groups identified that the combination of a lack of formal training, limited prior experience of managing these risks, and an absence of agreed-upon standards of assessment resulted in reactive rather than proactive approaches to digital risk assessment.

**Trade-Off Between Assessment and Privacy**

All trainees acknowledged a trade-off between respecting their patients’ private internet use and accurately quantifying existing digital risks. This tension was most evident in the 3 groups’ differing attitudes concerning the ethics of searching for patients on the web to assess risk. This topic arose spontaneously in all the groups with multiple participants recalling prior experiences of patient’s family members and other patients (on an inpatient unit) or the patients themselves informing medical teams of reporting of risk on social media, for example, posting about suicidal ideation.

In the core trainee and general adult groups, participants reported how they either independently searched or were encouraged, in some cases, by their team/consultant to search for patients on the web and used the information to inform risk assessments or monitor mental states via public posting on web-based platforms. Some trainees, in particular those in the CAMHS group, felt strongly that this was an unjustified invasion of privacy, which might compromise their therapeutic relationship, and was outside of their role as psychiatrists. Participants in the other groups, by contrast, largely argued that psychiatry is by definition concerned with the private information and questioned further whether information on the web could still be described as strictly private given that it is a public domain. Another tension arose here between information gathering to assess risk and the significance of the patient’s awareness of those risks. If a patient cannot identify the risks of their web use, the core trainees reasoned that they were less likely to disclose the behavior in the first place, making the search for collateral information all the more necessary:

It's on the internet, it's not like you've gone into their house and unlocked a drawer and tried to find their personal documents. It's something that anyone could, you know, in theory find. [R4 core]

But I don’t think it’s our job as doctors to be looking at people’s social media and then managing...what they do. Because I think that's a step too far, I think that’s not our role. I think if someone's on social media and they're posting things and people who look at their social media have a responsibility to act on that. In the same way that if someone was at school and saying worrying things the people around them would have a responsibility to act on that and bring it to you. [R1 CAMHS]
Double-Edged Sword

The second theme was the double-edged nature of digital use, balancing risks with a range of perceived benefits for patients. Despite reporting many experiences of digital risks, such as access to prosuicide websites, all trainees felt that digital engagement brought their patients many discernible benefits by promoting social inclusion and keeping them in step with societal culture. Many were also familiar with resources for self-management, such as access to online peer support forums, various mental health apps, and the patient’s ability to seek relevant sources of information independent of service providers:

We encourage our patients to be part of the society, we avoid stigma, isolation, and we try to integrate them into the society. But the society is going (in) a different direction, and technology is being a major part of our life. We can argue whether this is all good or bad... [R4 core]

Broadcasting Mental State

All 3 groups reported prior experience of patients using social media to broadcast their thoughts and feelings on the web. This was identified as particularly risky, with trainees describing multiple examples where this exposed patients to cyberbullying and other negative social repercussions. Concern arose particularly where repercussions were unanticipated by patients as they were frequently unwell at the time of posting. However, some trainees had experienced cases where this form of public expression had in fact acted as an alert to friends and family and to mental health professionals involved. This was either because they were explicitly or implicitly asking for help through online posting or because unusual or disturbing posts triggered referrals and interventions from family and friends:

Sometimes maybe it can be helpful if they share. They may not share with me, but they may share their suicidal thoughts on Facebook, so that will be a good alarming point for us. It will help sometimes; it may help us to pick up the risk. [R2 core]

Anonymity

Many trainees cited examples where the anonymity of other internet users exacerbated the impact and ferocity of cyberbullying and meant that they were unable to address this. They perceived that people were often more disinhibited on the web owing to the lack of accountability or repercussions. However, anonymity was also cited as a benefit for patients who find it difficult to talk about mental health problems in person. They were able to find a forum on the web where they could discuss sensitive issues protected by their anonymity:

I think people are just a lot more disinhibited online. And I think that can be a good thing because it might mean that someone will open up about something that they would not speak to somebody about in person...But then that can also be a bad thing because people then might be horrible in ways that they would never be in person, if you post something someone could be really, really unpleasant about you in a really upsetting hurtful way, which then has an impact on your mental health. And it stays there...forever. [R3 CAMHS]

Vulnerability

Although the use of the internet poses potential risks to any individual, trainees were concerned that their patients were particularly vulnerable for reasons of diminished capacity and emotional instability. Exposure to abuse or risky behaviors on the web could lead to extreme risks for someone who was unwell and/or had impaired ability to make proportionate or safe decisions:

One of the patients had her ex-partner put up sexually inappropriate material of her on Facebook, and she wasn’t in a position where she could deal with that. And actually that made her suicidal ideation significantly worse. And there have been psychotic patients who have misinterpreted things on, you know, the apps like Tinder and meeting apps. And that puts them in a lot of risk as well because they end up meeting people in very vulnerable situations. [R1 core]

A Life Curated

The CAMHS group warned that the opportunity to construct a curated online life on social media sites can create pressures on adolescents to conceal difficulties and fixate on unachievable goals of perfectionism. This discrepancy between what is real and what is on the web can undermine the potential benefits of social media sites, reinforcing patients’ low self-esteem and exacerbating existing mental health problems. It can also prevent patients from forming rewarding social connections in which they feel able to confide in their peers about their difficulties. The benefit, however, of controlling what the world can see is that the internet can be one place where people may not know that someone is unwell and where they can exist free from the stigma and the judgment of others:

there’s almost like this real-life image and there’s the cyber image, and how they’re portrayed inside of there. And how they’re perceived by others in this cyber world. [R2 CAMHS]

Web-Based Groups

All 3 groups discussed their patients’ use of online forums for support and information sharing. These interactions had both benefits and risks. The trainees reported examples of suicide pacts formed on the web or patients using groups for advice about how to lose weight, often termed pro-ana websites. They expressed concern that patients might be influenced by exposure to competitive dieting and methods to conceal self-harm or be drawn into imitating the habits of people they meet on the web. These risks were tempered by an acknowledgment of the significant benefit that patients reported from online peer support forums, which were accessible whenever and wherever they needed. For patients who experienced a particular crisis at night, this was particularly important as a source of support.
Discussion

Principal Findings

In this first mixed methods study investigating psychiatrists’ experience of assessing their patients’ digital risk, we found that there was widespread awareness among psychiatry trainees of patients’ digital risks but variation in the depth of their assessment in routine practice. Despite the fact that child and adolescent trainee psychiatrists have more exposure to online risks, they are not more likely to ask patients about the impact of their digital lives. They were, however, more likely to ask about specific areas of risk, such as sexualized web behavior and accessing suicide websites.

An in-depth exploration of this issue through focus group interviews found that explanations for the discrepancy between awareness of risk and the tendency not to assess it routinely and comprehensively are related to anxieties over transgressing boundaries, lack of training, and the fear of repercussions of asking these questions. Trainees reported a lack of confidence in knowing what specific question to ask and whether this was acceptable and expressed concerns about potential boundary violations that may occur if searching for information about their patients online. Our study also revealed the extent to which trainees value their patients’ access to digital tools. Trainees saw digital engagement as an opportunity to reduce social isolation and an opportunity to enhance self-management and recovery in keeping with the current direction of modern mental health care.

To date, there is a paucity of research on digital risk assessment in psychiatry. However, the fear of the negative impact of asking questions about harmful use of the internet is analogous to the widespread belief that asking about suicidal ideation increases the risk of suicide attempts, which has been discredited [27]. Most participants lacked training in asking questions related to digital risk but stated that they would value this; there is potential that greater experience in assessing this domain may ameliorate the concerns about the harmful impact of assessment.

The uncertainty over the ethics, legality, and impact of searching for one’s patients on the internet have been discussed in the literature [28,29]. In our study, the ethics of researching the online behavior of patients when disclosure is not forthcoming appeared to pivot on patients’ awareness of risks, but different trainees interpreted the ethical significance differently. Some argued that if the patient intended the information to be public, then there was no violation, but if they were unaware of its public nature, either through illness or lack of capacity, then the information should be regarded as private, the assumption being that the patient’s awareness or lack thereof has the power to define the status of the information. Conversely, other trainees saw unknown or misunderstood public exposure of intended private data as part of the digital risk assessment itself and something they should be striving to protect their patients from. Both positions therefore find justification through intention; one seeks to define what is private through what is intended as private and the second defines risk where intention is absent. This example reveals the struggle to understand where these new lines should be drawn and what a psychiatrist’s role should be within this new paradigm. Where does a psychiatrist’s responsibility to the patient’s mental health end and their right to privacy begin?

Strengths and Limitations

To our knowledge, this is the first study to explore attitudes toward digital risk among psychiatry trainees. Our mixed methods approach allowed us to gain both breadth and depth in our analysis, with the quantitative findings informing the qualitative phase. We sampled from a large metropolitan area and achieved wide participation in our focus groups. The main limitation of our study is the generalizability of findings to psychiatrists in settings beyond the United Kingdom. However, we are not aware of any similar studies done in any other countries, and given the high internet use in the United Kingdom and rising use of the internet internationally, we would strongly encourage mental health clinicians in other countries to take note of our findings, do similar surveys, and develop their digital risk guidance tailored to their population. The response rate was relatively low, despite efforts to survey all attendees of the conference both through an electronic and paper copy. As there is no published questionnaire for assessing experiences of digital risk, we developed our own tool, using a multidisciplinary team of digital experts and extensive piloting, but we were not able to validate this. Our qualitative study responses may have been influenced by social desirability bias, as focus groups consisted partly of colleagues who worked together. This led to the suppression of any opinions, which deviated from apparent social norms, thereby censuring the debate. Finally, these data, from 2013 to 2016, may not reflect current practice and experience as digital literacy may have increased, but digital risk may also have increased. Given the lack of other studies on this topic, our study represents the best available evidence.

Conclusions

Our study identified generally high levels of self-reported awareness among psychiatry trainees of internet-related risk behavior, but we also found wide variation in their confidence in assessing this risk in routine practice and barriers to assessment of digital risk. Future research should aim to assess the generalizability of these findings to clinicians working in other mental health settings and track changes in experience as well as the effectiveness of measures to improve awareness of digital risk. Our findings have important implications for clinical practice and policy. Professionals working in mental health services need to evolve their practice in line with the technological revolution. In the United Kingdom, the Department for Digital, Culture, Media, and Sport has published a strategy for web safety that is underpinned by 3 principles: (1) what is unacceptable offline should be unacceptable online, (2) all users should be empowered to manage online risks and stay safe, and (3) technology companies have a responsibility to their users. They have developed a legislative framework for hate crime and an action plan for older people and are working closely with the Department for Education to ensure that schools have the support and resources to support children, parents, and carers [30]. MindEd, a free educational resource for teachers and parents addressing children and young people’s mental health, has training modules on online risk and resilience and
online safety and well-being [31]. The Information Commissioner's Office, a nondepartmental public body, has written a code of practice for age-appropriate design of web services that is subject to parliamentary approval [32]. Beyond these resources, digital risk must be acknowledged by clinical professional and regulatory bodies, and we recommend that the Royal College of Psychiatrists and Health Education England lead on providing training on digital risk assessment and ethical frameworks for clinicians on researching web behavior of their patients and that similar approaches are adopted in other countries. Digital risk assessment should be embedded in policies and procedures for mental health trusts so that they become usual practice, so that clinicians at all stages of training learn about enhanced risk assessment and from risk incidents. Digital literacy is an important skill for the future of health services, and there is an urgent need to promote good clinical practice and prevent a potential blind spot in psychiatric risk assessment.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire.
[DOC File, 106 KB - mental_v7i7e19008_app1.doc]

Multimedia Appendix 2

Topic guide.
[DOC File, 42 KB - mental_v7i7e19008_app2.doc]

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Abbreviations

CAMHS: child and adolescent mental health services
NHS: National Health Service
Design of a Digital Comic Creator (It’s Me) to Facilitate Social Skills Training for Children With Autism Spectrum Disorder: Design Research Approach

Gijs Terlouw¹,², MSc; Job TB van ‘t Veer¹, PhD; Jelle T Prins³, PhD; Derek A Kuipers⁴, PhD; Jean-Pierre E N Pierie²,⁵,⁶, MD, PhD

Abstract

Background: Children with autism spectrum disorder (ASD) often face difficulties in social situations and are often lagging in terms of social skills. Many interventions designed for children with ASD emphasize improving social skills. Although many interventions demonstrate that targeted social skills can be improved in clinical settings, developed social skills are not necessarily applied in children's daily lives at school, sometimes because classmates continue to show negative bias toward children with ASD. Children with ASD do not blame the difficult social situations they encounter on their lack of social skills; their main goal is to be accepted by peers.

Objective: This study aims to design a comic creator—It’s me—that would create comics to serve as transformational boundary objects to facilitate and enact a horizontal interaction structure between high-functioning children with ASD and their peers, aiming to increase mutual understanding between children at school.

Methods: This research project and this study are structured around the Design Research Framework in order to develop the comic through an iterative-incremental process. Three test sessions, which included 13, 6, and 47 children, respectively, were initiated where the focus shifted in time from usability during the first two tests to the initial assessment of acceptance and feasibility in the third session. A stakeholder review, which included six experts, took place after the second test session.

Results: A digital comic creator, It’s me, was produced within this study. Children can create their own personal comic by filling in a digital questionnaire. Based on concepts of peer support, psychoeducation, and horizontal interaction, It’s me has a rigorous base of underlying concepts that have been translated into design. Based on the first test sessions, the comic has shown its potential to initiate personal conversations between children. Teachers are convinced that It’s me can be of added value in their classrooms.

Conclusions: It’s me aims to initiate more in-depth conversations between peers, which should lead to more mutual understanding and better relationships between children with ASD and their peers. The first test sessions showed that It’s me has the potential to enact horizontal interaction and greater understanding among peers. It’s me was designed as a boundary object, aiming to connect the objectives of different stakeholders, and to trigger reflection and transformation learning mechanisms. The applied design research approach might be of added value in the acceptance and adoption of the intervention because children, professionals, and teachers see added value in the tool, each from their own perspectives.
**Introduction**

**Background**

Children with autism spectrum disorder (ASD) often face difficulties in social situations and are often lagging in terms of social skills [1,2]. In social situations, children with ASD find it difficult to interpret verbal and nonverbal behavior and face difficulties in maintaining conversations and understanding the intentions of others [3-5]. Children with ASD show a lack of intuitive judgments within social contexts [3,6], often avoid eye contact [7-9], and do not spontaneously interact with other people [3,4]. Children with ASD have a higher risk of developing depressive or anxious feelings [10]. Many interventions designed for children with ASD emphasize improving social skills [11], with the aim, among other things, of being more in tune with peers. However, in social contexts, such as school, children with ASD are more likely to be victims of peer harassment and are more likely to be excluded by peers [12-17]. Although many interventions demonstrate that targeted social skills can be improved in clinical settings, developed social skills are not necessarily applied in children's daily lives at school [11,18]. Even when participants do improve social skills, sometimes classmates continue to show negative bias toward children with ASD [19]. In our earlier research, we reported that high-functioning children with ASD from 10 to 12 years of age do not blame the difficult situations they encounter at school on their lack of social skills [20]. Their main goal is to be accepted by peers and be a part of the group. Children with ASD do not necessarily see the link between improving their social skills and pursuing that goal. Because the classroom is the primary setting in which peer rejection is determined [19], interventions that incorporate the peer-group context can be of added value alongside traditional social skills training for children with ASD.

In autism research, there is a growing interest in the development of digital interventions [21]. Developed interventions range from simulation-based interventions for practicing social skills [22], use of smart glasses for coaching users in social communication [23], interventions using virtual reality [24-26], interventions based on a gamification approach [27-29], social training interventions using social media [30], and interventions aiming to train users with skills within a serious game [31,32]. Most of those interventions focus on the child with ASD and aim to develop a set of specific skills. Those interventions are often based on a traditional skills-based approach, just like most of their analog counterparts. Within a skills-based approach in social skills training, basic social skills, such as greeting, turn-taking, emotion recognition, and asking questions, are essential developmental goals [33,34]. Those interventions frequently take place outside the natural environment of the child, which reduces the opportunity to practice the learned social skills in natural settings [35]. School is the pre-eminent place where the skills learned should be put into practice.

In a skills-based approach, the professionals, but sometimes also the peers, are often positioned in the role of an expert who models and prompts desired social behaviors [34,36]. In doing so, this approach is not focused on facilitating a horizontal interaction structure between peers, because peers have a different status than the children with ASD. Interventions that create a vertical interaction structure can be useful to train specific skills but can limit the establishment of friendships and peer acceptance. Within a horizontal interaction structure, children have equal status within the interaction. Finke [37] specifically describes the limitations of a skills-based approach for the development of peer acceptance and friendship, where equivalence should be the starting point. Finke [37] notes the need to design instructional opportunities that “expose the knowledge, skills, and abilities of the individual with ASD” to facilitate “a horizontal interaction structure” across peers. Activities that include interactions that require members to have equal status, as well as ones that trigger members to communicate individuating information about themselves that disconfirms prevailing stereotypes, can increase social acceptance among group members [38]. For the design of a new intervention to enhance peer acceptance, these concepts offer a good starting point.

**Boundary Objects**

Over the past decades, there has been a growing interest in boundaries, boundary crossing, and boundary objects [39-41]. A boundary can be seen as a sociocultural difference between different groups or sites. Boundaries suggest continuity and discontinuity between sociocultural sites at the same time. In the example of social skills training for children with ASD, the children with ASD and professionals who facilitate social skills training are connected and have a shared concern. Both parties have an interest in making the children function better in social situations, but the children have different goals to pursue than do the professionals. Professionals mainly focus on improving social skills, while children want to establish equal relationships with their peers. In addition to the boundaries that exist between the child with ASD and the professional, there are also boundaries within the contexts in which the child functions. At school, for example, there is a boundary between children with and without ASD, because they often do not understand each other properly in social interactions.

To bridge boundaries, boundary objects (see Figure 1) [41] can fulfill an important function. Many authors [40-43] have recognized the importance of boundary objects to support social interaction, to connect different sites, and to enable a shared understanding among different groups, sites, persons, or stakeholders. Boundary objects are flexible in adapting to the local needs and constraints of different parties. The acknowledgment and discussion of those differences are key to enabling a shared understanding among different sites or groups [44].

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**KEYWORDS**

autism; serious media; boundary object; comic; design research
Akkerman and Bakker [40] describe four learning mechanisms that can take place at boundaries: identification, coordination, reflection, and transformation. Typical in identification processes is that the boundaries between sites are encountered and reconstructed, enhancing renewed sensemaking without necessarily overcoming discontinuities. The coordination mechanism establishes effortless movement and constructive alignment between different sites, only as far as necessary. The reflection mechanism enacts an expanded set of perspectives and new construction of identities. The transformation mechanism can entail or develop new, in-between practices and sites. Most of the current social skills interventions seem to focus on strengthening the children's coordination learning mechanisms, where the child learns skills as tools to interact as smoothly as possible with other sociocultural systems. The reflection and transformation mechanisms are seldom used, while it is precisely these mechanisms that could lead to a rebalancing of relationships between children with ASD and their peers, whereby individuals understand each other's perspectives and can construct a good way of interacting with each other. From the reflection and transformation mechanisms, the child with ASD would not only have to adapt to the systems around him or her, but the systems around him or her would also adapt to the child. However, a solid boundary object will be needed to enact these mechanisms.

**Figure 1.** Boundary objects.

### Comics as Boundary Objects

Comics are a narrative medium that integrates text and visual imagery [45]. Comics can trigger specific affective processes of, and responses by, readers [46,47], which makes them suitable to tell complex and emotionally rich stories [48] without requiring an individual to read long or complicated texts. Good comics should be able to enact narrative transportation. Narrative transportation occurs whenever a reader experiences a feeling of empathy for the characters and has a vivid imagination of the story plot [49,50]. When carefully composed, comics can, therefore, be a novel and creative way to learn and teach about difficult themes, such as illness or disabilities [48]. In health care, comics are already used to promote public awareness and enhance patient care for various problems, including cancer [47,51,52], HIV [53], diabetes [54], and mental illness [55].

This study aims to design a digital comic creator—*It’s me*—that would create comics to serve as transformational boundary objects, which would facilitate and enact a horizontal interaction structure between high-functioning children with ASD and their peers. This creation should serve as a support tool to initiate more in-depth conversations between children about what they are good at as well as about areas where they perceive more difficulties, whether or not this is because of their disability. This tool aims to increase mutual understanding between children with ASD and their peers to create a safe environment at school. This intervention intends to be complementary to existing interventions and is based on a different perspective and approach. This paper describes the design research process of the tool and the first field tests that were used to investigate usability, acceptance, and feasibility.

### Methods

#### Study Design

This research project and this study are structured around the Design Research Framework (see Figure 2) [56,57]. This framework facilitates the development of serious media interventions through an iterative-incremental process. The focus of these iterations shifts during the process, along with nonlinear design steps [58]. After the phase where the focus was on assessing needs, analyzing content, and context [20], this study focuses more on the construction and utilization of prototypes.

During the design process, the social system is frequently exposed to various design methods and prototypes. Those methods and prototypes are regarded as boundary objects [42], which help to map out the perspective of different stakeholders during the process. At the same time, they have an influence on the social system of stakeholders from a dialogical learning perspective. In our earlier research [20], we focused on the identification and coordination mechanisms. During this study, where the prototypes are becoming increasingly more mature, the focus in the social system will shift to the learning mechanisms of reflection and transformation. The ultimate goal...
of the transformation mechanism in this project is that the developed intervention will be able to disrupt existing cultural patterns and allow better interaction between high-functioning children with ASD and their peers.

In this study, several prototypes of *It’s me* were tested with children and other important stakeholders. Three test sessions were initiated, where the focus shifted in time from usability in the first two tests to the initial assessment of *early indicators of success* [59], acceptance, and perceived usefulness in the third test. Between the second and third test sessions, a stakeholder review took place.

**Figure 2.** The Design Research Framework. DIL: design-in-the-large; DIS: design-in-the-small.

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**Test Session 1: Usability Tests**

For the first test session, a mixed group of 13 children was selected; children were 10-12 years of age. A collaborating, primary special education school recruited the children. In the Netherlands, primary special education schools have the same core objectives and curriculum as regular primary schools. Yet, primary special education schools offer extra help for children with additional needs. The groups in primary special education schools are smaller, and there are more teachers and experts available to assist the children. Out of the 13 recruited children, 7 (54%) were diagnosed with ASD and 6 (46%) needed extra assistance for other causes. The children and their parents gave informed consent. All retrieved data have been processed anonymously.

For the first test session, we developed a prototype (see Figures 3 and 4). In this prototype, the children could fill in a questionnaire. Based on the answers they gave in the questionnaire, a personal comic was generated. The items consisted of questions and prompts and were composed by the authors together with six experts. Three of those experts work as social skills trainers in child psychiatry; they are familiar with social skills training in a clinical setting. The other three experts work at primary special education schools and are familiar with the target group and the challenges in social interactions that these children face at school. The questionnaire contained items about what the children are good at and where they perceive more difficulty. The items from the questionnaire can be found in Textbox 1. The main goal of this first test was to evaluate the prototype regarding usability, to check whether the children understood the items, and to receive feedback from the children on the look and feel of the comic. The children were also observed during the session. After the session, we interviewed the children about their experiences with the tool.
Figure 3. Worksheets, cards, and website prototype for test session 1.
Figure 4. Comic strip prototype for test session 1.

It's me, David!

My name is David and I like to play games and chat.

I'm very good with computers. I can find everything on the Internet. My speciality is touch typing.

I prefer to play indoors and together with others. Just ask me to play!

I am bothered when you're taking me out of consideration.

If I don't feel well, just leave me alone for a while. That'll calm me down.

I prefer to work together on a computer.

When I'm not feeling well, I get very quiet. Don't ask me anything if I'm very quiet.

My classmates say I'm very good at explaining things and games.
Textbox 1. Items from the questionnaire.

1. What’s your name?
2. How old are you?
3. My hobbies are...
4. My favorite subject at school is...
5. I am good at...
6. Nobody knows that...
7. I prefer to play together / I prefer to play alone.
8. I prefer to play outside / I prefer to play inside.
9. What is the best way for you to be approached to play together?
10. I’m not very good with...
11. I can’t stand it as well when...
12. In class, I don’t like it when...
13. I prefer to work alone / I prefer to work together.
14. If I have to work together, it’s best if...
15. What helps you get through a day at school?
16. If I don’t feel good, you can tell by the way...
17. The best way to help me is by...
18. Peer: What's nice about...
19. Peer: What does your classmate do very well?

Test Session 2: Cocreative Refining Session
The second test session took place at the same primary special education school as did the first session. The school recruited 6 different children to participate; 3 (50%) of them were diagnosed with ASD and 3 (50%) of them were children who needed extra assistance for other causes. All the participating children were between 10 and 12 years old. For this second test session, modifications were made to the prototype. The main difference was the presentation of the items, where we added sample answers for clarification (see Figure 5). The children and their parents gave informed consent. All retrieved data have been processed anonymously.

One aim of the second session was to check whether the adjustments in the presentation of the items helped the children to better understand them. Another aim of the second session was to get feedback and input on the appearance of the comic. Through a creative working method, children made their own sketches and drawings to elaborate on the existing comic artwork, then they explained their drawings and paintings. The discussion about the elaborations the children made aimed to gather insights about what the children thought was important in the appearance of the comic.
Expert Review

To ensure that the generated comics would provide enough material for in-depth conversations between peers afterward, six social skills training experts who work in child psychiatry were consulted to give their input; these were different experts than those in test session 1. During the session, the entire prototype, from the questionnaire to the generated comic strip, were reviewed step by step in a walk-through session. The experts were invited to share their initial reactions and findings during each step of the process. After the walk-through, the experts gave input regarding the content of the conversation that should take place between children based on the comic. The experts gave informed consent. All retrieved data have been processed anonymously.

Test Session 3: Test and Evaluate

The third test aimed to investigate whether the designed intervention had enough potential for the intended purpose, whether children and other stakeholders accepted the tool, and whether the tool seemed to have added value for children and their teachers. In this phase of the design process, research was aimed at improving the design and at locating design constraints necessary to use the tool in a meaningful way. In the evaluation, it was decided not to make a distinction between children diagnosed with ASD and children not diagnosed with ASD. Both groups of children are considered equally important in this phase for examining acceptance and perceived usefulness, since the tool is intended to be used by both groups at the same time.

For the third test session, a mixed group of 47 children aged 10-12 years old participated; 19 of those children (40%) were diagnosed with ASD. A collaborating, primary special education school recruited the children; this was a different school than the one in the previous sessions. Four classes participated in this session. During the session, the full prototype was tested by the children. For the test, children were taken out of the classroom in groups of 4. This way of testing allowed regular schoolwork to continue as much as possible. During the test session, the groups were supervised and guided by two research assistants.

During the test, participating children first completed the questionnaire (see Textbox 1) individually on a tablet device. The children were observed by both research assistants while answering the questions. The research assistants scored the behavior of the children independently at two preset moments: after precisely 1 minute and after precisely 5 minutes. The observed behavior of the children was scored on verbal and nonverbal behavior regarding how they reacted to the
questionnaire. The scoring categories were as follows: enthusiastic, disinterested, angry, insecure, and distracted. After 10 and 15 minutes, the children were scored on their social behavior. The scoring categories were as follows: helpful, approaching a peer, watching a peer, and making fun of someone. To increase the predetermined degree of reliability, the research assistants practiced the observing method by observing and scoring children during a regular school assignment, followed by exchanging and discussing the results. The research assistants repeated this several times until there was a high degree of consensus.

When all the children finished the questionnaire the comics were printed, and the children discussed their personal generated comics in groups of 4. During this phase, one research assistant focused on keeping the conversation going; the other one observed the children and scored their communicative behavior. The results were checked and discussed with the other research assistant afterward.

At the end of the session, all participants were invited to partake in an evaluation session. A questionnaire was used to ask the children about their experiences. Three closed questions and one open question were asked about the use of the tool itself. Five closed and three open questions were asked about whether the children had learned something from each other and, as a result, had developed more understanding for each other. Closed questions were answered using smileys (see Figure 6). The scores are reported in the Results section.

After the test sessions with the children, their five teachers were interviewed in a semistructured interview. The teachers were questioned on three topics: (1) How do they evaluate the tool regarding its usefulness on face validity? (2) What do they notice about the children after using the tool? and (3) Would they like to use the tool in their professional practice in the future? The data from these interviews were analyzed using a general inductive approach [60].

The children, their parents, and the teachers gave informed consent. All retrieved data have been processed anonymously.

Results

Test Sessions 1 and 2

During the first two test sessions, the emphasis was on usability. The test sessions showed that the system has good overall usability. Children could easily use the tool and did not run into any problems when using the tool. However, it was noticeable that children with ASD interpreted some of the questions differently in the first version of the prototype. They often asked for help to clarify the questions or to get some sample answers. For this reason, sample answers were added to the prototype for the second test session. During the second test session, children needed less help.

During the first user tests, some early indicators of the intended purpose of the tool became visible. Children helped each other during the session, talked about their comics, and asked each other about their comics. The conversations quickly transcended the superficial, in which children actively gave each other feedback and exchanged how they interpreted certain behaviors by the children. For example, a peer pointed out that one of the children could not hide her frustration as well as she thought: “I can see it right away when you’re frustrated.” The girl replied, “Really? I didn’t think anybody saw that.” In another conversation, one of the children actively asked for help: “Especially when I am scowling; I often need some help.” His peer replied, “We thought we should leave you alone when you looked that way.” Those conversations arose quite naturally. It turned out, however, that children were hesitant when asked if they would like to share their comic strips with other classmates. An essential condition for the children should be that everyone will share their stories.

The main feedback from the children during the first two test sessions focused on the look and feel of the comic, which mainly manifested itself during the creative session in which children drew on the generated comics. According to the children, the characters were very simple, and the backgrounds were experienced as quite dull. The children also had a minimal choice in shaping their character; they could only choose between a boy or a girl. From the computer games they play and the cartoons they watch, children turned out to be accustomed to high-quality illustrations and many possibilities in personalizing their characters.
Expert Review

The experts gave the prototype an overall positive review and had only a few concerns. Some concerns were about the way the questions and the sample answers were phrased. Based on the feedback from the experts, adjustments were made to the questions and sample answers. The experts also had some comments about the meaning of the visual aspect. One expert mentioned the following:

Children with ASD can sometimes pay a lot of attention to detail. If the cartoon character says he likes to play outside, but is inside in the illustration, a child with ASD can already disengage. Also, in the end, the cartoon character must be able to look like the child itself. Otherwise, it may be difficult for children to keep realizing that the comic is about themselves.

In addition to the comments about the comic and the system, experts gave input on how to design a session to put the comic to use as part of an intervention in the actual school context.

The Prototype

For the final prototype, new artwork was created and was produced by a professional illustrator. To keep the system easy to modify, we used Google Forms to create and administer the questionnaire. The advantage of this system is that different people can easily adjust the questions if necessary. By using an add-on (ie, Form Publisher), the comics based on the answers from the children are generated on a preset template. These comics are sent as PDF files to the researchers and an email address of choice, usually that of the professional, parent, or involved teacher. Figure 7 shows a sample of a generated comic.

In the artwork and template, all preparations have been made to make the comic strip suitable for personalized characters. However, for this test, we limited the choice between a version with a boy or a girl. If the children did not appreciate the new look and feel during the test, we still had the opportunity to adjust things. Also, in this way, the prototype communicates its flexibility so that different stakeholders still feel invited to provide input. A completed comic can be found in Multimedia Appendix 1.
Test Session 3

The third test showed that the majority of the children could use the system without help. Children could fill in the questionnaire with relative ease, although some questions required a little more in-depth answers, and children sometimes had to think for a while before they could formulate an answer. Only 2 children with dyslexia experienced more difficulties during the test and needed more help to complete the questionnaire; these children were not diagnosed with ASD. The observations show that children in the first part of the workshop were mainly enthusiastic, as can be seen in Table 1. A single child showed disinterest, and 1 child looked insecure while filling in the questionnaire. A few children became distracted while filling in the questionnaire.

The general tendency during the test session was that when children had finished completing their questionnaires, they started helping the other children. Also, when children got stuck...
with a specific question, they were often supported by peers or asked each other for help. This behavior occurred naturally without the intervention of the research assistants. The observations also show that in the second phase of the session, the children were mainly helpful, approached each other, or watched each other's screens, as can be seen in Table 2. In only 1 case, a child was making fun of someone else.

Conversations based on the comics were about the personal characteristics of the children. Both the positive and the perceived-as-difficult characteristics of the children were discussed. The general atmosphere during the conversations was safe and thoughtful. In some discussions, children mentioned how they experienced and interpreted their own specific behavior and that of their peers. Children actively gave each other feedback during these conversations. The evaluation (see Table 3) shows that two-thirds of the children knew better how to help peers in the classroom and how to make contact with each other after discussing the comic. More than half of the children indicated afterward that the questionnaire was not very easy to fill in. After asking what the reasons were, this was mainly due to the personal nature of the questions. The personal nature of the items meant that children sometimes had to think carefully. Children were also not very used to questions about this type of personal issue.

The teachers were very positive about the comic and were already thinking about how they would use the tool themselves in their classrooms. One teacher said the following:

*It is useful for the beginning of the school year, during the introduction week. Each year, the children are mixed, and all come to a new class. For children with ASD, who are not real talkers, it is useful to get to know each other. The comic is an accessible way to do that.*

Another teacher added the following:

*I think this tool has added value for everyone. I have a vision of the world of my colleagues and the children in my class. But is that also the vision they have about themselves? I think I know things about you, but is that also the story you would tell about yourself? The tool is a great way to discuss this.*

Apart from the fact that teachers reflected on how they would use the tool themselves, during the tests the teachers also learned new things about the children in their classroom. One teacher said the following:

*I looked at the comics myself and I was quite surprised by some of them; I got some new insights. You don't just find out particular things when you have a regular conversation...This comic is a bit closer to the children. The comic is about the children themselves instead of about someone else, and that's the beauty of it.*

The teachers also see it as an advantage that the teachers themselves do not necessarily initiate the conversation. Through generated comics, discussions arise more naturally. According to the teachers, children are also more honest because the tool makes them feel as though they are really doing this for themselves instead of doing it for school.

The main feedback from the tests focused on the limited possibilities for personalization of the characters in the comic. Both children and teachers found this to be the most significant limitation. Children indicated that they saw personalizing their characters as an element that would increase the fun factor. Teachers appointed a somewhat deeper layer on this topic. One of the teachers formulated it as follows:

*Children with autism sometimes focus very much on details, and if the details are not right, then the child will feel less connected to the comic. This also might apply for other children, for example, children with a different cultural background.*

**Table 1. Observations during the first part of the workshop.**

<table>
<thead>
<tr>
<th>Observation time points</th>
<th>Observed behavior (N=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Enthusiastic, n (%)</td>
</tr>
<tr>
<td>1 minute after the test</td>
<td></td>
</tr>
<tr>
<td>Observer 1</td>
<td>44 (94)</td>
</tr>
<tr>
<td>Observer 2</td>
<td>44 (94)</td>
</tr>
<tr>
<td>5 minutes after the test</td>
<td></td>
</tr>
<tr>
<td>Observer 1</td>
<td>40 (85)</td>
</tr>
<tr>
<td>Observer 2</td>
<td>39 (83)</td>
</tr>
</tbody>
</table>
Table 2. Observations during the second part of the workshop.

<table>
<thead>
<tr>
<th>Observation time points</th>
<th>Social behavior (N=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Helpful, n (%)</td>
</tr>
<tr>
<td>10 minutes after the test</td>
<td>Observer 1</td>
</tr>
<tr>
<td></td>
<td>Observer 2</td>
</tr>
<tr>
<td>15 minutes after the test</td>
<td>Observer 1</td>
</tr>
<tr>
<td></td>
<td>Observer 2</td>
</tr>
</tbody>
</table>

Table 3. Evaluation of the questionnaires.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response to questions§ (N=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes, n (%)</td>
</tr>
<tr>
<td>1. I thought it was a fun assignment to do.</td>
<td>39 (83)</td>
</tr>
<tr>
<td>2. I like the way it looks.</td>
<td>33 (70)</td>
</tr>
<tr>
<td>3. The questions are easy to answer.</td>
<td>20 (43)</td>
</tr>
<tr>
<td>4. I now know better what the others are good at and what the others are less good at.</td>
<td>28 (60)</td>
</tr>
<tr>
<td>5. I know better now how I can help others.</td>
<td>30 (64)</td>
</tr>
<tr>
<td>6. I know better now how to make contact.</td>
<td>28 (60)</td>
</tr>
<tr>
<td>7. Discussing the comic was easy for me.</td>
<td>28 (60)</td>
</tr>
<tr>
<td>8. I'd like to do this assignment again.</td>
<td>29 (62)</td>
</tr>
</tbody>
</table>

§Questions were answered using smileys, as seen in Figure 6; in that figure, the green smiley on the left indicates “yes,” the yellow smiley in the middle indicates “neutral,” and the red smiley on the right indicates “no.”

Discussion

Principal Findings

Children with ASD regularly face challenges in social situations and are more likely to be excluded by peers. Many interventions for children with ASD are focused on improving social skills. Although many interventions demonstrate that targeted social skills can be improved in clinical settings, developed social skills do not necessarily get applied in children's daily lives at school [11,18]. One of the possible reasons for this is that classmates continue to show negative bias toward children with ASD, even when children do improve social skills [19]. Children with ASD have a higher risk of being victims of peer harassment and peer exclusion [12-15]. Although social skills training can contribute to social functioning and, therefore, more social acceptance, children with ASD do not necessarily experience this link directly [20].

This study focused on developing a tool to contribute to more mutual understanding among children with and without ASD at school. In this study, we designed the tool It's me, a medium that creates a personal comic about someone’s talents and perceived difficulties. Comics as a medium hold the promise to trigger different affective processes of, and responses by, readers [33,34], which makes them suitable to tell complex and emotionally rich stories [35]. Through It's me, children with and without ASD can tell their stories about who they are in a light and accessible way. Although the personal questions are sometimes tricky to answer for the children, the comic has shown its potential to initiate personal conversations between children in which they learn new things from each other and gain more understanding for each other. After the tests, teachers indicated that they had gained new insights from the information in the comics and that they found It's me useful for increasing social acceptance in their classroom.

Based on concepts of peer support [61], psychoeducation [62], and horizontal interaction, It's me is based on different underlying concepts that have been translated into design. The tests seem to reflect these underlying concepts, at least for the period during and just after the use of It's me. The main idea of It's me assumes that greater understanding between children leads to less peer harassment and increased inclusion of children who are different in a certain way. Teachers are convinced that It's me can be of added value in their classroom and that It's me can contribute to an improved group dynamic. It's me tries to create a safe context at school in which learned social skills should ideally be applied. It's me does not aim to replace existing social skills training but attempts to be complementary by intervening from a different perspective and in a different context.

Equivalence between the participants is an essential element in the application of It's me. The developed tool consciously focuses on both talents as well as on topics where children
The tool seems promising based on these first results but requires future work on two themes. The first theme is to finish the development phase of the tool and add a few functionalities. This development includes more features to personalize the comic, regarding both the characters and the background pictures. The second theme is to design a series of lessons. These lessons can be a manual for facilitators that will help guide them in the usage of the tool and to give them directions on how to lead the conversations based on the comics. For a facilitator, it is essential to guarantee a safe atmosphere during the conversations. However, at the same time, facilitators should create depth within the discussions if this does not occur naturally. By using the tool in a targeted way, it is possible to investigate the sustainable effect among students in classes over a more extended period, which is an interesting topic for future research.

During the design process, we tested several prototypes with different stakeholders. Many insights were gained from the reactions of the stakeholders to the prototypes. During the test sessions, it was established that various stakeholders, including high-functioning children with ASD and their peers, professionals, and teachers, exposed processes of perspective taking and making. These processes can be linked to the reflection learning mechanism that boundary objects can enact ([40]). The first signs of a common problem space, necessary for transformation, manifested itself at the end of the design research process, during the conversations based on the comics and during the evaluation with teachers.

Through prototypes, the intervening effects of the tool within a social system became apparent in the early stages of the design process. As a result, various design constraints have been localized. The importance of a safe atmosphere during the conversations is one of those constraints. When localized, constraints can be addressed within the rest of the design process. Through testing with prototypes, it also became evident whether the prototypes could function as boundary objects and, thus, whether the tool would be able to adapt to the local needs and constraints of different parties. The focus on this feature of boundary objects was essential in finding the right design. In the specific case of this study, you can see that the developed tool was experienced as something useful for professionals, teachers, and children, albeit from a different perspective. The professionals see the potential of the tool to create a more constructive context at school for the application of skills that children learn in social skills training. Children with ASD see a fun tool that helps them to initiate a conversation with peers. Finally, teachers see added value in the tool in making difficult personal themes discussable in the classroom.

The design research approach we used in this study, which aimed to design an intervention that successfully functions as a boundary object, might be beneficial in the acceptance and adoption of the intervention. Because boundary objects are addressing different local needs, everyone identifies with a boundary object in a certain way. In the design process of It’s me, the learning mechanisms of identification, coordination, and reflection passed in sequence among the different stakeholders. The applied research and design strategy helped us to continuously monitor whether the developed tool had added value for the various stakeholders. This strategy can be interesting for other designers and researchers who are dealing with a case involving multiple stakeholder groups or social-cultural systems that have different objectives. Boundary objects can bridge the gap between various stakeholders by representing different objectives from different interpretations without prioritizing an objective of a specific social-cultural system.

**Conclusions**

Children with ASD regularly face challenges in social interactions, especially at school. In this study, a serious media digital tool, It’s me, was designed to facilitate and enact horizontal communication between high-functioning children with ASD and their peers at school. Based on concepts of peer support and psychoeducation, It’s me aims to initiate in-depth conversations between peers, which should lead to more mutual understanding and better relationships. The first test sessions showed that the tool was easy to use for the target group, and the tool seemed to have the potential to initiate personal conversations among children. It’s me was designed as a boundary object that aims to connect the objectives of different stakeholders. Due to this focus during the design process, we gathered a lot of insights about the potential of the tool along the way. The applied design research approach might be of added value in the acceptance and adoption of the intervention, because children, professionals, and teachers saw added value in the tool, each from their own perspectives.

**Acknowledgments**

We would like to thank the children, parents, and professionals who participated in the study. We thank the Aquamarinj and Reestoverschool, the two schools that participated as test locations. This study took place within the Sovatass project, subsidized by Sia under file number RAAK.PUB03.038. The participating bachelor’s degree and master’s degree students are also thanked for their contributions as research assistants. Finally, special thanks to Wendy Verkerk, the illustrator of the prototype.
Conflicts of Interest
None declared.

Multimedia Appendix 1
A completed comic (in Dutch).

[PDF File (Adobe PDF File), 252 KB - mental_v7i7e17260_app1.pdf ]

References


Abbreviations

ASD: autism spectrum disorder

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An Internet-Based Cognitive Behavioral Program for Adolescents With Anxiety: Pilot Randomized Controlled Trial

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Abstract

Background: Internet-based cognitive behavioral therapy (ICBT) is a treatment approach recently developed and studied to provide frontline treatment to adolescents with anxiety disorders.

Objective: This study aimed to pilot procedures and obtain data on methodological processes and intervention satisfaction to determine the feasibility of a definitive randomized controlled trial (RCT) to test the effectiveness of a self-managed ICBT program, Breathe (Being Real, Easing Anxiety: Tools Helping Electronically), for adolescents with anxiety concerns.

Methods: This study employed a two-arm, multisite, pilot RCT. Adolescents aged 13 to 17 years with a self-identified anxiety concern were recruited online from health care settings and school-based mental health care services across Canada between April 2014 and May 2016. We compared 8 weeks of ICBT with ad hoc telephone and email support (Breathe experimental group) to access to a static webpage listing anxiety resources (control group). The primary outcome was the change in self-reported anxiety from baseline to 8 weeks (posttreatment), which was used to determine the sample size for a definitive RCT. Secondary outcomes were recruitment and retention rates, a minimal clinically important difference (MCID) for the primary outcome, intervention acceptability and satisfaction, use of cointerventions, and health care resource use, including a cost-consequence analysis.

Results: Of the 588 adolescents screened, 94 were eligible and enrolled in the study (49 adolescents were allocated to Breathe and 45 were allocated to the control group). Analysis was based on 74% (70/94) of adolescents who completed baseline measures and progressed through the study. Enrolled adolescents were, on average, 15.3 years old (SD 1.2) and female (63/70, 90%). Retention rates at 8 weeks were 28% (13/46; Breathe group) and 58% (24/43; control group). Overall, 39% (14/36) of adolescents provided feedback on completion of the Breathe program. Adolescents’ scores on a satisfaction survey indicated a moderate level of satisfaction. All but one adolescent indicated that Breathe was easy to use and they understood all the material presented. The most frequent barrier identified for program completion was difficulty in completing exposure activities. The power analysis indicated that 177 adolescents per group would be needed to detect a medium effect size (d=0.3) between groups in a definitive
Introduction

Background: Anxiety, Cognitive Behavioral Therapy, and Internet-Based Approaches

Anxiety disorders are the most prevalent of mental illnesses to be diagnosed before the age of 18 years. Approximately 1 in every 3 adolescents will meet criteria for an anxiety disorder in their lifetime [1]. The global burden of such disorders in adolescence is significant. In 2010, anxiety disorders accounted for 14.6% of disability-adjusted life years (DALYs), with the highest proportion of total DALYs seen in young people aged 10 to 29 years [2].

The current classification system for diagnosing anxiety disorders identifies several types: separation anxiety disorder, selective mutism, generalized anxiety disorder (GAD), social phobia, specific phobia, panic disorder, and agoraphobia [3]. In general, these disorders are characterized by excessive, persistent fear or worry that interferes with day-to-day functioning; such impairments can be pervasive, affecting activities of daily living, school performance, and interpersonal relationships [4]. General worries are common among adolescents, and those who experience impairments that do not meet the threshold for any particular diagnosis may be considered as having a subthreshold disorder. Research exploring subthreshold anxiety among adolescents is limited; however, a 2014 study by Burstein et al [5] found that the prevalence of subthreshold GAD among adolescents in the United States was 2-fold compared with adolescents diagnosed with GAD. Eventually, subthreshold disorders may lead to a need for treatment [6].

Cognitive behavioral therapy (CBT) is a well-established first-line treatment for anxiety disorders in adolescents [4,7,8] and can reduce the risk of chronic anxiety if delivered early and effectively [9]. CBT conceptualizes anxiety as arising from maladaptive patterns of cognition and behavior, with treatment focusing on addressing the factors that maintain an adolescent’s symptoms rather than understanding the etiology of the disorder [7]. Accordingly, therapeutic content focuses on teaching skills for replacing anxious thoughts with a more realistic and adaptive approach, developing skills to cope with and reduce anxiety symptoms, and exposure to feared situations to address anxiety-driven behavior and avoidance.

Although trained mental health professionals have traditionally delivered CBT, the structured, skill-based, and sequential nature of CBT translates well to computer-based delivery. A computer-based approach to CBT delivery can involve accessing a program via the internet (internet-based CBT; ICBT), which typically involves therapeutic content being presented in web-based, structured modules in a progressive format. Technology-based features such as multimedia (eg, videos and audio files) and interactive user formats (eg, drop-down response menus) may be used to deliver therapeutic content. In some ICBT programs, therapist support may also be included in the form of messages, phone calls, or in-person contact [10].

A total of four randomized controlled trials (RCTs) provide evidence of the treatment effects of ICBT for adolescents with anxiety disorders [11-14]; two other studies with adolescent populations have been recently published, but their focus was on establishing feasibility [15,16]. The 9-session program developed by Tillfors et al [13], which represents the earliest published RCT of ICBT, targeted social fears (namely public speaking) among high school students who met diagnostic criteria for social anxiety disorder. Posttreatment, significant improvements were reported in favor of ICBT (compared with wait-list control) on measures of social anxiety (Social Phobia Screening Questionnaire for Children [17], between-group Cohen d effect size =1.28), general anxiety (Beck Anxiety Inventory [18], d=1.47), and depression (Montgomery-Åsberg Depression Rating Scale [19], d=1.39) [13]. In another study, Spence et al [12] reported comparable, significant changes in clinician ratings of anxiety severity among adolescents with a markedly impairing anxiety disorder (predominantly GAD and social phobia) who completed 10 ICBT sessions (P<.001) and clinic-based, face-to-face delivery of CBT (P<.001); in contrast, those in a wait-list control condition displayed no significant change in severity [12]. In a recent single-group open trial published by Silfvermagel et al [11], a large within-group treatment effect emerged for adolescents with mild-to-moderate anxiety who completed 6 to 9 ICBT treatment modules (d=2.51). Most recently, Stjerneklar et al [14] reported that, compared with wait-list control, more adolescents who received ICBT were classified as being free of their primary anxiety disorder as well as any other anxiety disorder posttreatment (P<.05), with the odds of being free of their primary disorder appearing 3.60 times greater for recipients of ICBT. Participation in ICBT was also associated with greater improvements in clinician-rated diagnostic severity (P<.05) and adolescent- and mother-rated.

Conclusions: Adolescents were moderately satisfied with Breathe. However, program adjustments will be needed to address attrition and reduce perceived barriers to completing key aspects of the program. A definitive RCT to evaluate the effectiveness of the program is feasible if protocol adjustments are made to improve recruitment and retention to ensure timely study completion and increase the completeness of the data at each outcome measurement time point.

Trial Registration: ClinicalTrials.gov NCT02059226; http://clinicaltrials.gov/ct2/show/NCT02059226.

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KEYWORDS
internet; cognitive behavioral therapy; adolescents; anxiety; randomized controlled trial; pilot

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improvement in anxiety symptoms ($P=.001$). Many positive effects of ICBT were maintained at the 3-month follow-up, including freedom from anxiety diagnoses and subjective improvement in symptomatology. At this time, broad recommendations for future research within the ICBT field include conducting power calculations to ensure adequate sample sizes, defining primary outcomes before conducting the study, presenting results from intention-to-treat analyses, and measuring and reporting treatment adherence [20].

**Objectives**

We conducted a pilot RCT to inform the planning of a definitive RCT to test the effectiveness of the ICBT program, Breathe (Being Real, Easing Anxiety: Tools Helping Electronically) compared with a static webpage listing anxiety resources (considered a form of usual self-led care during internet use). In the pilot RCT, we set out to (1) determine a sample size for the definitive RCT; (2) define a minimal clinically important difference (MCID), as defined by adolescents, for the primary outcome measure; (3) estimate recruitment and retention rates to determine the number of study sites needed and the timeline for recruitment; (4) measure intervention acceptability to inform critical intervention changes; (5) determine the use of cointerventions; and (6) conduct a cost-consequence analysis to inform a cost-effectiveness analysis for the definitive RCT.

**Methods**

The study design was a two-arm pilot RCT (Breathe vs a static webpage) conducted with adolescents aged 13 to 17 years across Canada. We received approval from the Health Research Ethics Boards at the University of Alberta (Edmonton, Alberta), Izaak Walton Killam Health Centre (Halifax, Nova Scotia), and the Children’s Hospital of Eastern Ontario (Ottawa, Ontario) to conduct the study. The study protocol was registered with ClinicalTrials.gov (NCT02059226) and published [21].

**Recruitment**

We recruited adolescents between April 2014 and May 2016 over the course of 3 recruitment cycles. Near the end of each cycle, we reviewed the effect of the different recruitment strategies that we employed. Cycle 1 recruitment spanned April 2014 to August 2015 and involved a soft launch with health care professionals providing study pamphlets to prospective participants seeking mental health care from emergency departments, mobile or school-based crisis teams, and primary care clinics in Edmonton, Alberta; Halifax, Nova Scotia; and Ottawa, Ontario. Cycle 2 spanned 12 months (September 2014 to September 2015) and involved the implementation of a communication strategy with health care providers and study site contacts. The communication strategy involved the distribution of study updates through email (using MailChimp) [22] on a monthly basis and fostering relationships between Breathe research staff and recruitment partners through teleconferences and site visits, as requested. In cycle 3 (October 2015 to May 2016), we introduced a social media recruitment strategy (Facebook, Twitter, and Instagram) with posts that appeared when adolescents searched or posted about anxiety or stress. These posts directed adolescents to the study website, which provided details about the study, instructions for eligibility screening and potential enrolment, information on anxiety disorders, and contact information for the research team.

**Screening for Study Eligibility**

Youth eligible for participation were Canadian adolescents aged 13 to 17 years who (1) could read and write English, (2) had regular access to a telephone and a computer system with a high-speed internet service, (3) were able to use a computer to interact with web-based material, and (4) reported the presence of anxiety symptoms (Multimedia Appendix 1).

The exclusion criterion was adolescent self-report of suicidal thoughts in the past week. In cycle 1 recruitment, we initially had a second exclusion criterion, receipt of face-to-face CBT; however, we removed this criterion midway in the first recruitment cycle (cycle 1) due to emails from adolescents who found it confusing (eg, unaware of what CBT is, difficulty distinguishing CBT from other health care services such as support from a guidance counselor). Upon reviewing the questions we asked adolescents about their participation in other services that would result in ineligibility, we inferred that adolescents were seeking the Breathe program as an adjunct to other counseling and school-based services (not necessarily CBT-based) and that this would likely reflect how the program would be used in a real-world setting. Although we originally implemented this criterion as a way of reducing the potential for cointervention during the definitive trial, removing it increased the extent to which the planned definitive trial would evaluate real-world treatment effectiveness. At the time of this protocol change, 150 adolescents had been deemed ineligible for study enrolment due to this criterion.

We screened adolescents for study eligibility using a 2-stage process:

- **Stage 1:** During stage 1, we screened adolescents on inclusion criteria 1 to 3 and the second exclusion criterion until it was removed. Adolescents used a secure web-based process to answer questions to determine eligibility [23]. Telephone-based and email support during this stage were available from a research team member.
- **Stage 2:** Adolescents who met the first set of criteria proceeded to stage 2 screening. Stage 2 screening was conducted via the secure, internet-based platform, Intelligent Research Intervention Software (IRIS) [24]. During this stage, we assessed adolescents on inclusion criteria 4 and 5, and exclusion criterion 1.

We screened adolescents for anxiety symptoms using the Screen for Child Anxiety-Related Emotional Disorders (SCARED) [25].

To be eligible for study participation at this stage, SCARED scores needed to indicate the presence of anxiety symptoms. Adolescents were not excluded from study participation based on their SCARED scores. Although we originally thought that the Breathe program could be used by adolescents with mild-to-moderate anxiety symptoms [21], we did not exclude adolescents whose SCARED scores indicated severe anxiety symptoms. This approach in our pilot trial allowed us to determine who was accessing the program and identify the target population for the definitive trial.
We assessed the risk of deliberate self-harm using the 4-item Ask Suicide-Screening Questions (ASQ) [26]. Adolescents who responded yes to any of the questions received a safety telephone call from a research team member who evaluated intent/severity/immediacy of risk before deciding on the adolescent’s safety and ability to participate. Adolescents who indicated an immediate risk of self-harm by responding yes to question 3 on the ASQ (“In the past week, have you been having thoughts about killing yourself?”) were excluded from the trial and received brief telephone-based support from the research team member who encouraged the adolescent to seek mental health care appropriate to their level of need.

**Informed Consent/Assent**

Adolescents aged 15 to 17 years were asked to consent to the study on their own behalf; adolescents aged 13 and 14 years were asked to assent to study participation. We also required parental consent for all adolescents aged 13 and 14 years, even if they were assessed as being able to consent. The intent was to have parents involved so that they could support their child with the enrolment process.

Consent/assent from eligible adolescents was indicated electronically via the secure myStudies website [23]. The first webpage confirmed that the individual understood that he/she could ask questions about the study at any time during the study or in the future. Each webpage included a Contact Us button that provided a pop-up email box with toll-free phone and email contact information for a member of the research team. The Contact Us button triggered a message to the participant that a research team member would contact them to answer any questions they may have before proceeding with consent/assent. Individuals were also given the option of saving or printing a blank copy of the informed consent form to read and review on their own instead of proceeding immediately to consent at that time. During the consent/assent process, individuals were guided through a series of sections describing what it meant to participate (eg, reiterating the youth’s right to withdraw from the study at any time) and asking them to confirm (through true/false and yes/no questions) that they understood the study, its risks and benefits, and/or had any questions. True/False questions were added before the final consent/assent webpage to ensure that the individual understood the study information. If an individual answered incorrectly, a pop-up box with the correct answer and explanation appeared. The script was designed to give individuals ample time to make an informed decision about participation. Once consent/assent was indicated, the date and time of consent/assent were recorded by the myStudies website [23].

**Randomization and Blinding**

Randomization took place after informed consent/assent was obtained. Adolescents were randomly assigned using a computer-generated allocation sequence with a 1:1 ratio to 1 of 2 groups. A graduate student trainee affiliated with the project generated this sequence and an email was sent to each participant with information on their assigned intervention and log-in/website information to begin participation. A permuted block randomization procedure [27] with random block sizes of 4 to 6 was used. Given the methodological objectives of the pilot study, no blinding took place.

**Experimental Group: The Breathe Program**

**Program Details**

Consistent with published treatment recommendations [7], the Breathe program is a newly developed 8-module CBT program that involves: (1) multimedia-based education about anxiety problems and approaches to overcoming anxiety (eg, reviewing why exposure exercises are important); (2) self-assessment activities to determine level of treatment and safety needs; (3) activities that teach users about anxiety sensitivity; how to identify anxious thoughts, and how to develop realistic thinking about anxiety-producing situations; (4) activities for practicing coping and relaxation skills with self-assessment of performance and rewards; (5) development of a hierarchy of feared situations and steps for gradual and repeated exposure to feared situations (using imagery and in vivo activities); (6) contingency management (examining the function of anxiety from a reinforcement perspective) and modeling (viewing videos of others confronting feared situations); and (7) skills for maintenance and relapse prevention. An overview of module content is provided in Table 1.

Animations, embedded video, audio playback, graphic novel style vignettes, image maps, timed prompts, and on-screen pop-ups were used in each module to provide an interactive and multimodal experience. Each module included 4 components: Check-in, which asked the youth to assess and rate their social-emotional functioning over the past week (Figure 1); Discover, which introduced the module’s key topics; Check-out, which asked the youth to reflect on their responses to module content; and Try Out, which outlined activities for the adolescent to choose to practice the module’s key concepts and skills. Check-in/Check-out ratings that indicated thoughts of self-harm triggered a safety video and pop-up box, encouraging the adolescent to notify a parent/guardian of their thoughts and to seek immediate help. For each module, adolescents were given a choice as to whether they wanted parents to receive an email that included educational materials about the nature of adolescent anxiety and highlights of key topics that they worked on for that module. During program use, adolescents were also provided with the email contact of a trained research team member who could answer questions about the program and/or treatment (including discussion of distressing issues that may be activated during treatment). The program underwent an evaluation for usability with adolescents and clinicians before the start of the trial to improve the intervention’s technical interface, therapeutic messaging, and user experience (eg, esthetics, presentation of rating scales) [28].
Table 1. Overview of Being Real, Easing Anxiety: Tools Helping Electronically (Breathe) program content.

<table>
<thead>
<tr>
<th>Module</th>
<th>Content overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1</td>
<td>Psychoeducation</td>
</tr>
<tr>
<td></td>
<td>• Introduction to Breathe and the topic of anxiety (eg, fight or flight response, normalization of anxiety)</td>
</tr>
<tr>
<td>Module 2</td>
<td>Realistic thinking</td>
</tr>
<tr>
<td></td>
<td>• Introduction to unrealistic beliefs and their role in anxiety</td>
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<tr>
<td></td>
<td>• Strategies for catching, challenging, and changing unrealistic beliefs</td>
</tr>
<tr>
<td>Module 3</td>
<td>Cognitive distortions</td>
</tr>
<tr>
<td></td>
<td>• Overview of relationship between thoughts, feelings, and behavior</td>
</tr>
<tr>
<td></td>
<td>• Introduction to common thinking traps that fuel anxiety</td>
</tr>
<tr>
<td>Module 4</td>
<td>Relaxation skills</td>
</tr>
<tr>
<td></td>
<td>• Introduction to/practice with relaxation strategies (deep breathing, visualization, and progressive muscle relaxation)</td>
</tr>
<tr>
<td>Module 5</td>
<td>Avoiding avoidance</td>
</tr>
<tr>
<td></td>
<td>• Introduction to the role of behavior (particularly avoidance) in fueling anxiety</td>
</tr>
<tr>
<td></td>
<td>• Creation of a rewards list for taking steps toward facing anxiety</td>
</tr>
<tr>
<td>Module 6</td>
<td>Constructing a fear hierarchy</td>
</tr>
<tr>
<td></td>
<td>• Instructions for creating a fear hierarchy, including examples of hierarchies</td>
</tr>
<tr>
<td></td>
<td>• Creation of a fear hierarchy</td>
</tr>
<tr>
<td>Module 7</td>
<td>Fear hierarchy practice</td>
</tr>
<tr>
<td></td>
<td>• Introduction to strategies for completing exposures and facing fears (eg, video examples of other youth working on fear hierarchies and visualization activities)</td>
</tr>
<tr>
<td>Module 8</td>
<td>Concept integration</td>
</tr>
<tr>
<td></td>
<td>• Reinforcement of links between strategies for identifying/challenging unrealistic beliefs, negative thinking, and behavioral changes</td>
</tr>
<tr>
<td></td>
<td>• Strategies for addressing challenges that often accompany anxiety (eg, social skills and body image)</td>
</tr>
</tbody>
</table>
Figure 1. Being Real, Easing Anxiety: Tools Helping Electronically check-in activity.

Persuasive Design Mechanisms

Breathe was delivered via IRIS, the same platform used for eligibility screening. The platform supports the integration of persuasive design [29] and enables a personalized program experience for adolescents via 3 primary mechanisms: (1) tailoring content, which involved adolescents providing information for the program to use during the module (Figure 2); (2) self-monitoring that enabled the adolescent to track their own behavior toward intended outcomes; and (3) automated reminders—for example, adolescents were instructed at the beginning of the trial to use the program weekly and those who did not log in for 1 week received an email encouraging them to complete their weekly module.
Control Group: Static Webpage
Adolescents assigned to the control group received minimal intervention—access to a secure, password-protected static study webpage housed in IRIS. The website offered suggested anxiety-related trade publications, print-based workbooks for adolescents, and the names of national and local organizations and websites where the adolescent might find support. There was no interactivity or personalization included in the webpage. Adolescents assigned to the control group were provided with the option to access the Breathe program for clinical use at the end of their 8-week control group participation.

Safety Monitoring
Among those adolescents allocated to the Breathe program, a graduate student trainee monitored adolescent well-being under the supervision of a child and adolescent psychiatrist and the primary investigator. Adolescent well-being was monitored via adolescents’ answers in the check-in and check-out components of the program. Automated indicators built into the IRIS program flagged safety issues (eg, decompensation in anxiety symptoms, thoughts of self-harm), and an email notification was sent to the trainee. The trainee would then (1) develop a plan of action and discuss it with the psychiatrist and principal investigator and (2) subsequently contact the adolescent and their parent(s) by phone follow-up within 36 hours. Serious adverse events were to be reported to the institutional ethics board. Among adolescents randomized to the control group, the website provided contact information for local emergency resources (crisis lines, emergency department, and/or other crisis mental health resources).

Study Procedures
Study participation did not begin until the adolescent logged into their assigned intervention via IRIS. Once logged in, participants could access either the Breathe website or the static webpage and could complete the study outcome measures. Outcome measures were available to complete at baseline (available immediately upon first log-in; preintervention), after the completion of module 8 (postintervention; experimental group) or 8 weeks of website access (postintervention; control group), and at 3 months postintervention (follow-up).
Data Collection

During Eligibility Screening
We used the SCARED [25] to screen interested adolescents for anxiety symptoms. The SCARED is a 41-item self-report screen for symptoms of panic disorder, social anxiety disorder, and GAD in clinical and community adolescent samples as based on diagnostic criteria [30-32]. Adolescents responded to the 41 items of anxiety symptoms/experiences as not/hardly ever true, somewhat/sometimes true, or very/often true.

During Study Participation

Study Recruitment and Retention
A study log was used by a research coordinator to track the number of adolescents who were screened as eligible and were enrolled or not enrolled in the study as well as those who completed outcome measures at postintervention and 3-month follow-up.

Demographic Characteristics
Self-reported age, gender, and province of residence, as well as adolescent and parent contact information (ie, telephone number and email), were collected from enrolled adolescents via IRIS before starting the intervention.

Anxiety Symptoms
We used the total score from the Multidimensional Anxiety Scale for Children–Second Edition (MASC2; 50 items) to measure anxiety symptoms pre- and postintervention. The MASC2 is one of the most widely used self-report measures in clinical trials in adolescents with anxiety disorders. It assesses physical symptoms, social anxiety, harm avoidance, separation/panic, and total anxiety, and has excellent 3-month test-retest reliability [33] and validity [34,35]. MASC2 software scores adolescent responses, produces a total raw score, and converts raw scores to T scores (a standardized score that allows for individual scores on a dimension to be compared with those from a broader population in which the dimension is normally distributed). On the MASC2, converting raw scores into T scores allows for anxiety scores to be differentiated as average/typical (scores between 45 and 55), slightly above average (scores between 56 and 60), above average (scores between 61 and 65), much above average (scores between 66 and 70), and clinical diagnosis (score>70) [33].

We administered the MASC2 to adolescents in the experimental group at baseline and at each posttreatment time point. We used the data collected at the 3-month time point to estimate data completion rates for the full-scale trial. Adolescents in the control group completed the MASC2 at baseline and 8 weeks after study enrolment.

Minimal Clinically Important Difference
The MCID was defined using data collected from adolescents allocated to the experimental group following module 8 completion (posttreatment). Adolescents were asked to indicate the minimum change in anxiety for which they would consider it worthwhile to participate in the Breathe program. We used adolescents’ self-reported global ratings of change on a 10-point Likert scale (−5=a very great deal worse to +5=a very great deal better), a commonly used anchor [36,37]. We did not collect data from adolescents who completed the Breathe program after their 8-week period in the control group.

Program Acceptability
Adolescents allocated to the Breathe program answered 16 questions on program acceptability after completing module 8. An instrument was designed specifically for this study to assess ease of program use, sense of privacy, and delivery format and content. The research team reviewed the instrument for face and content validity. For 10 questions, a 4-point Likert scale (strongly disagree to strongly agree) was used. We originally intended to use a 5-point scale but removed a neutral option on the scale to improve the interpretability of adolescents’ ratings. Scores ranged from 10 to 40, with higher scores indicating higher acceptability. Of the remaining 6 questions, one asked adolescents to identify topics they would like to see in future Breathe programs by selecting from a list of options (eg, bullying, specific phobias). Two questions allowed adolescents to identify the top 3 most motivating program features and 3 most helpful modules from provided lists. Three questions were open-ended, allowing adolescents to note challenges or barriers that they faced in taking part in the trial, the extent to which they used the skills learned, and any technical issues encountered while completing the program.

We assessed treatment adherence to further evaluate program acceptability. Adherence was measured by documenting the number of modules completed by adolescents allocated to the Breathe program. We also recorded whether adolescents allocated to the control intervention accessed the website during the 8-week assignment period. Adherence data were recorded by and stored in IRIS.

Health Care Resource Use
We asked adolescents allocated to Breathe to report on the nature and frequency of health care use (cointerventions, emergency department visits, other treatments, and medication) during completion of the program. This information was collected following module 8 completion. We also detailed software development and maintenance costs (for Breathe program maintenance and delivery) and any training and personnel costs associated with the Breathe program.

Outcomes
The primary outcome was self-reported change in anxiety symptoms from baseline to 8 weeks posttreatment. Given the purpose of this pilot trial, primary outcome data were not used to estimate treatment effects. Rather, the outcome data were described and used to inform the sample size needed for a definitive trial. Secondary outcomes were study recruitment and retention rates, MCID, program acceptability, and health care resource use during the trial.

Sample Size
The sample size calculation for the pilot RCT was based on obtaining data to determine the sample size necessary for a definitive RCT [38,39]. We set out to enroll 80 adolescents (40 assigned to each group) and expected to retain 40 adolescents (20 per group) at the 8-week time point. We estimated that we
would need 20 adolescents per group at the 8-week time point to estimate SDs and provide 80% CIs for SDs and 95% CIs for recruitment and retention proportions with sufficient levels of precision in our calculations.

Analysis

Primary Outcome

For each group, we calculated the mean difference in raw MASC2 scores (and SDs) from baseline to 8 weeks (postintervention). Per protocol, we used data from adolescents who had completed the MASC2 both pre- and postintervention for this analysis. A two-sided two-sample t test power analysis was conducted for the change in score from baseline to postintervention to calculate the sample required per group in a definitive RCT [40]. Given the various effect sizes based on different comparators and the heterogeneity between previous studies [20], we were conservative and decided that we wanted to be able to detect a medium treatment effect ($d=0.3$) of the intervention on our primary outcome for the experimental group in the definitive RCT. We used the software R for the sample calculation (type I error=0.05; power=0.80).

Secondary Outcomes

We used descriptive statistics (eg, mean and frequency) to summarize demographic characteristics, recruitment and retention rates, health care utilization, and program acceptability. Participant data were considered unknown if no answer was recorded. We used SPSS version 24 for all secondary analyses [41].

We defined the recruitment rate as the number of adolescents enrolled during the study period divided by the number of adolescents eligible to participate during the study period. The recruitment rate was iteratively calculated throughout the trial to assess the adequacy of the recruitment strategy and formally determined at 26 months (the conclusion of the study recruitment/enrolment period) to determine an overall timeline for the definitive trial. Retention rates were defined as the number of adolescents who completed outcome measures at the 8-week (posttreatment retention) and 3-month (follow-up) time points divided by the number of adolescents enrolled. We used the 8-week retention rate to adjust the sample size for the definitive trial (eg, to adjust for anticipated study attrition).

We intended to use adolescent global ratings of change (within the ranges of $+2$ to $+3$ or $−3$ to $−2$ for reported change using a 10-point Likert scale) reported at the end of Breathe program completion to estimate the MCID value [42]. However, only 13 of the 36 adolescents who received the Breathe program reported data for this outcome, and we considered the data set inadequate to support the analysis. Instead, we report the global ratings of change for these participants with no calculation of the MCID. We will carry over the MCID objective to the definitive trial with a larger sample size.

Analysis of program acceptability data included summarizing the number of modules completed, and examining whether there were differences (eg, by gender) between program completers (>75% of modules) and noncompleters to identify potential confounders that would need to be adjusted for in the definitive RCT. We summarized responses to the satisfaction instrument using mean and frequencies and collated answers to open-ended questions. Completers and noncompleters were compared using two-sided two-sample $t$ tests for continuous data and chi-square tests of independence for categorical data. A $P$ value less than .05 was considered to be statistically significant.

We intended for health care resource use data to inform a preliminary cost-consequence analysis [43,44]. However, data for this outcome were largely missing, and the data set was not adequate to support this analysis. Instead, we report the type and frequency of health care use and the crude costs associated with the Breathe program. We will investigate the cost-consequence objective in the definitive trial with a larger sample size.

Results

Recruitment and Retention Rates

Recruitment commenced in April 2014 and continued until the end of May 2016 for a 26-month recruitment period. During this time, 588 adolescents were screened for study eligibility. A total of 94 adolescents were confirmed eligible for study participation (94/588, 15.9% of those screened; 95% CI 13.2% to 19.3%); all consented and were enrolled in the study. The success rates of the 3 recruitment cycles are presented in Table 2. The most dramatic increase in recruitment was observed following the introduction of social media to the recruitment strategy with an approximate increase of 300% in enrolled adolescents when comparing cycles 1 and 2 (29 months combined) with cycle 3 (8 months).

The flow of participants through the trial is shown in Figure 3. We could not confirm the eligibility of 146 adolescents at stage 2 screening as they did not complete screening measures: 111 did not complete the SCARED and the ASQ, and 35 completed the SCARED but not the ASQ. Thus, we enrolled 94 of 240 potentially eligible adolescents (39.2% recruitment rate). A total of 49 adolescents were allocated to the Breathe program, and of these adolescents, 36 accessed the program; 45 adolescents were allocated to the control intervention, and of these adolescents, 34 accessed this intervention. The study’s retention rate at 8 weeks was 28% (13/46; 95% CI 17%–44%) for the Breathe intervention group and 58% (25/43; 95% CI 42%–73%) for the control group. The overall 8-week retention rate (both groups combined) was 43% (38/89; 95% CI 32%–54%). The retention rate at 3 months among adolescents allocated to the Breathe intervention group was 24% (11/46). The analysis was based on the 70 adolescents who completed baseline measures and did not withdraw from the study. No serious adverse events were detected during the study.

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O’Connor et al

JMIR MENTAL HEALTH

JMIR Ment Health 2020 | vol. 7 | iss. 7 | e13356 | p.161

(page number not for citation purposes)
Table 2. Number of youth recruited in each recruitment cycle.

<table>
<thead>
<tr>
<th>Group</th>
<th>Cycle 1, n (%)</th>
<th>Cycle 2, n (%)</th>
<th>Cycle 3, n (%)</th>
<th>Total across cycles, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Youth interested and screened</td>
<td>11 (19)</td>
<td>33 (56)</td>
<td>544 (92.5)</td>
<td>588 (100.0)</td>
</tr>
<tr>
<td>Youth enrolled</td>
<td>5 (5)</td>
<td>14 (15)</td>
<td>75 (80)</td>
<td>94 (100)</td>
</tr>
</tbody>
</table>

Figure 3. Consolidated Standards of Reporting Trials diagram describing flow of participants through the study. ASQ: Ask Suicide-Screening Questions; CBT: cognitive behavioral therapy; SCARED: Screen for Child Anxiety-Related Emotional Disorders.

Description of the Study Sample

Participant characteristics are shown in Table 3. The average age was 15.3 years (SD 1.2; range 13 to 17 years), and the majority of participants were female (63/70, 90%). On the basis of baseline MASC2 T scores, 7/70 (10%) adolescents reported average levels of anxiety, 3/70 (4%) reported slightly above-average levels, 5/70 (7%) reported above-average levels, 7/70 (10%) reported much above-average levels, and 46/70...
(66%) were at a level consistent with a clinical diagnosis of anxiety.

Table 3. Baseline characteristics of participants by study group.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total (N=70)</th>
<th>Breatheb intervention group (n=36)</th>
<th>Control group (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15.3 (1.2)</td>
<td>15.6 (1.1)</td>
<td>15.1 (1.4)</td>
</tr>
<tr>
<td>No response, n (%)</td>
<td>2 (3)</td>
<td>1 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>63 (90)</td>
<td>34 (94)</td>
<td>29 (85)</td>
</tr>
<tr>
<td>Male</td>
<td>6 (9)</td>
<td>2 (6)</td>
<td>4 (12)</td>
</tr>
<tr>
<td>No response</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>**Geographic region in Canada, n (%)**b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Coast</td>
<td>6 (9)</td>
<td>2 (6)</td>
<td>4 (12)</td>
</tr>
<tr>
<td>Prairies</td>
<td>36 (51)</td>
<td>18 (50)</td>
<td>18 (53)</td>
</tr>
<tr>
<td>Central</td>
<td>22 (31)</td>
<td>13 (36)</td>
<td>9 (27)</td>
</tr>
<tr>
<td>Atlantic</td>
<td>6 (9)</td>
<td>3 (8)</td>
<td>3 (9)</td>
</tr>
<tr>
<td><strong>MASC2 c T score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>71.4 (12.0)</td>
<td>71.7 (13.3)</td>
<td>71.2 (10.6)</td>
</tr>
<tr>
<td>IQRd (Q1, Q3)</td>
<td>14 (66.0, 80.0)</td>
<td>22 (62.0, 83.0)</td>
<td>11 (68.0, 78.0)</td>
</tr>
<tr>
<td>No response, n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

aBreathe: Being Real, Easing Anxiety; Tools Helping Electronically.
bThe West Coast region includes British Columbia; the Prairies region includes Alberta, Manitoba, and Saskatchewan; the Central region includes Ontario and Quebec; the Atlantic region includes Nova Scotia, Newfoundland, New Brunswick, and Prince Edward Island.
dIQRs are reported as MASC2 scores were not normally distributed as identified by Shapiro-Wilk tests (P<.05).

Anxiety Change Scores and Sample Size for a Definitive Randomized Control Trial

A total of 38 participants completed the MASC2 measure at both the baseline and the 8-week posttreatment time points (13/36 in the Breathe intervention group and 25/34 in the control group). Among adolescents in the experimental group, the mean change in raw MASC2 scores from 8-weeks posttreatment to baseline was −7.9 (SD 15.7). The 80% CI for the SD generated for the 8-weeks posttreatment to baseline change score was 12.6 to 21.7. For the control group, the mean change in MASC2 scores from 8-weeks posttreatment to baseline was −9.0 (SD 15.4). The 80% CI for the SD generated for the 8-weeks posttreatment to baseline change score was 13.1 to 19.1. Assuming 80% power and 5% type I error rate, 177 adolescents per group (354 total) will be able to detect an effect size of 0.3 using a two-sided two-sample t test for means. The pilot data suggest that the pooled SD could be 15.7, translating the effect size of 0.3 to a detectable difference of 4.7 in change scores between the Breathe group and the control group.

Global Ratings of Change

Of the 13 adolescents who rated their change in anxiety symptoms after completing the Breathe program, 6 reported a somewhat better change and 7 reported a much better change.

Program Acceptability

Of the 36 adolescents who received the Breathe program, 13 (36%) completed all 8 modules (Figure 4) and 2 (6%) did not complete any modules. Program completers and noncompleters did not differ significantly in their responses to any of the 4 ASQ screening questions (P=.32, .93, .49, and .49), the manner in which they learned about the study (social media/on the web, health care provider/guidance counselor, friend, or not specified; P=.17), age (P=.85), or baseline MASC2 T scores (P=.44). Completers and noncompleters could not be compared on self-identified gender due to the limited number of males enrolled in the study.
In total, 39% (14/36) of adolescents provided feedback on the Breathe program (Table 4). The mean satisfaction score among these adolescents was 28.5/40 (SD 4.0), indicating modest satisfaction. All but 1 adolescent indicated that the Breathe program was easy to use and that they understood all the material presented within the program; 36% (5/14) of participants noted that it was difficult to complete the Try Out (homework) pages each week. All participants liked that the program was completed on the web, with 79% (11/14) indicating no concerns with privacy. Responses were divided as to whether the program should include a social media component (5/14 in agreement), be more personalized to the participant (7/14 in agreement), and include a module for parents (8/14 in agreement). The most common barriers to program completion were difficulty completing exposure activities and remembering/finding time to complete modules, among other life commitments. Additional feedback provided by Breathe users is provided in the Multimedia Appendices 2-Multimedia Appendices 4.

Table 4. Adolescent feedback on the Being Real, Easing Anxiety: Tools Helping Electronically (Breathe) program.

<table>
<thead>
<tr>
<th>Item</th>
<th>Adolescent rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Strongly disagreed, n(%)</td>
</tr>
<tr>
<td>The Breathe program was easy to use.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>I understood all the material/content outlined in the Breathe program.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>I had concerns regarding my privacy while completing the Breathe program.</td>
<td>6 (43)</td>
</tr>
<tr>
<td>I liked that the Breathe program was completed online.</td>
<td>0 (0)</td>
</tr>
<tr>
<td>The Try Out pages were hard to complete each week.</td>
<td>2 (14)</td>
</tr>
<tr>
<td>The email reminders sent to me by the Breathe program were helpful.</td>
<td>4 (29)</td>
</tr>
<tr>
<td>The length of the modules in the Breathe program was too long.</td>
<td>4 (29)</td>
</tr>
<tr>
<td>The Breathe program should have a social media component.</td>
<td>3 (21)</td>
</tr>
<tr>
<td>I would like the Breathe program to be more personalized to me.</td>
<td>2 (14)</td>
</tr>
<tr>
<td>I think my mom/dad/guardian should have had their own parent modules in the Breathe program.</td>
<td>5 (36)</td>
</tr>
</tbody>
</table>
Health Care Resource Use

In terms of costs to develop the Breathe program, software development totaled Can $51,405 (US $36,462), whereas personnel costs associated with program development and maintenance during the study (eg, technician and programmer costs) totaled Can $73,172 (US $51,911).

With regard to health care resource use outside Breathe, 39% (14/36) of adolescents in the study answered questions about health care resource use during the Breathe program. We summarize the findings from these adolescents, but acknowledge that the results may not reflect all adolescents allocated to the Breathe program. Counsellors (of unspecified professional background, designation, or theoretical orientation) were the most commonly used resources; 50% (7/14) respondents reported having seen a counselor for anxiety at least once during their participation in Breathe, with 5 having attended 5 or fewer visits and 2 having attended 9 or more. A total of 43% (6/14) respondents had visited family physicians for anxiety-related concerns, although these visits occurred only once for all but one of this group. Other resources were accessed relatively infrequently, with the exception of 1 adolescent who accessed social work 7 times over the course of Breathe (Table 5). During the trial, no adolescents were identified as requiring additional support based on their responses to survey questions completed before and after each module.

Table 5. Health care resource use reported by adolescents after completion of module 8 of the Being Real, Easing Anxiety: Tools Helping Electronically program.

<table>
<thead>
<tr>
<th>Resource used</th>
<th>Responsea</th>
<th>Frequency of use for accessors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>No, n (%)</td>
<td>Yes, n (%)</td>
</tr>
<tr>
<td>Counsellor</td>
<td>13 (93)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Psychologist</td>
<td>11 (79)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>12 (86)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Social worker</td>
<td>12 (86)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Family physician</td>
<td>8 (57)</td>
<td>6 (43)</td>
</tr>
<tr>
<td>Emergency department</td>
<td>11 (79)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>13 (93)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Other treatment</td>
<td>12 (86)</td>
<td>2 (14)</td>
</tr>
</tbody>
</table>

aThe total is greater than 100%; adolescents could report more than one resource having been used.

Discussion

Principal Findings

This RCT piloted procedures and obtained data on acceptability to determine feasibility for a definitive RCT that would test the effectiveness of an ICBT program for adolescent anxiety. The 3 key lessons learned from conducting the pilot study and being applied to plan for the definitive trial as follows: (1) adolescents did not use all the Breathe resources provided, and adjustments to the program were necessary to increase program completion in the definitive trial; (2) recruitment by social media was the most successful modality for recruiting adolescents into the study and should be the primary recruitment strategy in the definitive trial to ensure timely study completion; and (3) protocol adjustments are necessary to increase study retention at each measurement time point to improve outcome data collection.

Several adjustments were made to the Breathe program in an effort to support adolescents’ abilities to navigate and complete the program. First, we streamlined content and reduced the number of modules from 8 to 6. This decision was based on our observation of a leveling off of completion around sessions 5 to 6. To achieve this reduction, the flow of Breathe content was streamlined and focused, and content considered unessential or potentially overwhelming was removed (eg, numerous exercises highlighting the same concept). We also increased the use of video content in the 6 modules as this mode was described as inspiring by adolescents and created new first-person narrative videos to reinforce concepts and support adolescents in relating topics to their own lives. Second, we noted that participant feedback pointed to Breathe’s exposure component as a significant barrier to successful program completion. Although exposure is widely viewed as one of the most important components of therapy in terms of producing lasting change in anxiety symptoms, it does produce discomfort and may have contributed to the lower retention rate in the Breathe group as compared with the control intervention. We made 2 changes to exposure activities in the Breathe program. First, we adjusted the flow of our content so that exposures were first introduced in module 2 (not module 6, as originally designed); with this change, the concept could be introduced gradually and promote adolescents’ sense of positive change as a result of participating in the program. Second, we added telephone-based support from a coach to module 2. The coach will help the adolescent build an exposure activity plan tailored to their specific needs, clarify any confusion about how to set up an exposure activity, and address perceptions of self-efficacy in completing exposure activities. A recent systematic review suggests that this type of ICBT support (ie, human components) may boost ICBT adherence and engagement, particularly when delivered at
critical points in a program that participants may find difficult or taxing [45].

In this pilot study, we enrolled 94 adolescents over a 26-month period (approximately 4 adolescents enrolled per month). This recruitment rate is not feasible for enrolling 354 adolescents (before attrition) in the definitive RCT. In testing different recruitment strategies, however, we learned that recruitment was most successful via social media (39/94, 42% enrolled). We were able to recruit approximately 4 times the number of adolescents in cycle 3 (n=75) once we launched our social media strategy, compared with cycles 1 and 2 during which we relied on health care providers. For the definitive trial, we plan to hire a communications specialist to assist with social media recruitment efforts. The communication specialist’s role will be governed by the following key objectives: (1) to create study awareness and inform the target audiences (parents, adolescents, and health care providers) about the Breathe program and study; (2) to increase traffic to the study website; and (3) to increase recruitment of study participants, including specifically targeting males. More broadly, our social media strategy will involve consideration of the functions of each communication strategy and any associated costs (eg, advertising), development of study-branded, tailored content, including that geared toward males (eg, sport performance stress) to increase their recruitment; an established approach for social media use (eg, frequency of posts, refreshing content), and a strategy to enhance user privacy (eg, use of marketing headlines so that personal disclosure is limited when social media content is viewed) and safety (eg, monitoring of web-based posts).

To improve study retention in the definitive trial, we will budget for financial tokens of appreciation in an effort to increase the response rate to study questionnaires (US $25 for completing posttreatment questionnaires; US $25 for completing follow-up questionnaires). We will also streamline the initial screening steps for consent and eligibility to reduce early dropout and will include those identifying as receiving CBT and other forms of treatment for anxiety. As other similar trials did not report such low retention rates nor offered incentives [8-11], we do not know what to expect in terms of the impact of this strategy on study retention, but hope that it will increase our retention to 75% at postintervention and 50% at the 3-month follow-up. Accounting for a 50% attrition rate at the 3-month follow-up, 708 adolescents would need to be enrolled in the definitive trial to achieve our desired sample size.

Another important aspect of this pilot trial was our intent to define an MCID for adolescent anxiety. However, challenges with retention did not permit us to calculate an MCID as planned. A critical aspect of all ICBT programs is the degree of improvement adolescent users experience as a result of their use. The use of MCID estimates could help adolescents, parents, and health care providers select among ICBT programs with different effects and anticipate the meaningfulness of the expected differences in their effects (ie, their clinical significance). Moving forward, within the broader literature, there is no minimum sample size necessary for calculating an MCID for a patient-reported outcome for adolescent anxiety. However, studies exploring the use of MCID scores in intervention-based research noted that this value has been calculated and used meaningfully in studies with sample sizes of a minimum of approximately 60 participants [46]. Should our efforts to improve study retention in the definitive trial be successful, we will have sufficient data to calculate an MCID. This MCID will be used to support the interpretation of results from this trial as opposed to defining a sufficient sample size (to calculate statistical significance) as originally planned.

Limitations

The most significant limitation of this pilot RCT was the lack of data at posttreatment and 3-month follow-up. Unlike in the pilot, where posttreatment and 3-month follow-up MASCs were only administered if/when participants completed all program modules, administration of follow-up questionnaires in the definitive RCT will occur independently of program progress—ideally increasing the data available at both follow-up points and limiting the extent to which it is subject to selection bias. Another important limitation was our reliance on adolescents’ own recall when providing information about their utilization of other health care services. Addressing this limitation is challenging, given the privacy considerations and logistics that would be associated with verifying self-report data with information from other sources. However, as discussed previously, support from research staff will be made available to participants throughout their involvement in the full-scale trial, and they will be encouraged to contact staff with any questions that may arise as they provide this information.

A final limitation was the exclusion of 150 adolescents early on in the trial due to their report of CBT participation. Although we do not know how many of these adolescents would have consented/assented to participate in Breathe, their exclusion introduces the potential for further selection bias in the study. In this study, initial recruitment in cycles 1 and 2 was also very slow until a social media component was included in cycle 3. That these changes occurred during the pilot study and not the definitive trial is important, and we do not anticipate needing to adjust this inclusion/exclusion criterion or the recruitment modality utilizing social media further. In the definitive trial, efforts will also be focused on increasing the number of male participants, which was a limitation to our pilot trial’s study population.

Conclusions

This study aimed to determine the feasibility of a definitive RCT exploring the effectiveness of Breathe, an ICBT program for adolescents reporting anxiety, by piloting procedures and assessing intervention acceptability. Adolescents enrolled in Breathe reported modest satisfaction with the program, with most indicating that it had been easy to use and was readily understood. Still, adjustments to the program are required to reduce attrition and address the barriers that adolescents encounter when attempting to complete key program elements. These adjustments, including streamlining program access and content and providing phone coaching support for adolescents around challenging elements of the program, will ideally increase recruitment and retention within the study, thereby promoting timely completion of the Breathe program and supporting the completeness of our dataset at each outcome time point. Ultimately, with these adjustments, the definitive
RCT will allow for a more in-depth exploration of the impact of the Breathe program on adolescents with anxiety and inform ICBT utilization within mental health care systems.

Acknowledgments
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Authors’ Contributions
KO analyzed and interpreted the data, and drafted the initial manuscript. AB contributed to the design of the study, obtained funding for the study, supervised the study, and analyzed and interpreted the data. PM contributed to the design of the study, obtained funding for the study, supervised the study, and helped interpret the data. LW supervised the study and analyzed and interpreted the data. AR acquired the data and analyzed and interpreted the data. SC contributed to the design of the study, supervised the study, and interpreted the data. MJ contributed to the design of the study, supervised the study, and interpreted the data. EF supervised the study and interpreted the data. DJ contributed to the design of the study and interpreted the data. RR contributed to the design of the study and oversaw data analysis. AO contributed to the design of the study and interpreted the data. AJ contributed to the design of the study and interpreted the data. AN conceptualized and designed the study, obtained funding for the study, supervised the study, acquired the data, analyzed and interpreted the data, and helped draft the initial manuscript. All authors critically revised the manuscript for important intellectual content and approved the final manuscript as submitted.

Conflicts of Interest
During this work, AN held a CIHR New Investigator Award and RR held a Health Scholar award from Alberta Innovates—Health Solutions. PM holds a Tier I Canada Research Chair. The other authors have no conflicts to declare.

Multimedia Appendix 1
Trial inclusion and exclusion criteria.
[PNG File, 92 KB - mental_v7i7e13356_app1.png]

Multimedia Appendix 2
Adolescents’ ratings of most inspiring Being Real, Easing Anxiety: Tools Helping Electronically features.
[PNG File, 303 KB - mental_v7i7e13356_app2.png]

Multimedia Appendix 3
Adolescents’ ratings of most helpful Being Real, Easing Anxiety: Tools Helping Electronically modules.
[PNG File, 160 KB - mental_v7i7e13356_app3.png]

Multimedia Appendix 4
Open-ended responses from adolescents on the extent to which they used the skills learned and topics to include in the Being Real, Easing Anxiety: Tools Helping Electronically program.
[PNG File, 107 KB - mental_v7i7e13356_app4.png]

References


DALY: disability-adjusted life year
GAD: Generalized Anxiety Disorder
ICBT: internet-based cognitive behavioral therapy
IRIS: Intelligent Research Intervention Software
MASC2: Multidimensional Anxiety Scale for Children–Second Edition
MCID: minimal clinically important difference
RCT: randomized controlled trial
SCARED: Screen for Child Anxiety-Related Emotional Disorders

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The Effect of Shame on Patients With Social Anxiety Disorder in Internet-Based Cognitive Behavioral Therapy: Randomized Controlled Trial

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Abstract

Background: Prior research has demonstrated the efficacy of internet-based cognitive behavioral therapy (ICBT) for social anxiety disorder (SAD). However, it is unclear how shame influences the efficacy of this treatment.

Objective: This study aimed to investigate the role shame played in the ICBT treatment process for participants with SAD.

Methods: A total of 104 Chinese participants (73 females; age: mean 24.92, SD 4.59 years) were randomly assigned to self-help ICBT, guided ICBT, or wait list control groups. For the guided ICBT group, half of the participants were assigned to the group at a time due to resource constraints. This led to a time difference among the three groups. Participants were assessed before and immediately after the intervention using the Social Interaction Anxiety Scale (SIAS), Social Phobia Scale (SPS), and Experience of Shame Scale (ESS).

Results: Participants’ social anxiety symptoms (self-help: differences between pre- and posttreatment SIAS=−12.71; Cohen d=1.01; 95% CI 9.08 to 16.32; P<.001 and differences between pre- and posttreatment SPS=11.13; Cohen d=0.89; 95% CI 6.98 to 15.28; P<.001; guided: SIAS=19.45; Cohen d=1.20; 95% CI 14.67 to 24.24; P<.001 and SPS=13.45; Cohen d=0.96; 95% CI 8.26 to 18.64; P<.001) and shame proneness (self-help: differences between pre- and posttreatment ESS=7.34; Cohen d=0.75; 95% CI 3.99 to 10.69; P<.001 and guided: differences between pre- and posttreatment ESS=9.97; Cohen d=0.88; 95% CI 5.36 to 14.57; P<.001) in both the self-help and guided ICBT groups reduced significantly after treatment, with no significant differences between the two intervention groups. Across all the ICBT sessions, the only significant predictors of reductions in shame proneness were the average number of words participants wrote in the exposure module (β=−.222; SE 0.175; t96=2.317; P=.02) and gender (β=-.33; SE 0.002; t77=-3.13; P=.002). We also found a mediation effect, wherein reductions in shame fully mediated the relationship between the average number of words participants wrote in the exposure module and reductions in social anxiety symptoms (SIAS: β=−.0049; SE 0.0016; 95% CI −0.0085 to −0.0019 and SPS: β=−0.0039; SE 0.0015; 95% CI −0.0075 to −0.0012).

Conclusions: The findings of this study suggest that participants’ engagement in the exposure module in ICBT alleviates social anxiety symptoms by reducing the levels of shame proneness. Our study provides a new perspective for understanding the role of shame in the treatment of social anxiety. The possible mechanisms of the mediation effect and clinical implications are discussed.

Trial Registration: Chinese Clinical Trial Registry ChiCTR1900021952; http://www.chictr.org.cn/showproj.aspx?proj=36977
Introduction

Background

Internet-based cognitive behavioral therapy (ICBT) entails similar content to conventional in-person cognitive behavioral therapy (CBT), which has been proven to have treatment effects equivalent to pharmacological treatments [1,2]. ICBT is developing rapidly because of its convenience, low cost, and wide range of use. ICBT has shown significant and long-standing effects for various psychiatric disorders [3-5], especially social anxiety disorder (SAD) [6]. A longitudinal study showed that improvements in SAD symptoms after ICBT were maintained at 5-year follow-up [7].

Shame shares many similarities with social anxiety, including self-directed attention; fear of negative evaluations from others; and regarding oneself as unwelcome, unattractive, or worthless in others’ view [8-10]. Shame proneness, as a dispositional affective sensitivity to the emotion of shame, is a stable trait that refers to individuals’ cognitive, affective, and behavioral responses to transgressions [11,12]. Empirical and meta-analytic studies suggest that shame plays an important role in the development and maintenance of social anxiety [13,14]. Helsel’s [15] study of children’s SAD and shame experiences showed that certain degrees of shame experience could cause social anxiety. Some studies also showed significant correlations between shame proneness, SAD, social avoidance, and distress [16-18]. Several studies also showed that both individual and group CBT significantly reduce shame in patients with SAD [16,19]. However, they did not explore which part of CBT changes participants’ shame proneness. Hedman et al [20] proposed cognitive modification and exposure exercises as possible mechanisms.

Some empirical studies have investigated the relationship between shame and social anxiety through self-reported scales [13,17,18], and shame has been suggested to play an important role in SAD. In a longitudinal study, Li et al [21] verified the important influence of shame on social anxiety and found that reductions in shame proneness led to improvements in social anxiety. In addition, several studies found that CBT and compassion-focused therapy (a treatment specifically designed for people with high levels of shame) reduced patients’ body shame [22,23]. Although some studies have explored the relationship between shame and social anxiety symptoms, it is still unknown what role shame plays in the ICBT treatment of SAD.

Objective of This Study

In this study, we investigated the following questions among a sample of Chinese individuals with SAD: (1) Is shame proneness significantly reduced over the course of treatment using a Chinese version of the ICBT? and (2) If so, which modules in the ICBT influence the levels of shame proneness? We hypothesized that the levels of shame proneness would be reduced over the course of ICBT treatment and that shame proneness would mediate the relationship between ICBT modules and social anxiety symptoms. If successful, this investigation will further elucidate the treatment of SAD and contribute new insights into the development of more detailed and targeted ICBT programs.

Methods

Study Design and Approval

This research was an 8-week clinical trial. Participants were recruited from 2015 to 2017 in two different stages: a pilot study, which consisted of only the self-help and the wait list control (WLC) groups, and a controlled trial with 3 groups. All data came from a larger program of ICBT. This study was approved by the local ethics committee and registered in Peking University. The trial registration number is ChiCTR1900021952.

Participants and Eligibility Criteria

We used a community sample in the study. Participants were recruited through different internet platforms, and they were informed about the basic information, aim, and procedure of the study. Individuals who were interested in the study were required to finish several self-reported questionnaires on the website (N=1479). In addition, they were invited to participate in the Chinese version of the Mini International Neuropsychiatric Interview (MINI; N=784) [24,25]. The MINI was conducted either face-to-face or through telephone by 3 masters-level graduate students and 1 doctoral student in clinical psychology, all of whom have learned and practiced MINI under the guidance of a professional psychiatrist and have gained certain clinical interview skills.

The main inclusion criteria were as follows: participants who were older than 18 years and who met the diagnostic criteria of SAD in the Structural Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Axis I Disorders. Their Social Interaction Anxiety Scale (SIAS) score was higher than 22, with Social Phobia Scale (SPS) score higher than 33. They did not take any antipsychotic drugs or undergo other psychological treatments in the last year, and they did not meet the diagnostic criteria of schizophrenia, bipolar disorder, and high suicidal tendency. Participants had to agree that they could finish the 8-week ICBT program and the posttreatment measurements. Detailed information of the screening process and the eligibility criteria are shown in Figure 1.
Participants’ Basic Information
A total of 104 participants, including 31 males and 73 females, aged 18 to 45 years (mean 24.92, SD 4.59 years) met the criteria and agreed to attend the treatment program.

Measures
Experience of Shame Scale
The 25-item Experience of Shame Scale was composed by Qian et al [26] and designed to measure participants’ shame proneness. Higher scores represent higher shame proneness. The scale has high reliability and validity (standard Cronbach alpha=.87).

Social Interaction Anxiety Scale and Social Phobia Scale
SIAS is a 19-item scale, originally composed by Mattick and Clarke and revised into a Chinese version [27,28]. SIAS is used to evaluate the degree of individuals’ feeling of anxiety and fear in a social interaction situation, such as being in a party or talking to others. SPS is another scale that assesses the anxiety and avoidance when individuals are being observed by others in social situations [28]. These two scales are often used together, and they both have high internal reliability (0.87 for SIAS and 0.90 for SPS) and retest reliability (0.86 for SIAS and 0.85 for SPS). The criterion-related validity of SIAS is 0.514 and of SPS is 0.479.
Beck Depression Inventory

The Chinese version of the Beck Depression Inventory (BDI) scale is widely used in the measurement of depressive symptoms, with high reliability (standard Cronbach alpha=0.890 and split-half reliability=0.879) and validity [29]. Prior research showed that the relationship between SAD and depression is high [30]; thus, to eliminate the influence of depressive symptoms, the BDI score and the result of MINI were both seen as excluding criteria for the screening process.

Mini International Neuropsychiatric Interview

The MINI [25] is a structured interview with high internal reliability (0.94) and test-retest reliability (0.97), designed to access participants’ psychotic symptoms according to DSM-IV, revised. The interview takes approximately 30 min.

The primary outcome measures were changes in the ESS score and the relationships of ESS and ICBT, whereas others were recorded as secondary outcomes.

The Internet-Based Cognitive Behavioral Therapy Program

The ICBT program is an internet-based self-help cognitive behavioral intervention course and was first developed at the University of Bern [6]. The original materials were translated and revised twice by 9 clinical psychologists from the School of Psychological and Cognitive Sciences at Peking University. Except for some course practices that were modified because of cultural differences, no other contents were changed.

The 8-week courses can roughly be divided into 5 parts. First, motivation arousing, which guides the participants to think about and write down why they want to change and what life would be like if social anxiety symptoms reduce. Relaxation training would also be introduced to participants in this module. Second, psychoeducation, which explains the relevant theories of SAD, the concepts of negative thoughts, safety behaviors, self-focus attention, and their relationships, helping participants gradually construct the case formulation of their own. Third, cognitive construct, which instructs participants to identify and re-examine their nonadaptive negative thoughts and to take notes on the rational thinking form, which will guide them to replace nonadaptive thoughts with adaptive ones. Fourth, attention training, which helps participants to focus more on the external environment other than themselves. Fifth, exposure and problem solving, which aim to help participants to confront the situations that may cause anxiety, to try behavioral experiments, and to solve problems.

Overall, two forms of the ICBT intervention were included in the study: the self-help ICBT and guided ICBT. A total of 3 therapists were included in the program, all of whom were masters-level graduate students in clinical psychology, who had undergone formal CBT training and had at least 1 year of experience of individual counseling, and they were supervised by a licensed clinical psychologist on a weekly basis. Each therapist assists a certain number of participants when needed in the guided group. The assistance of the therapists consisted of a weekly email to each patient, aiming at motivating and reinforcing their usage of the ICBT program. Furthermore, therapists answered participants’ questions about the ICBT program. Therapists also needed to know the basic information of their patients and their progress in the program, the last time of their visit, and the homework record. Approximately 15 min were needed to prepare and reply to the email per patient for each week. The program had an independent network platform for therapists, and they can check the login information and relative data of all participants on the platform (such as their homework and the time they spent on each module).

Information Collecting and Research Process

After the screening process, the participants would first sign the digital informed consent form via internet and were provided with the instructions of the program. After which they would be divided into 3 groups: guided group, self-help group, and WLC group. Each individual needed to fill out the SPS, SIAS, and ESS scales before and immediately after completing the ICBT program (or 2 months later for the WLC group).

Statistical Analysis

All analyses were conducted using SPSS version 20 (IBM Corp). First, differences among various groups in demographic and pretreatment clinical variables were tested using chi-square and one-way analysis of variance (ANOVA) tests. Repeated measures of ANOVA were also conducted to verify the participants’ improvement after ICBT.

For further analysis, we introduced a variable, residual gain (RG), to indicate the intervention changes. A linear regression model was fitted to find the specific modules of ICBT, which have an impact on RG of shame proneness. Afterward, we conducted a mediation analysis to investigate the role of shame proneness in the ICBT treatment. The results related to ESS (shame proneness) were regarded as the primary outcome.

Results

Participants

The descriptive statistics of all variable scores are shown in Table 1. In total, participants’ mean age was 24.92 (SD 4.59) years, and 70.2% (73/104) of them were female. Using pretreatment scores of SPS, SIAS, and ESS as dependent variables, we conducted three 2 (gender) × 3 (group) univariate ANOVA. The results showed did not yield significant main effects of group (SIAS: $F_{2,98}=1.532; $P=.22; partial $\eta^2=0.03; $SPS: $F_{2,98}=1.034; $P=.359; partial $\eta^2=0.021; and ESS: $F_{2,98}=0.257; $P=.77; partial $\eta^2=0.005) and gender (SIAS: $F_{1,98}=0.102; $P=.75; partial $\eta^2=0.001; $SPS: $F_{1,98}=0.084; $P=.77; partial $\eta^2=0.001; and ESS: $F_{1,98}=0.257; $P=.77; partial $\eta^2=0.005), and the interaction effects were also not significant (SIAS: $F_{2,98}=0.489; $P=.615; partial $\eta^2=0.01; $SPS: $F_{2,98}=1.571; $P=.21; partial $\eta^2=0.031; and ESS: $F_{2,98}=0.176; $P=.839; partial $\eta^2=0.004). This suggested that the 3 groups of participants had the same level of shame and social anxiety before ICBT.
Table 1. The descriptive statistics of all variables before and after the treatment.

<table>
<thead>
<tr>
<th>Sociodemographics</th>
<th>Intervention (n=80)</th>
<th>Guided (n=33)</th>
<th>Wait list (n=24)</th>
<th>F (df)</th>
<th>P value</th>
<th>Chi-square (df=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Values d</td>
<td>Values d</td>
<td>Values d</td>
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</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>34 (72)</td>
<td>NA 22 (67)</td>
<td>NA 17 (71)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>25.91 (4.25)</td>
<td>NA 24.73 (5.40)</td>
<td>NA 23.25 (3.59)</td>
<td></td>
<td>N/A</td>
<td>2.81 (2,101) .07</td>
</tr>
<tr>
<td>Education level, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low/middle</td>
<td>31 (66)</td>
<td>NA 22 (67)</td>
<td>NA 16 (67)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>High</td>
<td>16 (34)</td>
<td>NA 11 (33)</td>
<td>NA 8 (33)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAD</td>
<td>23 (49)</td>
<td>NA 15 (45)</td>
<td>NA 9 (38)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SAD+MDD c</td>
<td>9 (19)</td>
<td>NA 9 (27)</td>
<td>NA 6 (25)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SAD+AD d</td>
<td>8 (17)</td>
<td>NA 5 (15)</td>
<td>NA 5 (20)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SAD+MDD+AD</td>
<td>7 (15)</td>
<td>NA 4 (12)</td>
<td>NA 4 (16)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Experience of Shame Scale, mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretreatment</td>
<td>75.45 (10.53)</td>
<td>NA 74.61 (12.94)</td>
<td>NA 76.29 (12.48)</td>
<td></td>
<td>0.14 (2,101) .87</td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>68.11 (13.92)</td>
<td>NA 64.64 (14.97)</td>
<td>NA 76.92 (13.13)</td>
<td></td>
<td>5.47 (2,101) .006</td>
<td></td>
</tr>
<tr>
<td>Social Interaction Anxiety Scale, mean (SD)</td>
<td>N/A 101 N/A</td>
<td>1.20 N/A</td>
<td>0.21 N/A</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pretreatment</td>
<td>66.62 (10.62)</td>
<td>NA 70.67 (9.36)</td>
<td>NA 66.04 (10.61)</td>
<td></td>
<td>1.96 (2,101) .15</td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>53.91 (14.80)</td>
<td>NA 51.21 (13.25)</td>
<td>NA 66.50 (13.11)</td>
<td></td>
<td>9.27 (2,101) &lt;.001</td>
<td></td>
</tr>
<tr>
<td>Social Phobia Scale, mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretreatment</td>
<td>56.02 (14.16)</td>
<td>NA 53.48 (13.87)</td>
<td>NA 55.42 (13.74)</td>
<td></td>
<td>0.33 (2,101) .72</td>
<td></td>
</tr>
<tr>
<td>Posttreatment</td>
<td>44.89 (17.54)</td>
<td>NA 40.03 (14.99)</td>
<td>NA 56.29 (16.90)</td>
<td></td>
<td>6.83 (2,101) .002</td>
<td></td>
</tr>
</tbody>
</table>

aN/A: not applicable.
bSAD: social anxiety disorder.
cMDD: major depressive disorder.
dAD: other anxiety disorders.

Dropout Rate and Adherence

The dropout rate difference between the self-help (32.86%) and guided (52.86%) ICBT groups was significant, with higher dropout rate in the guided group ($\chi^2$=5.7; P=.02). In addition, we identified another two adherence indexes, the number of modules and homework finished in the ICBT program. A moderation analysis was conducted to investigate whether shame proneness moderated the relationship between ICBT form and treatment adherence. The results did not yield any significant effect (for the module number: $\beta$=−.0193; SE 0.0374; 95% CI −0.0938 to 0.0551 and for the homework number: $\beta$=−.0393; SE 0.0406; 95% CI −0.1202 to 0.0415). In this regard, shame proneness is not a moderator in the relationship between the form of ICBT and treatment adherence.

Primary Outcomes

We used repeated measures of ANOVA to access whether ICBT can reduce participants’ shame proneness. The results showed that the interaction effect of group and time on ESS ($F_{2,135}=8.44$; $P<.001$; partial $\eta^2=0.11$) was significant. Simple effect analysis showed that after treatment, the ESS scores of intervention groups were significantly reduced (self-help: mean deviation [MD]=7.34; Cohen $d$=0.80; 95% CI 3.99 to 10.69; $P<.001$ and guided: MD=9.97; Cohen $d$=0.88; 95% CI 5.36 to 14.58; $P<.001$). As a result, ICBT was effective for the reduction of both social anxiety symptoms (SIAS and SPS) and shame proneness (ESS).

The Analysis of Effect of Internet-Based Cognitive Behavioral Therapy on Shame Proneness

In our study, RG (post-pre) was used as an improvement index of the ICBT treatment. RG is calculated as follows: $Z_2^2=(Z_1^2×r_{12})$, in which $Z_2$ means the Z score of posttreatment, $Z_1$ is the pretreatment Z score, and r12 refers to the Pearson correlation of pre- and posttreatment scores [31]. The greater the absolute value is, the more the participant improves. Compared with the difference between pre- and posttest, the
RG is not correlated with the pretest score, therefore eliminating the interference of the irrelevant variable.

To investigate the relationship between different levels of shame and ICBT, we analyzed the Pearson correlation between the pretest ESS score (ESS-pre) and the RG of social anxiety (RG-SIAS and RG-SPS). The results did not show significant correlations (RG-SIAS: \( r = -0.02 \); \( P = .98 \) and RG-SPS: \( r = 0.12 \); \( P = .31 \)). This result showed that ICBT had the same effect among participants with different shame levels.

Thus, we further investigated which module of ICBT had an effect on the decrease of shame. Using the feedback system of the network platform, we analyzed the Pearson correlation between each module’s involvement (using frequency and time as the indexes) and pretest ESS score and RG-ESS (the RG of ESS). The results showed that there was no significant correlation between pretest ESS and any involvement index; however, the frequency of relaxation training (\( r = -0.24 \) [.01<\( P < .05 \); \( P = .03 \]), the total number of words in graded exposure (\( r = -0.23 \) [.01<\( P < .05 \); \( P = .04 \]), the average number of words of graded exposure (\( r = -0.36 \) \([ P < .01 \); \( P = .001 \]), and the average number of words of systematic problem solving (\( r = -0.25 \) [.01<\( P < .05 \); \( P = .03 \)) all had significant correlations with RG-ESS. In another words, there were no differences among participants with different degrees of shame proneness on their initiative preference of treatment tasks, but the more the intervention helped in the relaxation training, problem solving, and exposure modules of ICBT, the more they improved on their shame level.

Furthermore, we used ENTERING method to perform a linear regression analysis on gender, age, group, the frequency of relaxation training, the total number of words writing in graded exposure and the average number of words writing in graded exposure as well as systematic problems. This linear regression analysis determined whether these parameters had influenced the score of RG-ESS. The results showed that the goodness-of-fit was the highest when the regression model included only gender and the average number of words of graded exposure as the predictive variables (\( R^2 \text{ adjusted} = 0.147; F_{1,77} = 7.97; P = .002 \)). The regression coefficients (\( \beta \)) and the corresponding tests of significance are presented in Table 2. These results showed that both gender and the average number of words of exposure had a significant influence on the decrease in shame proneness: women improved more than men and the more the number of words of exposure, the more reduction in their shame level. Furthermore, we also calculated the Pearson correlation between the average number of words of exposure and participants’ depressive symptoms and found no significant correlation (with pretest BDI: \( r = 0.09 \); \( P = .44 \) and with posttest BDI: \( r = -0.15 \); \( P = .20 \)), indicating that depressive symptoms did not show an impact on the involvement of exposure module and its effect on shame proneness.

### Table 2. The regression coefficients of the regression model.

<table>
<thead>
<tr>
<th>Variable</th>
<th>( \beta )</th>
<th>SE</th>
<th>( t \text{ value} (df=2,77) )</th>
<th>( P \text{ value} )</th>
<th>Tolerance</th>
<th>Variance inflation factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>N/A</td>
<td>N/A</td>
<td>1.10</td>
<td>.27</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Gender</td>
<td>.21</td>
<td>0.175</td>
<td>1.97</td>
<td>.05</td>
<td>0.98</td>
<td>1.02</td>
</tr>
<tr>
<td>The average number of words of graded exposure</td>
<td>-.33</td>
<td>0.002</td>
<td>-3.13</td>
<td>.002</td>
<td>0.98</td>
<td>1.02</td>
</tr>
</tbody>
</table>

\( ^a \)N/A: not applicable.

**The Mediation Effect of the Change of Shame Level**

To further investigate the relationship among ICBT, shame proneness, and social anxiety, we did a mediation analysis. We used the average number of words of the exposure module as the predictive variable, the RG of ESS (the decrease of shame) as the mediation variable, and the RG of SIAS and SPS (the improvement of social anxiety) as dependent variables. The results of our analysis revealed evidence of a significant indirect effect of the average number of words of the exposure module on the improvement of social anxiety symptoms via their decrease of shame (for SIAS: \( \beta = -.0049 \); SE 0.0016; 95% CI -0.0085 to -0.0019 and for SPS: \( \beta = -.0039 \); SE 0.0015; 95% CI -0.0075 to -0.0012). Two graphical depictions of the model were seen in Figures 2 and 3, along with the statistics measuring the significance of each predictive pathway. Consistent with the results, the average number of words in the exposure module significantly predicted the RG of ESS (a path: \( \beta = -.0076 \); SE 0.0022; \( t_{78} = -3.52 \); \( P < .001 \)). In addition, the higher the improvement of shame, the higher the improvement of social anxiety symptoms (b path; for SIAS: \( \beta = 0.36 \); SE 0.1366; \( t_{78} = 4.68 \); \( P < .001 \) and for SPS: \( \beta = 0.50 \); SE 0.1380; \( t_{78} = 3.65 \); \( P < .001 \)). Furthermore, the direct effect of the number of words in exposure to social anxiety improvement after controlling for the mediating influence of the decrease in shame proneness (RG-ESS) was not significant (c’ path; for SIAS: \( \beta = -.0030 \); SE 0.0022; \( t_{78} = -1.34 \); \( P = .18 \) and for SPS: \( \beta = -0.0035 \); SE 0.0023; \( t_{78} = -0.65 \); \( P = .52 \)). The mediation effects were still significant even if depressive symptoms were controlled. These results suggest that the decrease of shame level fully mediates the improvement of social anxiety symptoms (CI does not include 0).
Secondary Outcomes

Changes in Social Anxiety and Their Level of Shame After Internet-Based Cognitive Behavioral Therapy

We conducted a group (self-help, guided, and WLC) × time (pre-/posttreatment) repeated measures of ANOVA analysis to access the treatment effect of ICBT. The results showed that the interaction effects of group and time on SIAS ($F_{2,101}=18.59; P<.001$; partial $\eta^2=0.27$) and SPS ($F_{2,101}=7.91; P=.001$; partial $\eta^2=0.14$) were significant. Simple effect analysis showed that the post-SIAS and post-SPS scores were significantly lower than pretreatment in both the self-help (SIAS: $t_{46}=7.06; d=1.01; 95\% CI 9.08 to 16.32; P<.001$ and SPS: $t_{46}=4.41; d=0.89; 95\% CI 3.99 to 10.69; P<.001$) and guided groups (SIAS: $t_{32}=8.28; d=1.20; 95\% CI 14.67 to 24.24; P<.001$ and SPS: $t_{32}=5.28; d=0.96; 95\% CI 8.26 to 18.64; P<.001$) but not in the WLC group.

The Influence of Two Treatment Groups on Treatment Effects

We used the RG of SIAS, SPS, and ESS as dependent variables and conducted independent $t$ analysis to explore the group differences of treatment effect. The results showed that there was a marginal significant difference between SIAS RGs of the two groups ($t_{78}=1.88; P=0.06$); guided group showed more improvement than the self-help group. In addition, the RGs of two groups’ ESS ($t_{78}=1.09; P=0.28$) and SPS ($t_{78}=1.07; P=0.29$) had no significant difference. In other words, the SIAS score of the guided group was improved than that of the self-help group, but there was no difference between the two groups’ changes of shame level.

Discussion

Principal Findings and Interpretation

Our study used the Chinese version of the ICBT program to investigate whether shame can be significantly reduced during the treatment of SAD and which modules of ICBT exert an influence on the decrease of shame proneness. This study found significant reductions in participants’ shame proneness and social anxiety scores over the course of ICBT treatment in both the self-help and guided groups. Our study also suggested that gender (being female) and level of involvement in the exposure module (ie, higher average word count in completed homework assignments) were the only two significant predictors of reductions in shame proneness.

Furthermore, shame proneness fully mediated the relationship between the participants’ average word count in the exposure module and change in social anxiety scores. That is, greater engagement in the exposure module led to greater improvements in shame proneness, which, in turn, led to greater improvements in social anxiety symptoms.

As for the dropout rate and adherence, our results showed that the dropout rate of the guided group was significantly higher than that of the self-help ICBT group, and shame proneness
was not a moderator in the relationship between the form of ICBT and treatment adherence.

**Comparison With Prior Work**

The effectiveness of both the self-help and guided ICBT on SAD showed in this study is consistent with previous research [6,32-34]. Primary and secondary outcome measures showed significant changes and moderate to large treatment effects after the ICBT program. This is comparable with the treatment effects reported in a recent study [34]. Furthermore, our results indicated that shame played a role in this process.

The relationship between shame and social anxiety has long been debated. According to the psychoevolutionary model [13,35], individuals with social anxiety tend to excessively focus on their social rank and think of themselves in an inferior position, which causes a series of reactions, such as avoiding eye contact, blushing, and timidity [36]. Shame plays an important role in this process [37]. A longitudinal study demonstrated that a clinical group intervention that aimed at reducing shame-proneness could also reduce participants’ social anxiety symptoms. Li et al [38], indicated that shame proneness might be a risk factor of SAD. Neuroimaging studies also support this theory. Using structural magnetic resonance imaging scans, Syal et al [39] found that the gray matter of the frontal, temporal, parietal, and insular cortices of the right hemisphere of patients with SAD was thinner than those of controls. Particularly, thinner anterior cingulate cortex and posterior cingulate cortex (PCC) thickness were associated with higher levels of shame proneness [40] as well as higher severity of social anxiety symptoms [39,41]. According to prior studies, PCC is considered to be involved in the process of social cognition [42] and re-experiencing of past events [43], which are both essential to the maintenance of shame proneness.

In addition, our study indicated that shame proneness played a mediation role in the relationship between the participants’ average word count in the exposure module of the ICBT and change in social anxiety scores. Some previous evidence might explain the mediational model. Many studies have confirmed that early negative experiences (such as emotional neglect and abuse) have an influence on feelings of shame and social anxiety, which are subsequently internalized, causing more stable shameful-based schemas [44,45]. To support this view, Fung and Alden [46] demonstrated that being rejected in social situations exerted an influence on the subsequent development of social anxiety. Other researchers further proposed and verified the following path: early negative experience causes shame proneness, which predicts a coping strategy of self-criticism to hide one’s perceived defects and prevent the shameful situation from re-emerging, which eventually develops into social anxiety symptoms [47]. Together, these findings indicate that early negative experiences, which are usually treated using exposure therapy, might be important factors in the etiology of shame proneness and social anxiety. As such, it is not surprising that numerous studies have suggested that shame proneness can be alleviated through exposure [48-50] and that shame proneness mediates the relationship between the interruption of avoidant behaviors and reductions in social anxiety. Furthermore, our study showed a higher dropout rate in the guided ICBT group compared with the self-help group. This might be because of more perceived burden of participants in the guided group, who thought of the email support as another homework. Haug et al [51] offered an explanation that the mature ICBT program has already included the motivation enhancement and psychodevelopment, which are the main aims of the therapists’ guidance. Therefore, the guidance is not necessarily helpful to the intervention. The relationship between the guided ICBT and adherence is mixed in previous studies [52,53]. This inconsistency might be related to the different forms and time length of the guidance. In addition, two more progressive adherence variables were identified in our research, and we found that shame proneness was not a moderator in the relationship between the form of ICBT and treatment adherence. Our results indicated that adding more contact with the therapist did not have an impact on adherence and homework completion. A possible explanation is that the email guidance, essentially internet based, may be too short in time to develop a good therapeutic alliance, which is an important factor to provide reinforcement for adherence. Therefore, the additional improvement of therapeutic contact could not be taken place via email.

**Limitations**

There are several limitations worth noting in this study. First, our study did not investigate the follow-up effect of ICBT on shame proneness and social anxiety symptoms. Future research is needed to explore the long-term effects of ICBT on these constructs and their interaction. Second, it remains possible that the sequence of the interventions may have contributed to the mediation effect. ICBT is a continuous therapy with 8 different modules, in which exposure is the last one. Participants’ motivation and involvement of the exposure might be influenced by previous modules, which we were not able to differentiate in this study. Finally, in our study, the exposure was implemented as a one-time intervention, whereas the measurement of shame proneness was measured as change over the course of the 8-week intervention, which may also confound the effects of other aspects of the intervention. Future dismantling studies are needed to separate these influences and further verify this mediation effect by using only the exposure intervention rather than the entire ICBT package.

**Conclusions**

In accordance with the theories mentioned earlier, our results suggest that shame proneness is an important factor in treating SAD and can be reduced through engagement in a web-based, self-guided exposure treatment. To our knowledge, this is the first study to investigate the mediation effect of shame proneness in the relationship between ICBT (particularly the exposure component of ICBT) and social anxiety symptoms. Our results suggest that among all the ICBT modules we investigated, only the completion of the exposure component significantly improved social anxiety symptoms by reducing the level of shame proneness. In short, this investigation further elucidates a process-based approach to alleviate shame and social anxiety and contribute insights into the development of more tailored exposure-based ICBT programs.
Acknowledgments

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Conflicts of Interest

None declared.

Editorial Notice: This randomized study was not prospectively registered. The editor granted an exception of ICMJE rules for prospective registration of randomized trials because the risk of bias appears low. The authors’ explanation for non-registration is that resource constraints led to a time difference among the intervention groups. They believed this would have prevented this study from being considered as a randomized controlled trial. Readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

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therapy with and without an initial face-to-face psychoeducation session for social anxiety disorder: A pilot randomized

Abbreviations

ANOVA: analysis of variance
BDI: Beck Depression Inventory
CBT: cognitive behavioral therapy
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition
ESS: Experience of Shame Scale
ICBT: internet-based cognitive behavioral therapy
MD: mean deviation
MINI: Mini International Neuropsychiatric Interview
PCC: posterior cingulate cortex
RG: residual gain
SAD: social anxiety disorder
SIAS: Social Interaction Anxiety Scale
SPS: Social Phobia Scale
WLC: wait list control
The Effect of Shame on Patients With Social Anxiety Disorder in Internet-Based Cognitive Behavioral Therapy: Randomized Controlled Trial

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Original Paper

Effectiveness of an 8-Week Web-Based Mindfulness Virtual Community Intervention for University Students on Symptoms of Stress, Anxiety, and Depression: Randomized Controlled Trial

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This is a corrected version. See correction statement: https://mental.jmir.org/2020/9/e24131/

Abstract

Background: A student mental health crisis is increasingly acknowledged and will only intensify with the COVID-19 crisis. Given accessibility of methods with demonstrated efficacy in reducing depression and anxiety (eg, mindfulness meditation and cognitive behavioral therapy [CBT]) and limitations imposed by geographic obstructions and localized expertise, web-based alternatives have become vehicles for scaled-up delivery of benefits at modest cost. Mindfulness Virtual Community (MVC), a web-based program informed by CBT constructs and featuring online videos, discussion forums, and videoconferencing, was developed to target depression, anxiety, and experiences of excess stress among university students.

Objective: The aim of this study was to assess the effectiveness of an 8-week web-based mindfulness and CBT program in reducing symptoms of depression, anxiety, and stress (primary outcomes) and increasing mindfulness (secondary outcome) within a randomized controlled trial (RCT) with undergraduate students at a large Canadian university.

Methods: An RCT was designed to assess undergraduate students (n=160) who were randomly allocated to a web-based guided mindfulness–CBT condition (n=80) or to a waitlist control (WLC) condition (n=80). The 8-week intervention consisted of a web-based platform comprising (1) 12 video-based modules with psychoeducation on students’ preidentified life challenges and applied mindfulness practice; (2) anonymous peer-to-peer discussion forums; and (3) anonymous, group-based, professionally guided 20-minute live videoconferences. The outcomes (depression, anxiety, stress, and mindfulness) were measured via an online survey at baseline and at 8 weeks postintervention using the Patient Health Questionnaire-9 (PHQ9), the Beck Anxiety Inventory (BAI), the Perceived Stress Scale (PSS), and the Five Facets Mindfulness Questionnaire Short Form (FFMQ-SF). Analyses employed generalized estimation equation methods with AR(1) covariance structures and were adjusted for possible covariates (gender, age, country of birth, ethnicity, English as first language, paid work, unpaid work, relationship status, physical exercise, self-rated health, and access to private mental health counseling).

Results: Of the 159 students who provided T1 data, 32 were males and 125 were females with a mean age of 22.55 years. Participants in the MVC (n=79) and WLC (n=80) groups were similar in sociodemographic characteristics at T1 with the exception of gender and weekly hours of unpaid volunteer work. At postintervention follow-up, according to the adjusted comparisons, there were statistically significant between-group reductions in depression scores ($\beta=-2.21$, $P=.01$) and anxiety scores ($\beta=-4.82$,
P=.006), and a significant increase in mindfulness scores (β=4.84, P=.02) compared with the WLC group. There were no statistically significant differences in perceived stress for MVC (β=.64, P=.48) compared with WLC.

Conclusions: With the MVC intervention, there were significantly reduced depression and anxiety symptoms but no significant effect on perceived stress. Online mindfulness interventions can be effective in addressing common mental health conditions among postsecondary populations on a large scale, simultaneously reducing the current burden on traditional counseling services.

Trial Registration: ISRCTN Registry ISRCTN12249616; http://www.isrctn.com/ISRCTN12249616

(JMIR Ment Health 2020;7(7):e18595) doi:10.2196/18595

KEYWORDS

virtual community; virtual care; mindfulness; depression; anxiety; stress; students; online; randomized controlled trial; Canada

Introduction

Yearly, 1 in 5 people in Canada experience a mental health problem [1,2], and young people aged 15-24 are more likely to experience mental illness than any other age group [3]. In the United States about half of the population will meet the criteria for a DSM-IV disorder sometime in their lives [4]. However, the first onset of mental disorders occurs in childhood or adolescence [5], and it is estimated that 70% of mental health challenges have their onset during that period [6].

University students are experiencing increases in psychological distress on North American campuses. In 2013, a student survey of 32 Canadian postsecondary institutions reported high anxiety (56.5%), hopelessness (54%), seriously depressed mood (37.5%), and overwhelming anger (42%) [7,8]. A similar survey in 2016 revealed even higher distress levels [8]. In 2013, a study of 997 students at York University (site of this study) indicated that 57% reported depression scores sufficient for diagnosable clinical depression, whereas 33% reported anxiety scores in ranges typically indicative of panic disorder and generalized anxiety disorder [9]. The situation appears similar at universities in the United States [10,11] and worldwide—in 2018, the World Health Organization reported increasing mental disorders in college and university students worldwide [12]. Distress during university attendance is critical to address, especially considering that 70% of all mental health problems appear before the age of 25 and, when untreated, can become long-standing and significant impairments affecting multiple life domains [6].

University student distress is both an individual and a societal challenge. Losses in productivity at work and during study due to distress and mental disorders are associated with indirect but major economic burdens [13]. Canadian estimates show that mental disorders cost US $51 billion yearly, with 9.8% due to direct medical costs; 16.6% and 18.2% due to long-term and short-term work loss, respectively; and 55.4% due to the loss of healthy function (ie, loss of the utilities of vision, hearing, speech, mobility, dexterity, emotion, cognition, and pain as assessed in the Health Utilities Index Mark 3 system) [14].

While mental distress and disorders are becoming more prevalent in students, the counseling offered in colleges and universities is not keeping pace with demand. For example, from 2007 to 2012, full-time enrollment in the Ontario college system increased from 167,000 to 210,600 (a 26% increase), whereas the number of counselors employed in the college system increased from 146 to 152.7 (a 4.6% increase) [15]. This discrepancy leaves students underserved and counselors overwhelmed amidst the increasing distress [16].

Mindfulness-based interventions have been demonstrated to positively impact psychological and physical health [17-19] with multiple meta-analyses demonstrating positive impacts in clinical and nonclinical populations [20-24]. However, with large numbers of students (50,000-60,000 on some campuses) there may not be enough trained personnel to directly convey helpful mindfulness-based practices. A recent systematic review showed the impact of online mindfulness interventions on depression, anxiety, and stress [25]; however, there is no clear indication as to which specific intervention components were specifically effective. Moreover, in the electronic health (eHealth) domain, virtual communities (VCs) [26], that is, online communities, have been used in health care to provide e-education tools and online support with the goal of empowering active participants in health enhancement [27-29]. VCs can scale up mindfulness interventions at lower costs to wider ranges of students, especially those restricted from attending clinics due to time–place discontinuities. VCs preserve anonymity (with reductions in stigmatization) while promoting voluntary supportive interpersonal connections.

We developed a web-delivered mindfulness program (Mindfulness Virtual Community [MVC]) to reduce depression, anxiety, and stress in university students and conducted a randomized controlled trial (RCT) targeting undergraduate students at a Canadian university to examine its effectiveness. The MVC contained analytics to measure the use of each included component. Following a successful pilot RCT [29], we wanted to further investigate whether symptoms of depression, anxiety, and stress would be significantly reduced when compared with waitlist controls (WLCs).

Methods

Trial Design and Ethical Approval

This study consisted of a 2-arm parallel-design RCT comparing the web-based MVC program with a WLC group. The Human Participant Research Committee at York University provided research ethics approval for the RCT (Certificate No.: e2016-345).

Participants and Recruitment

Eligibility criteria were applied to recruit undergraduate students who were at least 18 years of age, reported English language
fluency, self-rated high confidence of completing the study, and were actively enrolled in an undergraduate program. Their ability to use a computer and smartphone and internet literacy were assumed to be de facto skills. Students were excluded if they indicated substance abuse or episodes of psychotic behaviors during the month prior to the trial.

The study was advertised using multiple strategies including study posters, class announcements on permission of course directors, and email invitations via listservs of student associations in the Faculty of Health and Faculty of Liberal Arts. Interested students contacted the research staff via email or phone and were screened for student registration, substance abuse, and indications of psychoses. If substance abuse or psychotic behaviors “interfered in routine life within last month,” students were excluded and provided with a list of accessible mental health resources. Eligible and willing students received detailed information in-person about the study and provided informed written consent. Participants had the option to receive an honorarium of CAD 50 (US $37.5) or 2% in course grade (for professors who gave this permission) or 3 credits (equivalent to 2% course grade) in the Undergraduate Research Participation Pool of the Department of Psychology. Each participant also received a resource list that included information about health and social services on campus and in the community (eg, the 24 × 7 Good to Talk helpline for postsecondary students in Ontario). Our protocol included a safety mechanism whereby participants were asked verbally and on the consent form to contact the research staff if they felt distress during the trial period so that “limited counseling with a clinical psychologist could be arranged, if needed.” The collaborating psychologist was at arm’s length from the trial. No instance of such request arose during the reported study period.

A sample of 480 students (240 students per group) was recruited over 3 semesters (Fall 2017, Winter 2018, and Fall 2018). However, the 3 samples could not be combined due to substantial differences in the campus environment. Notably, in the Fall 2017 semester the platform functionalities presented connection challenges to students and the platform did not capture the user analytics correctly via the built-in tools, a problem which was corrected for subsequent semesters. In addition, during the Winter 2018 semester the university was disrupted by an employee strike of 3 months’ duration. Prior to the Fall 2018 semester (the semester during which this study was undertaken), the strike was resolved and the university resumed routine functioning. This article is based on the sample recruited in Fall 2018 (September 23, 2018, to November 18, 2018).

Randomization

Participating students were randomized to the MVC intervention or the WLC using 1:1 block randomization. The randomized allocation sequence was computer generated by an offsite team member (RM), and allocations were concealed in sequentially numbered opaque envelopes [30]. These envelopes were opened only after written consent was obtained, ensuring that participants and research staff were blind prior to the allocation. Each participant in the MVC group received a unique ID and a temporary password; participants changed their passwords after the first login while IDs remained the same to eliminate the possibility of multiple accounts or identities. Participants in all groups completed online questionnaires at baseline (T1) and 8 weeks (T2).

Intervention

The MVC intervention was 8 weeks in duration. The intervention comprised 3 components: (1) 12 student-specific mental health modules conveyed by online video; (2) 3 anonymous discussion boards dedicated to depression, anxiety, and stress; and (3) an anonymous 20-minute group-based live videoconference led by a moderator (a counselor with a master’s degree in psychology and training in mindfulness) during which students could raise and discuss topics covered in the modules (Figure 1).

Figure 1. The mindfulness virtual community design.
Each of the 12 mental health modules consisted of 1 educational content video and 1 mindfulness practice video recorded in both male and female voices and offered in both high and low resolution (a total of 8 videos per module); participants could choose the type of video they wanted to watch for each module. The videos were available for participants 24 hours/day to watch or listen to on computers, phones, or tablets at their convenience. The module scripts and audio recordings were created by one of the investigators with extensive experience as a clinical psychologist and researcher in mindfulness (PR) [31-36], and they were based on mindfulness and cognitive behavioral therapy (CBT) principles and informed by the prior student-based focus group study [37,38]. The choice of moving and still images used in the creation of the videos involved collaborative work (PR, CEM, and FA). The topics of the 12 modules and the video duration (average durations of male voice and female voice videos) are presented in Table 1. The role played by the online mindfulness moderator evolved over time across a pilot study conducted in Winter 2017 [29].

Our study is currently at stage 2 of the National Institute of Health stage model [39]. It builds on a pilot study in which we tested the platform and consists of testing the MVC in a research context with research therapists/providers. As advised by Dimidjian and Segal [40], we have addressed clinician training and engagement in mindfulness based on analytics within the platform and self-report. However, practice time outside the intervention was not measured.

Table 1. Topics and duration of modules.

<table>
<thead>
<tr>
<th>Topics</th>
<th>Video duration (mm:ss)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Education videos</td>
</tr>
<tr>
<td>Overcoming stress, anxiety, and depression</td>
<td>7:09</td>
</tr>
<tr>
<td>Mindfulness and being a student</td>
<td>5:18</td>
</tr>
<tr>
<td>Mindfulness for better sleep</td>
<td>4:40</td>
</tr>
<tr>
<td>Thriving in a fast-changing world</td>
<td>7:23</td>
</tr>
<tr>
<td>Healthy intimacy</td>
<td>7:32</td>
</tr>
<tr>
<td>De-stigmatization</td>
<td>6:13</td>
</tr>
<tr>
<td>No more procrastination</td>
<td>3:42</td>
</tr>
<tr>
<td>Pain reduction and mindfulness</td>
<td>3:48</td>
</tr>
<tr>
<td>Healthy body image</td>
<td>5:44</td>
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<tr>
<td>Healthier eating</td>
<td>10:10</td>
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<tr>
<td>Overcoming eating</td>
<td>6:01</td>
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<tr>
<td>Relationships with family and friends</td>
<td>7:49</td>
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</tbody>
</table>

New modules were periodically released during the 8-week intervention period. Following release, they remained accessible to students for the remainder of the intervention period. The videoconferences were offered biweekly in three 20-minute evening sessions (Table 5). The students in the intervention group received email reminders from the project staff prior to the release of each new module and prior to the live videoconferences. Participants were encouraged to use the platform as often as desired. Access to technology and the internet was assumed to be of no consequence to participants; indeed, a focus group study that guided MVC design revealed that 94% (n=68/72) of the students had access to a smartphone and 93% (n=67/72) had access to laptops or personal computers at home, while all participants had free internet access on campus and almost all had internet access through smartphones or laptops [38].

The MVC was developed in partnership with the industry partner ForaHealthyme Inc. and constituted a virtual environment supportive of personal mindfulness practice and related CBT self-help and mutual help interactions between participants, and between participants and the moderator. There were 2 types of users: the student and the health professional (who moderated the discussion board dialogues and led the live videoconferences). Users had to use a login and a password to gain access to the MVC.

Once logged in, each student could (1) access the video (educational and mindfulness practice) modules; (2) access 3 peer-to-peer discussion boards, one for each of the 3 mental health conditions targeted by the RCT (anxiety, stress, and depression); (3) notify the moderator about any message posted that represented a problem to the student (eg, online bullying); (4) access a calendar to book an upcoming videoconference; (5) access a virtual videoconferencing room that allowed videoconferencing (camera and microphone being turned off as default) and private text-based chatting with the moderator; and (6) a resource page with contact information for various social and health services.

Once the moderator logged in, she accessed the same options as students with the following additional features: the ability to delete any message on the discussion boards deemed potentially distressing to other students; the ability to populate the calendar with dates and times for upcoming videoconference sessions; the ability to start a videoconference session (camera turned on by default); and the ability to respond privately to incoming text messages in the virtual videoconferencing room.
The moderator had weekly supervision sessions with the team clinician (PR) to optimize responses to the videoconferences and submitted weekly written reports (without individual names) about topics raised by students and her responses to them. The content of modules and the platform structure remained unchanged for the 8-week intervention. Only the name of the university which received the research grant and the partnering IT company name appeared on the main page of the platform.

**Primary and Secondary Outcomes and Measures**

The outcomes and other variables were measured by self-report questionnaires at T1 and T2. The primary RCT outcomes were depression, anxiety, and perceived stress, whereas mindfulness was measured as a secondary outcome. It was hypothesized that symptom scores for depression, anxiety, and stress at T2 would be significantly lower in the MVC group compared with those in the WLC group, and that scores for mindfulness at T2 would be significantly higher in the MVC group compared with those in the WLC group. The outcomes were measured with the following validated scales: Patient Health Questionnaire-9 (PHQ9) [41], Beck Anxiety Inventory (BAI) [42], Perceived Stress Scale (PSS) [43], and Five Facets Mindfulness Questionnaire Short Form (FFMQ-SF) [44]. Participants also completed a sociodemographic questionnaire at the T1 survey.

**Statistical Analysis and Sample Size**

The sample size was calculated for 80% power and 5% type I error to detect a standardized effect size of 0.5 or larger. The required sample size was found to be 63 students in each arm. We aimed to recruit 80 participants per arm expecting an attrition rate of 20% (n=16). Descriptive statistics were used to summarize the sample characteristics. Sample t test (two-tailed) for continuous measures and chi-square test for categorical variables were employed to compare the intervention and control groups at baseline.

The approach to the outcome analysis was intention to treat. To test whether the intervention could reduce depression, anxiety, and stress scores and increase mindfulness scores after 8 weeks, we utilized a generalized estimating equations method with an AR(1) covariance structure. Because there were not any patterns for missing data, missing observations (10%) were assumed to be missing at random, and a completed data set was obtained by estimating the missing observations with the multiple imputation method using the Markov chain Monte Carlo technique. Two models were considered for each dependent variable. Model 1 was fitted to investigate the effect of the interventions on depression, anxiety, stress, and mindfulness scores after 8 weeks. A negative significant effect of group assignment was interpreted as evidence that symptom scores for depression, anxiety, and stress at time point 2 were significantly reduced in the MVC group compared with the WLC group, whereas a positive significant effect of group assignment was interpreted as evidence that scores for mindfulness at time point 2 were significantly increased in the MVC group compared with the WLC group. In Model 2, demographic variables including sex, age, country of birth, ethnicity, English as first language, paid work, unpaid work, relationship status, physical exercise, self-rated health, and access to private mental health counseling were added to Model 1 to adjust for potential covariates. The analyses were performed using software SPSS version 26 (IBM).

**Results**

**Recruitment**

A total of 160 undergraduate students were randomized to the MVC (n=80) or WLC (n=80) groups. One student allocated to the intervention was excluded after randomization when he clarified that he was a graduate student and had misunderstood the eligibility criteria. One additional participant in the intervention group did not complete the baseline survey for mental health instruments but completed the demographic data. Of 158 eligible students who completed the full baseline survey, the attrition rate was 6.33% at T2 (n=10; Figure 2).
Demographics

Overall, there were 32 males (20.1%) and 125 females (78.6%) who participated with 2 students declaring gender fluid and nonbinary genders. The majority of participants were born outside of Canada (87/159, 54.7%) and reported English as their first language (93/159, 58.5%), and 20.1% (32/159) of the sample self-identified as White. The majority of participants did not have access to private mental health insurance (102/159, 64.1%). These and other characteristics were similarly distributed between the control and intervention groups (Table 2) with the exception of unpaid work, relationship, and gender: compared with the MVC group, participants in the WLC group worked on average more hours ($P=0.03$), were significantly more likely ($P=0.05$) to be single with no relationship (ie, not married nor common law, and engaged in a romantic relationship), and were significantly less likely to be single in relationship ($P=0.05$).

Finally, the proportion of females in the WLC group was significantly higher than that in the MVC group ($P=0.02$).

Table 3 presents the mean and standard deviation for depression (PHQ9), anxiety (BAI), stress (PSS), and mindfulness (FFMQ-SF) scores at 2 time points. The table also provides the Cohen $d$ effect sizes for mean difference in the MVC group compared with the control group at T2. The effect size shows that the levels of depression, anxiety, and stress decreased, whereas the level of mindfulness increased as a result of the intervention. There were no statistically significant differences at baseline for any of the mean scores of the 4 outcomes between the control and intervention groups. The effect sizes for PHQ9, BAI, and FFMQ-SF were between medium and large.
Table 2. Participant characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total (N=159)</th>
<th>Waitlist control (n=80)</th>
<th>MVC Intervention (n=79)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD); range</strong></td>
<td>22.55 (6.1); 18-55</td>
<td>22.3 (5.9); 18-55</td>
<td>22.8 (6.4) 18-54</td>
<td>.6</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>32 (20.1)</td>
<td>10 (12.5)</td>
<td>22 (27.8)</td>
<td>.02</td>
</tr>
<tr>
<td>Female</td>
<td>125 (78.6)</td>
<td>69 (86.3)</td>
<td>56 (70.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender fluid</strong></td>
<td>1 (0.6)</td>
<td>1 (1.3)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td><strong>Nonbinary</strong></td>
<td>1 (0.6)</td>
<td>0 (0)</td>
<td>1 (1.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Country of birth, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>Canada</td>
<td>72 (45.3)</td>
<td>31 (38.8)</td>
<td>41 (51.9)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>87 (54.7)</td>
<td>49 (61.2)</td>
<td>38 (48.1)</td>
<td></td>
</tr>
<tr>
<td><strong>First language, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.42</td>
</tr>
<tr>
<td>English</td>
<td>93 (58.5)</td>
<td>44 (55.0)</td>
<td>49 (62.0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>66 (41.5)</td>
<td>36 (45.0)</td>
<td>30 (37.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Single, no relationship</td>
<td>102 (64.2)</td>
<td>58 (72.5)</td>
<td>44 (55.7)</td>
<td></td>
</tr>
<tr>
<td>Single in relationship</td>
<td>38 (23.9)</td>
<td>12 (15.0)</td>
<td>26 (32.9)</td>
<td></td>
</tr>
<tr>
<td>Married/common law</td>
<td>9 (5.7)</td>
<td>4 (5.0)</td>
<td>5 (6.3)</td>
<td></td>
</tr>
<tr>
<td>Divorced/Separated/Widowed/other</td>
<td>10 (6.3)</td>
<td>6 (7.5)</td>
<td>4 (5.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.72</td>
</tr>
<tr>
<td>White</td>
<td>32 (20.1)</td>
<td>15 (18.8)</td>
<td>17 (21.5)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>23 (14.5)</td>
<td>10 (12.5)</td>
<td>13 (16.5)</td>
<td></td>
</tr>
<tr>
<td>South Asian</td>
<td>44 (27.7)</td>
<td>25 (31.2)</td>
<td>19 (24.1)</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>15 (9.4)</td>
<td>6 (7.5)</td>
<td>9 (11.4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>45 (28.3)</td>
<td>24 (30.0)</td>
<td>21 (26.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Self-rated health, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.10</td>
</tr>
<tr>
<td>Poor/fair</td>
<td>35 (22.0)</td>
<td>23 (28.7)</td>
<td>12 (15.1)</td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>56 (35.2)</td>
<td>28 (35.0)</td>
<td>28 (35.4)</td>
<td></td>
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<tr>
<td>Very good/excellent</td>
<td>67 (42.1)</td>
<td>29 (36.3)</td>
<td>38 (48.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Access to private mental health, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.51</td>
</tr>
<tr>
<td>Yes</td>
<td>56 (35.2)</td>
<td>26 (32.5)</td>
<td>30 (37.9)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>102 (64.1)</td>
<td>54 (67.5)</td>
<td>48 (61.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Weekly hours, mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td>.15</td>
</tr>
<tr>
<td>Paid work</td>
<td>8.5 (9.8)</td>
<td>7.38 (10.3)</td>
<td>9.63 (9.3)</td>
<td></td>
</tr>
<tr>
<td>Unpaid work</td>
<td>2.41 (3.8)</td>
<td>3.06 (4.6)</td>
<td>1.75 (2.7)</td>
<td>.03</td>
</tr>
<tr>
<td><strong>Weekly physical exercise in minutes</strong></td>
<td>124.5 (151.5)</td>
<td>108.1 (143)</td>
<td>140.9 (158.7)</td>
<td>.18</td>
</tr>
</tbody>
</table>

*Significant differences at *P*<.05 are highlighted in bold.
Table 3. Descriptive statistics for depression, anxiety, stress, and mindfulness scores.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N</th>
<th>Waitlist control, mean (SD)</th>
<th>MVC intervention, mean (SD)</th>
<th>P value*</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>T1</td>
<td>T2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ&lt;sup&gt;a&lt;/sup&gt;9-item</td>
<td></td>
<td>80</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9.91 (6.22)</td>
<td>11.21 (6.72)</td>
<td>.10</td>
<td>–0.69</td>
</tr>
<tr>
<td></td>
<td></td>
<td>78</td>
<td>68</td>
<td>.001</td>
<td>–0.74</td>
</tr>
<tr>
<td>BAI&lt;sup&gt;b&lt;/sup&gt;21-item</td>
<td></td>
<td>80</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>17.56 (12.17)</td>
<td>18.19 (13.18)</td>
<td>.17</td>
<td>–0.23</td>
</tr>
<tr>
<td></td>
<td></td>
<td>78</td>
<td>68</td>
<td>.005</td>
<td>0.47</td>
</tr>
<tr>
<td>PSS&lt;sup&gt;c&lt;/sup&gt;10-item</td>
<td></td>
<td>80</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>22.01 (5.32)</td>
<td>21.16 (5.01)</td>
<td>.12</td>
<td>–0.23</td>
</tr>
<tr>
<td>FFMQ-SF&lt;sup&gt;d&lt;/sup&gt;24-item</td>
<td></td>
<td>80</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>70.54 (13.79)</td>
<td>67.50 (14.71)</td>
<td>.64</td>
<td></td>
</tr>
</tbody>
</table>

*Significant differences at P<.05 are highlighted in bold.

<sup>a</sup>PHQ: Patient Health Questionnaire.
<sup>b</sup>BAI: Beck Anxiety Inventory.
<sup>c</sup>PSS: Perceived Stress Scale.
<sup>d</sup>FFMQ-SF: Five Facets Mindfulness Questionnaire Short Form.

Guided Web-Based Mindfulness Versus Waitlist Control

Results from Model 1 (unadjusted) and Model 2 (adjusted) are presented in Table 4. Comparing depression in the MVC group with the WLC group, there was a statistically significant score reduction for PHQ9 at T2 in both the unadjusted (β=–2.13, P=.016) and adjusted analyses (β=–2.21, P=.01). In relation to anxiety in the MVC group compared with the WLC group, there was a statistically significant reduction in BAI score at T2 in both the unadjusted (β=–4.89, P=.004) and adjusted (β=–4.82, P=.006) analyses. Compared with the WLC group, the MVC intervention had no statistically significant effect on PSS stress scores in either the unadjusted (β=–.66, P=.46) or the adjusted (β=–.64, P=.48) analysis. In relation to mindfulness in the MVC group compared with the WLC group, there was a statistically significant score reduction for FFMQ-SF at T2 in both the unadjusted (β=5.94, P=.004) and adjusted (β=4.84, P=.02) analyses.

Among all the other covariates, country of birth and self-rated overall health had significant effects on depression, anxiety, and mindfulness. The variables of ethnicity, English as first language, and age had significant effects on mindfulness only.

At T2, those participants who were born outside of Canada had 2.96 units (β=2.96, P=.02) higher depression, 4.91 units higher anxiety (β=4.91, P=.02), and 5.89 units lower mindfulness (β=–5.89, P=.03) compared with those born in Canada.

Participants with poor self-rated overall health reported 3.37 units (β=3.37, P=.001) higher depression, 7.75 units (β=7.75, P<.001) higher anxiety, and −10.94 units (β=–10.94, P<.001) lower mindfulness than participants with very good self-rated overall health.

Ethnicity was divided into 5 categories: White, South Asian, Chinese, Black, and Other. At T2, compared with students of white ethnicity, students with ethnicity other experienced about –6.56 units lower mindfulness (β=–6.56, P=.04). Moreover, students whose first language was English experienced 5.97 units (β=5.97, P=.01) higher mindfulness than students whose first language was not English. In addition, for every year increase in age, mindfulness rose by 0.54 units (β=.54, P=.01).
Table 4. Generalized estimation equation with multiple imputation for depression, anxiety, stress, and mindfulness scales (Model 1: unadjusted and Model 2: adjusted).

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Unadjusted (standard error)a, 95% CI</th>
<th>P value*</th>
<th>Adjustedb (standard error)b, 95% CI</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHQ-9-item</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>9.91 (0.69), 8.56 to 11.27</td>
<td>&lt;.001</td>
<td>9.62 (3.02), 3.67 to 15.57</td>
<td>.002</td>
</tr>
<tr>
<td>Time</td>
<td>1.30 (0.59), 0.13 to 2.47</td>
<td>.03</td>
<td>1.30 (0.60), 0.06 to 2.54</td>
<td>.03</td>
</tr>
<tr>
<td>Group</td>
<td>−1.51 (0.93), −3.34 to 0.32</td>
<td>.10</td>
<td>−1.01 (0.88), −2.74 to 0.72</td>
<td>.25</td>
</tr>
<tr>
<td>Time × Group</td>
<td>−2.13 (0.89), −3.87 to −0.39</td>
<td>.02</td>
<td>−2.21 (0.872), −3.92 to −0.50</td>
<td>.01</td>
</tr>
<tr>
<td><strong>BAI-21-item</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>17.56 (1.35), 14.91 to 20.2</td>
<td>&lt;.001</td>
<td>14.81 (5.16), 4.68 to 24.94</td>
<td>.004</td>
</tr>
<tr>
<td>Time</td>
<td>0.63 (1.21), −1.75 to 3.00</td>
<td>.61</td>
<td>0.63 (1.21), −1.74 to 3.0</td>
<td>.60</td>
</tr>
<tr>
<td>Group</td>
<td>−2.63 (1.89), −6.33 to 1.07</td>
<td>.16</td>
<td>−1.92 (1.75), −5.35 to 1.52</td>
<td>.27</td>
</tr>
<tr>
<td>Time × Group</td>
<td>−4.89 (1.72), −8.25 to −1.52</td>
<td>.004</td>
<td>−4.82 (1.75), −8.25 to −1.39</td>
<td>.006</td>
</tr>
<tr>
<td><strong>PSS-10-item</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>22.01 (0.59), 20.85 to 23.17</td>
<td>&lt;.001</td>
<td>20.16 (2.42), 15.35 to 24.97</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Time</td>
<td>−0.85 (0.57), −1.97 to 0.26</td>
<td>.14</td>
<td>−0.85 (0.57), −1.95 to 0.25</td>
<td>.14</td>
</tr>
<tr>
<td>Group</td>
<td>−1.39 (0.87), −3.11 to 0.32</td>
<td>.11</td>
<td>−1.15 (0.90), −2.92 to 0.62</td>
<td>.20</td>
</tr>
<tr>
<td>Time × Group</td>
<td>0.66 (0.89), −1.09 to 2.40</td>
<td>.46</td>
<td>0.64 (0.91), −1.15 to 2.43</td>
<td>.48</td>
</tr>
<tr>
<td><strong>FFMQ-SF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>70.54 (1.53), 67.53 to 73.54</td>
<td>&lt;.001</td>
<td>62.97 (6.92), 49.40 to 76.53</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Time</td>
<td>−3.39 (1.32), −5.98 to −0.80</td>
<td>.61</td>
<td>−3.34 (1.29), −5.86 to −0.81</td>
<td>.01</td>
</tr>
<tr>
<td>Group</td>
<td>0.68 (2.24), −3.71 to 5.1</td>
<td>.16</td>
<td>−1.12 (2.07), −5.18 to 2.94</td>
<td>.59</td>
</tr>
<tr>
<td>Time × Group</td>
<td>5.94 (2.03), 1.96 to 9.23</td>
<td>.004</td>
<td>4.84 (2.04), 0.81 to 8.87</td>
<td>.02</td>
</tr>
</tbody>
</table>

aP values <.05 are considered significant (shown with bold).
bStandard error of the mean score difference.
Adjusted for gender, age, country of birth, ethnicity, English as first language, paid work, unpaid work, relationship status, physical exercise, self-rated health, and access to private mental health counseling.
PHQ: Patient Health Questionnaire.
BAI: Beck Anxiety Inventory.
PSS: Perceived Stress Scale.
FFMQ-SF: Five Facets Mindfulness Questionnaire Short Form.

Platform Use

In the postintervention survey, participants reported the number of videos they had used and the frequency of use. Analyses demonstrated that participants reported watching a mean of 6 educational videos and 6 mindfulness videos per week. During the 8 weeks, the median reported watching times were 44.03 minutes for educational videos and 74.26 minutes for mindfulness videos, and the range was 0-301.93 minutes for educational videos and 0-445.53 minutes for mindfulness videos, which corresponds to 0-37.74 minutes for educational videos and 0-55.69 minutes for mindfulness videos, per week.

The survey also showed that 54% of the students (n=36/67) completed at least 50% of the videos, while the analytics showed that students logged on to the platform 444 times.

There was no statistically significant difference between the mean minutes used for listening to male voice videos versus female voice videos (t156=−1.2, P=91).

Videoconferencing sessions were run twice a week on Wednesdays and Fridays, 3 sessions each day, at 8:00 PM, 8:30 PM, and 9:00 PM (except for the first week where the sessions were held on Tuesday and Wednesday at 9:00 PM, 9:30 PM, and 10:00 PM due to moderator scheduling issues). The number of participants in each session is shown in Table 5.

The session from 8:00 to 8:30 PM was the most preferable; on average 2.25 students attended the first session (8:00-8:30 PM), 1.3 students attended the second sessions (8:30-9:00 PM), and 2.4 students attended the third session (9:00-9:30 PM). Overall, the number of participants who attended the videoconferencing sessions was low; on average, there were 1.92 participants per videoconferencing session. In the first 4 weeks, 60 participants...
attended the videoconferencing sessions, whereas in the last 4 weeks the number of attendees dropped to 32.

**Table 5.** Videoconferencing session attendance.

<table>
<thead>
<tr>
<th>Week and session 1</th>
<th>Session 2</th>
<th>Session 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>3</td>
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<tr>
<td>4</td>
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<td>2</td>
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</tr>
<tr>
<td>3</td>
<td>1</td>
<td>8</td>
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<tr>
<td>3</td>
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<td>2</td>
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<tr>
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<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>18</td>
</tr>
</tbody>
</table>

**Discussion**

**Principal Results**

The study investigated the effectiveness of MVC, an internet-based mindfulness–CBT environment designed to reduce symptoms of anxiety, depression, and stress in undergraduate students. The MVC intervention comprised brief online video-based modules with psychoeducational content and mindfulness practice content, peer-to-peer anonymous and asynchronous discussion forums, and 20-minute synchronous videoconferencing related to mindfulness practice with a moderator.

On testing, the MVC intervention significantly reduced depression scores (PHQ9) and anxiety scores (BAI), and significantly increased mindfulness (FFMQ-SF) compared with waitlist controls at 8 weeks. The mean depression scores of participants declined from the high end of mild depression to the low end. The intervention had no effect on stress levels (PSS), although a previous pilot MVC study showed significant reductions in stress levels in a similar population [29]. One reason for the absent effect could be higher baseline stress scores for this sample than in the pilot study (eg, 20.6 vs 19.2), which was possibly a consequence of several months of a strike that our sample experienced prior to start of Fall 2018.

In this study, the results show medium to high effect sizes for depression (−0.69) and anxiety (−0.74). This is within the higher range found in 3 studies of internet-based mindfulness [45-47], which showed significant effects on depressive symptoms at postintervention compared with control, and in which the between-group effect sizes ranged between 0.41 and 0.84. However, our study is somewhat differentiated by the mindfulness psychoeducation and practice modules being integrated with CBT principles.

Our analysis showed that students born outside of Canada and those who reported poor self-rated overall health had significantly higher depression and anxiety and lower
mindfulness compared with students born in Canada and students with very good self-rated overall health. This finding aligns with reports that suggest immigrants enter the country with better mental health (than the Canadian-born population) but confront higher risks for deteriorating health after arrival [48]. Given that in Canada both population and economic growth are driven by immigration, there is a need to develop mental health services to assist new immigrants (a need recognized by the Mental Health Commission of Canada [49]). Furthermore, the link between poor overall health and mental health is confirmed by existing literature, as people living with chronic physical health conditions experience depression and anxiety at two times the rate of the general population [50]. Both country of birth and poor health are important factors to consider in future solutions addressing depression, anxiety, and mindfulness on Canadian campuses. Future programs might involve adaptive cultural and racialized components (eg, language, symbols) while emphasizing physical health promotion.

As our analysis also showed that students whose first language was not English experienced lower mindfulness scores than those whose first language was English, a focus on addressing language barriers and the use of multilingual mindfulness interventions might be useful.

The mean minutes for the use of videos (4.93 minutes for educational videos and 7.16 minutes for mindfulness videos) reported by participants also support the results of increases in self-rated mindfulness (Five Facet Mindfulness Questionnaire), mood improvements, and anxiety reductions.

We did not measure the effect of the intervention beyond 8 weeks in the intervention group. Future research with long-term follow-up is essential to examine long-term changes. The videoconferencing sessions were expected to accommodate all students allocated to the intervention (ie, an average of 14 students per session for six 20-minute sessions a week). Nonetheless, most of the participants did not attend the videoconferencing given the low mean attendance. These findings indicate that students were mostly interested in self-learning and self-practice, which might be partially explained by anxieties about the possible privacy loss in conferencing sessions as expressed by students during the focus group discussions held prior to the RCT [37].

It is possible that MVC participation without any related social activity is more attractive to students and, given the reported results, nonetheless effective. It seems that the application of mindfulness practice requires no necessary social contact. Mindfulness practice without social exposures might be a feature that requires further study, especially as mindfulness itself is a promising technique for cultivating self-management [51]. Other studies on self-management of chronic conditions have shown positive health outcomes such as increased autonomy and improved care quality [52]. Students were engaged in videoconferencing in the first 4 weeks (60 attendees) compared with the last 4 weeks of the intervention (32 attendees). This can be explained by the decreased time availability near the end of the semester. The lack of interest in discussion forums may indicate that forums are redundant for youths when they are already involved in multiple social media messaging platforms.

Comparison With Prior Work

A recent systematic review on the effect of online mindfulness interventions [25] provides evidence that online mindfulness interventions significantly decrease symptoms of stress, depression, and anxiety; however, large sample studies are needed to have conclusive results. Indeed, 5 of the 10 reviewed studies had a sample larger than 100 participants [46,47,53-55]. Of the remaining 5 studies, 4 [45,56-58] had samples of between 50 and 100 participants, and 1 [59] had a sample of fewer than 50. The per-arm sample sizes were relatively small in 2 of the studies [58,59], where participants allocated to each arm were fewer than 30. Compared with these studies, our sample size was large (n=160). The findings of this study contribute evidence on the effectiveness of online mindfulness–CBT interventions in addressing the mental health challenges of undergraduate students. The existence of some objective analytics to analyze the use of the different components of the online platform is unique and will allow us to understand which components of the delivered program were most effectively used.

Our analysis points to the fact that students enrolled in our study were not interested in online discussion forums but were interested in connecting with a moderator via videoconferencing and in self-management of their symptoms using the online videos. This is important given that self-management of mental health conditions has the potential to be widely effective, while evidence of its effectiveness is modest [60]. Our work informs the rapidly evolving field of mental health self-management [61-63].

Strengths and Limitations

This is the one of the first clinical trials of an online interactive mindfulness–CBT program for undergraduate university students in Canada and is the first to include objective background analytics. The results show that discussion forums were never used, as students were more interested in self-management and connecting with a professional via videoconferencing. This is an important finding for the design of online mental health interventions. The self-rated data and analytics enabled us to analyze video use. Another strength of the study is that it involves testing the MVC in a research context with research therapists or providers, representing stage 2 of the National Institute of Health stage model [39], a necessary step toward stage 3 efficacy trials conducted in community settings using community providers [40].

A limitation of the study is that although participants were blind to the intervention and control conditions until they opened the allocation envelopes (after consenting), this was not a single-blinded trial. Another limitation is that the study measures the effect of the program over 8 weeks, while tests of longer-term effects (over 6 or 12 months) remain to be undertaken. A further limitation is the high female preponderance in both the control and intervention groups; however, this is in line with other studies that showed the same predisposition [64,65]. Future research projects might need to address gender distribution within the sampling scheme through stratification. Besides, our research is on one site only. Future research with larger samples of participants from multiple
universities and colleges would better test the generalizability of results. Missing data in the intervention group are also a limitation, but we mitigated the missing data by multiple imputation, a robust high-quality imputation method [66,67].

We also did not measure the participant’s mindfulness practice outside the platform, and hence we did not control for that analytic dimension.

Further, prior to the study, we did not verify with participants that the videoconferencing session times were aligned with their schedules, and we did not ask about these fits in the poststudy questionnaire. Such an alignment is important for the successful attendance of the videoconferencing sessions. Finally, the implementation was limited to one site.

Conclusions
Our results suggest that an 8-week-long online mindfulness–CBT video-based program is an effective intervention for undergraduate university students in reducing symptoms of depression and anxiety. Our findings also suggest that online mindfulness interventions offer an opportunity to address common mental health conditions among postsecondary populations on a large scale, simultaneously reducing the current burden on traditional counseling services.

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Authors’ Contributions
CE, FA, and PR designed the study and questionnaire, received the funds, and contributed equally. PR led module development, providing written content and voice. RM analyzed the data. CE verified the analysis and prepared the first draft, and all authors provided critical feedback and revised it. The MVC Team members are (alphabetically): Sahir Abbas, BSc; Yvonne Bohr, PhD; Manuela Ferrari, PhD; Wai Lun Alan Fung MD, ScD, FRCP; Louise Hartley, PhD; Amin Mawani, PhD; Kwame McKenzie, MD, FRCP; and Jan E. Odai, BA. These team members made contributions to several aspects of the project and results development. They all approve the final version and agree to be accountable for all aspects of the submitted paper. The trial protocol could be accessed on reasonable request to corresponding authors.

Conflicts of Interest
It is the understanding of the university and researchers that the Project Intellectual Property belongs to CEM, FA, and PR. The industry partner ForaHealthyMe.com owns all rights and title to the copyrights of any computer source code software that was developed out of this research project.

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37. El Morr et alJMIR MENTAL HEALTH


Abbreviations

- BAI: Beck Anxiety Inventory
- CBT: cognitive behavioral therapy
- FFQM-SF: Five Facets Mindfulness Questionnaire Short Form
- MVC: Mindfulness Virtual Community
- PHQ-9: Patient Health Questionnaire-9
- PSS: Perceived Stress Scale
- RCT: randomized controlled trial
- WLC: waitlist control
Efficacy of a Smartphone App Intervention for Reducing Caregiver Stress: Randomized Controlled Trial

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Abstract

Background: Caregivers play a pivotal role in maintaining an economically viable health care system, yet they are characterized by low levels of psychological well-being and consistently report unmet needs for psychological support. Mobile app–based (mobile health [mHealth]) interventions present a novel approach to both reducing stress and improving well-being.

Objective: This study aims to evaluate the effectiveness of a self-guided mobile app–based psychological intervention for people providing care to family or friends with a physical or mental disability.

Methods: In a randomized, single-blind, controlled trial, 183 caregivers recruited through the web were randomly allocated to either an intervention (n=73) or active control (n=110) condition. The intervention app contained treatment modules combining daily self-monitoring with third-wave (mindfulness-based) cognitive-behavioral therapies, whereas the active control app contained only self-monitoring features. Both programs were completed over a 5-week period. It was hypothesized that intervention app exposure would be associated with decreases in depression, anxiety, and stress, and increases in well-being, self-esteem, optimism, primary and secondary control, and social support. Outcomes were assessed at baseline, postintervention, and 3-4 months postintervention. App quality was also assessed.

Results: In total, 25% (18/73) of the intervention participants were lost to follow-up at 3 months, and 30.9% (34/110) of the participants from the wait-list control group dropped out before the postintervention survey. The intervention group experienced reductions in stress (b=−2.07; P=.04) and depressive symptoms (b=−1.36; P=.05) from baseline to postintervention. These changes were further enhanced from postintervention to follow-up, with the intervention group continuing to report lower levels of depression (b=−1.82; P=.03) and higher levels of emotional well-being (b=6.13; P<.001), optimism (b=0.78; P=.007), self-esteem (b=2.15; P=.001), support from family (b=2.66; P<.001), and subjective well-being (b=4.82; P<.001). On average, participants completed 2.5 (SD 1.05) out of 5 treatment modules. The overall quality of the app was also rated highly, with a mean score of 3.94 out of a maximum score of 5 (SD 0.58).

Conclusions: This study demonstrates that mHealth psychological interventions are an effective treatment option for caregivers experiencing high levels of stress. Recommendations for improving mHealth interventions for caregivers include offering flexibility and customization in the treatment design.

Trial Registration: Australian New Zealand Clinical Trial Registry ACTRN12616000996460; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371170
nHeath; mobile phone; caregiver; psychological stress; mental health

Introduction

Background

Caring for people living with physical or mental health difficulties can be a challenging role, one that is becoming increasingly common as trends in public policy move toward assisting people with disabilities to remain within their family environment for as long as possible [1]. A caregiver, or informal carer, is defined as a person who provides any informal, ongoing assistance to people with disabilities, including physical conditions and mental and behavioral disorders, such as developmental disability, or to older people (aged ≥65 years) [2]. Caregivers provide substantial social and economic contributions to their community, with approximately 2.7 million caregivers in Australia (12% of the population), 43.5 million in the United States (18% of the population), and 6.5 million in the United Kingdom (8% of the population), contributing over US $60 billion in unpaid care and support per year [2-5]. In Australia, over 50% of the caregivers provide care for more than 20 hours per week, which affects their capacity to participate in the workforce [2]. As a result, carers have a median weekly income estimated to be 42% lower than noncarers and experience limitations in opportunities for social connection and support [1,2].

Despite their challenging circumstances, caregivers have been reported to identify positive aspects associated with caregiving, including a sense of value in their role [6,7]. However, there can be costs to a caregiver’s subjective and objective well-being, particularly when the burden of care is high. The rates of mental and physical ill-health are substantially higher in caregivers than noncaregivers [1,8,9], including elevated symptoms of stress, depression, and anxiety; higher rates of psychiatric disorders; and reduced overall subjective well-being [10-12]. Notably, high rates of depression, anxiety, and stress have been reported in caregivers supporting people with intellectual disability [1], dementia [12,13], Parkinson disease [14], chronic childhood illness [15], autism [16], and a psychiatric disorder [17], alongside other forms of disability [18]. Caregiver stress is a particular concern when care recipients are affected by long-term or terminal illnesses, major cognitive impairment, or additional behavioral and emotional problems beyond the core symptomatology of their condition [1,19].

Compromised emotional well-being in caregivers (eg, mental disorders) may adversely impact care recipients. There is evidence, for example, that care recipients have poorer general health, mental health, and quality of life and exacerbated disability symptomatology when caregivers experience mental health problems [20,21]. The caregiver burden has also been associated with poorer caregiving quality, including the use of coercive or harmful management techniques, which may damage the relational bond between a caregiver and the care recipient [22-24]. Such relationships are likely to be bidirectional: more complex caregiving contexts may increase caregiver burden, and vice versa [20]. Furthermore, the experience of caregiver psychological difficulties is a risk factor for a breakdown in care and a shift to formal care arrangements, such as placement in a supervised care environment [25,26]. Thus, there is a growing recognition of the need to adopt a family systems approach to support people with disabilities and their caregivers alike [1].

Given the available evidence on the significance of caregiver burden, tailored interventions designed to reduce stress and promote well-being in carers are critically important. Among existing interventions, the primary psychological treatments are based on principles of cognitive behavioral therapy (CBT), which have been shown to reduce depression in caregivers [27,28]. Although the effects on anxiety and stress have received less attention, the extant literature is equivocal [12]. Previous studies have found that cognitive reframing may be particularly effective for reducing subjective stress, anxiety, and depressive symptomatology in caregivers [29,30]. This technique may be most pertinent in challenging unrealistic, self-defeating, and distressing cognitions about either the caregiving role or the care recipients’ behavior or condition. Another promising CBT technique for caregiver mental health is behavioral activation, whereby an individual is assisted to engage in enjoyable and meaningful activities and thereby develop or reconnect with gratifying or valued aspects of their lives [31,32]. Behavioral activation may help address the activity restriction commonly experienced by caregivers, a known depression risk [33]. Third-wave CBT techniques focusing on thoughts and emotions, such as mindfulness-based interventions, acceptance and commitment therapy, and dialectical behavior therapy, have also demonstrated efficacy in reducing a range of mental health conditions [34], including stress in caregivers of people with dementia [35], intellectual or developmental disabilities [36], and palliative illness [37]. Such approaches may be particularly useful for caregivers, encouraging acceptance of negative thoughts and emotions without judgment.

Although these approaches show promise, caregivers face a number of barriers to accessing in-person treatment programs, including economic, geographic, and mobility factors; limited time to engage in interventions; and difficulties in finding and/or affording the cost of suitable alternative caregiver support to attend treatment [38-40]. Furthermore, caregivers often report difficulties in prioritizing their own needs or setting aside time for nonessential activities, which may include treatment interventions [41]. Digital technologies may help address issues of accessibility to treatment, particularly when there are barriers to attending the more traditional face-to-face individual or group interventions. The benefits of digital programs include reduced costs, increased availability (particularly in geographical locations where services may be restricted), as well as convenience of use compared with traditional formats [42-44]. However, research is needed to determine the extent to which evidence-based techniques can be adapted to these new media.
platforms while preserving their efficacy in caregiver populations. A number of interventions have successfully adapted CBT techniques to digital platforms for carers using video teleconferencing, websites with text and/or web-based video education and coaching, and online discussion group technologies. Mobile app–based interventions are notably absent from the caregiver intervention literature, with the research needed to examine whether brief interventions, delivered through a mobile phone, can realistically deliver a usable service to caregivers.

Mobile app–based brief interventions offer a number of strengths over other digital delivery platforms. Their small size and portability allow an intervention to be readily accessed at times of greatest need [45]. Their use also allows for real-time symptom and activity monitoring, together with assessment of treatment progress via ecological momentary assessment (EMA) as well as the provision of personalized feedback [46]. Emerging literature suggests that psychological interventions delivered via smartphone devices can reduce anxiety [47], depression [48], and stress [49-51] and improve well-being [52] in the general population. To our knowledge, such interventions have not yet been trialed with caregivers.

Aims and Hypotheses
This study is a randomized controlled trial of a mobile app–based, self-directed psychological intervention for people who are providing care to family or friends with a physical and/or mental disability. It was hypothesized that the intervention would produce a greater reduction in stress, depression, and anxiety as well as increased well-being, compared with control participants (hypothesis 1). To assess the broader impact, we also evaluated emotional well-being, self-esteem, optimism, primary and secondary control, and perceived social support (secondary outcomes; hypothesis 2). We hypothesized that these improvements in self-reports will be maintained for 3 months postintervention for primary outcomes (hypothesis 3) and secondary outcomes (hypothesis 4). Although the intervention was designed to provide a range of modules with different techniques that could each be useful for improving outcomes, we tested the possibility that the effect of intervention allocation was moderated by the number of treatment modules completed. In particular, we predicted that improvements in primary and secondary outcomes would be stronger for individuals allocated to the treatment condition who engage in more modules (hypothesis 5). We also explored the usefulness of this form of intervention through caregivers’ perceptions of the app’s engagement, functionality, aesthetics, information, and quality, expecting positive ratings across these metrics for the intervention (hypothesis 6).

Methods
Design
The design of the trial was a 2 (condition: StressLess intervention and StressMonitor active control) × 3 (occasion: baseline, postintervention, and 4-month follow-up), parallel, single-blind, randomized controlled trial. This study was approved by the Deakin University Human Research Ethics Committee (2016-151) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000996460). A Consolidated Standards of Reporting Trials (CONSORT) checklist for this study is available in Multimedia Appendix 1. Furthermore, the CONSORT eHealth document [53] is also included in Multimedia Appendix 2.

Participants
Participants were recruited through a mix of traditional strategies and targeted social media advertising. Support was sought from caregiver organizations and services, who agreed to display study flyers (both in physical and digital forms) and allowed the research team to attend caregiver events and seminars for recruitment purposes. Social media advertising was conducted through Facebook, with separate advertisement campaigns targeting either Australians broadly or those with an interest in specific disability topics (eg, Attention deficit hyperactivity disorder awareness, Alzheimer’s awareness, and physical disability). Campaigns were restricted to adult Facebook users located in Australia accessing the platform through an Apple iOS device. Although the advertisements did not immediately identify the institutional affiliations of the research team, this was made clear in the plain language statement that participants were directed to via weblinks to start the program.

To be eligible to join the study, participants were required to be (1) an Australian resident, (2) aged 18 years or older, (3) fluent in English, (4) helping to support a friend or relative with a physical or mental condition/disability, (5) able to access an Apple iOS mobile phone device (iPhone or iPad) with internet access for the duration of the study, and (6) not have participated in an electronic health (eHealth) intervention (any technology-based health intervention, including mobile apps) within the previous 6 months. Smartphone app literacy was also a de facto eligibility criterion but was assumed by the participant’s willingness to sign up for the study. A CONSORT flow diagram is provided below (Figure 1). Recruitment to the baseline component of the study ran from September 2016 to April 2017.
**Sample Size Calculation**

The required sample size was powered with the following assumptions: (1) a moderate group difference (SD 0.5) between the intervention and active control groups for the primary and secondary outcomes at postintervention; (2) power set at 0.80; (3) $\alpha$ set at 0.05 (2 tailed); (4) expected attrition rate of 20% for the intervention group [54]; and (5) an allocation ratio of 3:2 (active control: intervention) under the expectation that attrition would be around 30% for the active control group, as they only receive self-monitoring features of the app and not intervention content during the control phase. Under these assumptions, the adjusted target sample size at baseline was 68 and 100 for the intervention and active control groups, respectively.

**Intervention: StressLess**

StressLess is a 5-week, self-directed intervention, based on the principles of second- and third-wave CBTs [55], delivered through a mobile app (Figure 2). The intervention provides psychoeducation (through text, video, audio, and graphics) and a series of interactive exercises or activities. The intervention comprises 5 modules (detailed in Multimedia Appendix 1): (1) an introduction involving psychoeducation about stress reduction and third-wave CBT; (2) values clarification and goal setting; (3) mindfulness skills involving observation of the self and connection with the present moment, cognitive diffusion, and acceptance; (4) well-being enhancement through positive psychology techniques and cognitive restructuring; and (5) behavioral activation to increase engagement in, and enjoyment of, pleasant or valued activities. A Troubleshooting tab was also available beyond the core intervention modules, which contained a series of activities to help with stress (e.g., destress with a body scan and breathing to diffuse negative thoughts). The intervention content was designed to provide a suite of therapeutic techniques with demonstrated efficacy in the broader literature, enabling participants’ autonomy in selecting the techniques that they feel work best for them. Participants could work through the modules at their own pace and in any order across the 5 weeks, but they were encouraged to complete one module per week in a recommended sequence. Each module that a participant completed was logged by the app to enable tracking of how many modules a participant tried.
In addition to the intervention modules, StressLess also supports users in self-monitoring their well-being through in-the-moment assessments (EMA). Participants were prompted to complete a self-monitoring assessment up to 4 times per day via the StressLess app notification function. Participants were prompted to complete either a 1 item check asking them to rate their current stress levels or a longer 1 min check assessing whether the participant had experienced a stressful event in the previous 30 min. The 1 min check involved assessments of coping and positive and negative affect. Coping was assessed using an eight-item checklist of various coping strategies (eg, distracted myself) for the recent stressful event. Momentary positive and negative effects were assessed using the Homeostatically Protected Mood Scale, described in Measures section [56,57]. Users were able to adjust the notification settings of the self-monitoring component, with the default number of sampling points set at 2 times per day (one in the morning after 8 AM and one in the afternoon/night before 10 PM). Self-monitoring EMA data were automatically collated by the mobile app and presented to users through a feedback bar chart. Source code for StressLess is available on request from the corresponding author.

**Active Control: StressMonitor**

The active control involved the mobile app StressMonitor. This comprised the same self-monitoring EMA function and feedback bar chart as the StressLess intervention but did not contain any intervention modules. The inclusion of an active control condition enabled the statistical separation of effects because of novelty (or burden) of completing app-based self-monitoring of mood from treatment outcomes.
Measures

Demographics

Items assessing participants’ caregiver roles were adapted from the Australian Bureau of Statistics’ (ABS) Survey of Disability, Aging, and Carers (SDAC) [58]. These assessed the impact of a participant’s caregiver role in terms of the respondent’s time, energy, emotions, finances, and daily activities, with response options ranging from 1 (not at all) to 4 (a lot). The care recipients’ disability type was also assessed using the ABS’ SDAC categories of sensory (eg, loss of sight and loss of hearing), intellectual (difficulty learning or understanding things), physical (eg, shortness of breath and chronic or recurrent pain or discomfort), psychosocial (eg, social or behavioral difficulties, memory problems, or periods of confusion), head injury/stroke, acquired brain injury, or other long-term conditions [58]. Importantly, all disability conditions were required to be long term and restrict the care recipients’ everyday activities.

Primary Intervention Outcomes

The primary outcomes were the participants’ stress levels, depression, anxiety, and subjective well-being. The first 3 variables were measured using the Depression Anxiety Stress Scale-21 [59]. This scale contains 21 items, separated into 3 subscales, assessing the self-reported frequency/severity of emotional states over the past week. The depression subscale contains items assessing the symptomatology of mood disorders, including hopelessness, low self-esteem, and low positive affect, for example, “I felt downhearted and blue” [59,60]. The anxiety subscale assesses the symptomatology of panic disorders through items on autonomic arousal, physiological hyperarousal, and the subjective feelings of fear, for example, “I was aware of dryness in my mouth.” The stress subscale assesses tension, agitation, and negative affect, for example, “I found it hard to wind down.” Higher subscale scores indicate more frequent/severe emotional states. The Depression Anxiety Stress Scale-21 has demonstrated robust psychometric properties, with the three-scale solution and internal consistency (α=0.78) being supported in Australian samples in the pen-and-paper form [60] and via web-based survey [61]. In this study, subscale-level internal consistency estimates ranged from 0.67 to 0.83 for anxiety, from 0.75 to 0.88 for depression, and from 0.67 to 0.81 for stress (full results provided as Multimedia Appendix 2).

The Personal Wellbeing Index (PWI) was used to assess the primary intervention outcome of participants’ subjective well-being [62]. PWI consists of 7 items asking respondents to rate how satisfied they are across 7 life domains: standard of living, personal health, achieving in life, personal relationships, personal safety, community connectedness, and future security. The ratings are made across an 11-point scale, ranging from 0 (no satisfaction at all) to 10 (completely satisfied), with higher scores indicating higher satisfaction. In addition, a total score was calculated from the 7 PWI items, scaled from 0 to 100. Psychometric evaluations of the PWI have demonstrated acceptable reliability (α=0.77) and factorial validity in Australian populations [63] as well as internationally [62]. Acceptable factor structure and internal consistency have also been achieved via web-based collection of PWI data [64]. In this study, internal consistency ranged from 0.71 to 0.90 across groups and time.

Secondary Outcomes

Beyond the primary outcome measures listed earlier, the study also assessed additional secondary variables that were predicted to improve after completing the intervention. Affective mood was assessed using the Homeostatically Protected Mood Scale [56,57]. Respondents were asked to rate how well 3 positive affective terms (content, happy, and alert) describe their feelings about their life in general, rated using an 11-point scale, ranging from 0 (not at all) to 10 (extremely), with higher scores on each indicating that higher affective mood psychometric evaluations of the Homeostatically Protected Mood Scale with Australian samples (both via pen-and-paper survey [57] and through the web [65]) have demonstrated strong internal consistency (α=0.85) [57,65] and convergent validity with other well-being measures, such as the PWI (rs=0.58-0.72) [57] and Satisfaction with Life scale (r=0.79) [65]. In this study, internal consistency ranged from 0.75 to 0.87 across groups and time.

Self-esteem was assessed using the Rosenberg Self-Esteem Scale [66]. This scale consists of 10 items assessing self-esteem (eg, “At times I think I am no good at all”), with response options completed using a 4-point scale, ranging from 1 (strongly disagree) to 4 (strongly agree). In an Australian sample, the measure has demonstrated excellent test-retest reliability (rs=0.53-0.69 over 4 years) and internal consistency (α=0.85) and was shown to correlate with constructs theoretically related to self-esteem, such as self-compassion (rs=0.36-0.63) [67]. For this study, Rosenberg’s original 5 positive items were included, thereby a single construct best described as positive self-esteem, with higher scores indicating higher self-esteem [66]. In this study, internal consistency ranged from 0.65 to 0.86 across groups and time.

Optimism was assessed using the optimism subscale from the Life Orientation Test-Revised [68]. This subscale comprises 3 items that measure the respondents’ generalized expectation of good outcomes in life, for example, “In uncertain times, I expect the best.” The responses are provided using a five-point scale, ranging from 0 (strongly disagree) to 4 (strongly agree), with higher scores indicating higher optimism. The measure has demonstrated acceptable psychometric properties in an Australian context with data collected through the web, including internal consistency (α=0.80) [68,69], and convergent validity with measures of life satisfaction (r=0.4) [68] and quality of life (r=0.5) [70]. In this study, internal consistency ranged from 0.62 to 0.84 across groups and time.

Primary and secondary control were assessed using an abbreviated version of the Primary and Secondary Control Scale (PSCS) [71,72]. The PSCS consists of 25 items assessing specific cognitive and behavioral strategies aimed at either control of environmental circumstances (primary control; eg, “when bad things happen, I put lots of time into overcoming it”) or control of internal states (secondary control; eg, “when bad things happen, I ignore it by thinking about other things”), to minimize psychological impacts. The response options were completed using an 11-point scale, ranging from 0 (do not agree at all) to 10 (agree completely), with higher scores indicating...
higher primary/secondary control. This study adapted the measure by selecting a subset of the items as the two-factor solution developed by Cousins with an Australian sample [71]. This comprised 5 items for the secondary control subscale from Cousins’ [71] avoidant control subscale, and the 6 best performing items were selected to form the primary control subscale from Cousins’ approach control subscale. Cousins [71] demonstrated acceptable internal consistency (α>0.72) for these 2 subscales in an Australian sample. In this study, internal consistency ranged from 0.75 to 0.87 for primary control and from 0.61 to 0.76 for secondary control across groups and time.

Social support was assessed using the Multidimensional Scale of Perceived Social Support [73]. This comprises 12 items assessing the perceived adequacy of support from family, friends, and significant other (eg, “I have a special person who is a real source of comfort to me”). Responses are recorded on a 7-point scale, ranging from 1 (very strongly disagree) to 7 (very strongly agree), and scoring is calculated for 3 subscales reflecting the 3 social support sources of (1) family, (2) friends, and (3) significant other. Higher scores indicate higher perceived social support from each social support source. Within an Australian sample, the Multidimensional Scale of Perceived Social Support has demonstrated strong internal consistency (α=0.90) and stability over a 1-year testing period (r=0.61) [74]. In this study, subscale-level internal consistency estimates ranged from 0.75 to 0.93 for family support, from 0.80 to 0.92 for support from friends, and from 0.80 to 0.93 for social support from others.

**App Quality**

The quality of the intervention app was assessed using the Mobile Application Rating Scale [75]. This scale comprises 23 items rated on a 5-point rating scale. The Mobile Application Rating Scale consists of 4 subscales: engagement, functionality, aesthetics, and information. The mean item score across the 4 subscales was used to determine an objective measure of the overall quality of the app, with higher scores indicating higher app quality. Furthermore, the Mobile Application Rating Scale also includes a subscale assessing the subjective quality of the app, consisting of items assessing whether the participant would recommend the app to others, plans to use the app again in the next 12 months, would pay to use the app, and their overall rating of the app out of 5. In this study, an adapted version of the Mobile Application Rating Scale was used, excluding the items assessing the entertainment value and evidence base for the app. These items were removed from the mean score calculation according to the guidelines [76].

**Procedure**

After providing informed consent via Qualtrics (by reading a plain language statement and then responding to a question about whether they consented) and meeting the study eligibility criteria, participants were invited to complete the baseline assessment as a web survey. Participants were then randomly allocated to either the active control or intervention arm using a 3:2 assignment in blocks of 5 created through Qualtrics (web-based survey provider of choice), with the expectation that attrition would be higher in the active control group because of lower incentive to remain in the study. Instructions were provided to participants detailing how to install the app (either StressLess or StressMonitor) on their mobile phone or iPad. The app is free and does not include any hidden costs. For both groups, the plain language statement provided via the baseline Qualtrics survey provided contact details for free helplines if the participants felt distressed at any stage because of the intervention. The StressLess and StressMonitor apps also contained these contact details in the app to remind participants that they could contact LifeLine (a free, Australian counseling service) if they felt distressed.

Following the download of the app, participants then completed 5 weeks with their assigned app, with weekly contact from the research team by either an email or phone call to maximize engagement. In more detail, a standard email was sent to all participants in each group in weeks 1, 2, 4, and 5 explaining an aspect of either the intervention or the active control program. For example, week 2 emails were titled Mindfulness with StressLess and Mood Monitoring: How does your mood change across the day? for the intervention and active control conditions, respectively. In addition, participants were contacted through a phone call in week 3 to answer any queries about the use of the app. These phone calls were used to identify any technical difficulties and to maintain engagement. They were not designed for therapeutic purposes.

Participants then completed the postintervention assessment as a web survey and were reimbursed for their time with a $50 voucher. The postintervention survey was identical for participants from both groups, with the exception that the intervention group received the app quality measure. Furthermore, active control participants who completed the postintervention survey were provided with instructions on how to download the intervention app from the iOS app store. Finally, intervention participants were invited to complete a follow-up survey 4 months after completing the postintervention assessment.

**Analysis**

Following the principles of intention-to-treat (ITT) analysis, individuals were retained in the group they were randomized to. Thus, even in cases where participants in the intervention group did not use the app at all (n=15), they were retained in the intervention group for the purposes of analysis. Missing data were handled using multiple imputation, with 50 imputations. By default, Mplus uses Monte Carlo Markov Chains with 100 iterations per imputation and chained equations to impute missing values for variables [77]. These imputed files were then imported into Mplus version 8 for multilevel modeling to test (1) the efficacy of the intervention compared with the control condition across study variables at postintervention for primary outcomes (hypothesis 1) and secondary outcomes (hypothesis 2), (2) the maintenance of treatment effects at the 4-month follow-up assessment for primary outcomes (hypotheses 3) and secondary outcomes (hypotheses 4), and (3) the impact of the number of modules completed on treatment efficacy (dose-response effects; hypothesis 5).

For the evaluation of efficacy, time was entered as a level 1 predictor (0=baseline and 1=postintervention). At level 2, group (0=control and 1=intervention) was included as a predictor of
the dependent variable (DV) as well as a moderator of the level 1 relationship between time and DV scores. This latter effect (a cross-level interaction) was used to ascertain whether the rate of improvement in symptoms was greater for intervention participants than for those in the control group (hypotheses 1 and 2). Maintenance effects were tested similarly, although the time effect compared postintervention (coded 0) against the 4-month follow-up time point (coded 1; hypotheses 3 and 4). As the follow-up data were only collected for the intervention group, there was no level 2 predictor for group. Dose-response effects were tested with the intervention group only, by moderating the time effect by the number of modules completed (hypothesis 5). Each outcome variable was modeled separately. Descriptive statistics were reported for the evaluation of user ratings of the intervention (hypothesis 6). All effects were tested at \( P = .05 \) (two-tailed) unless otherwise indicated.

**Results**

**Sample Characteristics and Caregiving Context**

The final sample consisted of 183 caregivers; Table 1 shows the demographic characteristics of the sample. The average participant was female (174/183, 95.1%), aged 39.5 (SD 6.27) years, and provided full-time home care to a child with a disability (145/183, 79.2%). The majority (107/183, 58.4%) of the participants reported that their care recipient received government funding for disability support, with no differences observed in the proportion of those accessing government funding for disability support between the intervention and active control groups. Support provided by participants included practical support (eg, cooking and cleaning: 169/183, 92.3%), nursing (eg, washing/dressing care recipient; reported by 77.9%), and emotional support (eg, talking to the care recipient about their problems; 178/183, 97.2%). Between groups, a greater proportion of participants in the intervention group reported providing nursing support to their care recipients than those in the active control group (\( \chi^2 = 6.4; P = .01 \)). For 65.1% (119/183) of the participants, no other person was providing support to their care recipient. Furthermore, 97.2% (178/183) of the participants reported that caring for their care recipient had adversely affected the amount of time they were able to spend on themselves. The 2 groups did not differ in either of these factors.

Compared with national caregiver data available from the ABS [2], this study’s sample included a lower proportion of caregivers who were male (current sample: 4.4% and ABS SDAC: 45%), of younger age (current sample mean age: 39.5 years and ABS SDAC mean age: 55 years), and less likely to provide care to a spouse (current sample: 6.0% and ABS SDAC: 40.0%).
<table>
<thead>
<tr>
<th>Variables</th>
<th>Intervention (n=73)</th>
<th>Active control (n=110)</th>
<th>Group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>t test (df)</td>
<td>Chi-square (df)</td>
<td>P value</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.16 (179)</td>
<td>1.52 (2)</td>
<td>.25</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household income, Aus $ (US $), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;15,000 (10,385)</td>
<td>5 (7)</td>
<td>5 (45)</td>
<td></td>
</tr>
<tr>
<td>15,000-30,000 (10,385-20,771)</td>
<td>19 (26)</td>
<td>19 (17)</td>
<td></td>
</tr>
<tr>
<td>31,000-60,000 (21,463-41,542)</td>
<td>16 (22)</td>
<td>16 (15)</td>
<td></td>
</tr>
<tr>
<td>61,000-100,000 (42,235-69,237)</td>
<td>34 (47)</td>
<td>34 (31)</td>
<td></td>
</tr>
<tr>
<td>101,000-150,000 (69,929-103,856)</td>
<td>21 (29)</td>
<td>21 (19)</td>
<td></td>
</tr>
<tr>
<td>&gt;150,000 (103,856)</td>
<td>15 (21)</td>
<td>15 (14)</td>
<td></td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time paid</td>
<td>11 (15)</td>
<td>15 (14)</td>
<td>0.07 (1)</td>
</tr>
<tr>
<td>Full-time study</td>
<td>9 (12)</td>
<td>10 (9)</td>
<td>0.49 (1)</td>
</tr>
<tr>
<td>Full-time home</td>
<td>31 (43)</td>
<td>35 (32)</td>
<td>2.16 (1)</td>
</tr>
<tr>
<td>Part-time paid</td>
<td>21 (29)</td>
<td>38 (34)</td>
<td>0.67 (1)</td>
</tr>
<tr>
<td>Casual paid</td>
<td>3 (4)</td>
<td>10 (9)</td>
<td>1.65 (1)</td>
</tr>
<tr>
<td>Part-time home</td>
<td>19 (26)</td>
<td>22 (20)</td>
<td>0.92 (1)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>5 (7)</td>
<td>8 (7)</td>
<td>0.01 (1)</td>
</tr>
<tr>
<td>Number of care recipients, n (%)</td>
<td>1.66 (0.82)</td>
<td>1.49 (0.71)</td>
<td>N/A</td>
</tr>
<tr>
<td>Primary care recipient, n (%)</td>
<td></td>
<td></td>
<td>1.50 (182)</td>
</tr>
<tr>
<td>Parent</td>
<td>5 (7)</td>
<td>6 (5)</td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>5 (7)</td>
<td>8 (7)</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>60 (82)</td>
<td>85 (77)</td>
<td></td>
</tr>
<tr>
<td>Friend</td>
<td>2 (3)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (1)</td>
<td>7 (6)</td>
<td></td>
</tr>
<tr>
<td>Care burden (hours per week), n (%)</td>
<td></td>
<td></td>
<td>4.31 (3)</td>
</tr>
<tr>
<td>&lt;20</td>
<td>4 (6)</td>
<td>12 (12)</td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>3 (4)</td>
<td>11 (11)</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>3 (4)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>&gt;40</td>
<td>59 (86)</td>
<td>76 (73)</td>
<td></td>
</tr>
<tr>
<td>Care recipient disability type, n (%)</td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Sensory</td>
<td>22 (42)</td>
<td>30 (48)</td>
<td>0.32 (1)</td>
</tr>
<tr>
<td>Intellectual</td>
<td>36 (69)</td>
<td>43 (68)</td>
<td>0.01 (1)</td>
</tr>
<tr>
<td>Physical</td>
<td>25 (48)</td>
<td>25 (40)</td>
<td>0.82 (1)</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>46 (88)</td>
<td>58 (92)</td>
<td>0.43 (1)</td>
</tr>
<tr>
<td>Head injury/stroke or acquired brain injury</td>
<td>1 (2)</td>
<td>3 (5)</td>
<td>0.68 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (31)</td>
<td>25 (40)</td>
<td>0.99 (1)</td>
</tr>
</tbody>
</table>
Hypothesis Testing

Table 2 provides the means and SDs for the study variables by group and time points. In general, participants in the intervention group exhibited improvement from baseline to postintervention on a number of (but not all) study variables.

Table 2. Descriptive statistics by group and time point for primary and secondary outcomes.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Active control, mean (SD)</th>
<th>Intervention, mean (SD)</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Postintervention</td>
<td>Baseline</td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td>18.82 (7.98)</td>
<td>18.94 (9.03)</td>
<td>17.03 (7.88)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>8.14 (6.76)</td>
<td>8.61 (6.90)</td>
<td>7.56 (7.60)</td>
</tr>
<tr>
<td>Depression</td>
<td>10.95 (8.00)</td>
<td>10.87 (8.58)</td>
<td>11.33 (8.67)</td>
</tr>
<tr>
<td>Subjective well-being</td>
<td>58.02 (15.18)</td>
<td>54.72 (17.06)</td>
<td>55.73 (16.15)</td>
</tr>
</tbody>
</table>

| **Secondary outcomes** | | | |
| Mood affect           | 52.92 (15.96)             | 52.37 (19.35)            | 55.48 (16.88) | 58.11 (15.56)     | 64.27 (16.06) |
| Optimism              | 5.74 (2.65)               | 5.81 (2.89)              | 6.33 (2.51)  | 6.60 (2.25)       | 7.41 (2.22)   |
| Primary control       | 40.41 (9.05)              | 41.50 (10.38)            | 40.51 (9.32) | 42.75 (7.09)      | 42.82 (7.62)  |
| Secondary control     | 17.88 (6.96)              | 15.39 (7.91)             | 20.80 (6.93) | 19.60 (8.89)      | 19.74 (7.53)  |
| Self-esteem           | 9.27 (2.33)               | 10.06 (2.36)             | 9.44 (2.77)  | 10.15 (2.49)      | 10.97 (2.32)  |
| Support_Family        | 16.56 (6.61)              | 17.34 (6.79)             | 16.39 (6.54) | 17.66 (6.21)      | 19.87 (5.39)  |
| Support_Friends       | 18.62 (5.47)              | 19.42 (5.94)             | 17.93 (5.65) | 19.68 (5.43)      | 20.08 (5.81)  |
| Support_Others        | 19.91 (5.89)              | 21.24 (5.45)             | 20.04 (5.72) | 20.91 (5.89)      | 23.68 (4.29)  |

Changes From Baseline to Postintervention (Intervention vs Control Group; Hypotheses 1 and 2)

Multilevel modeling indicated a significant time × group interaction by the postintervention time point for the primary outcomes of anxiety (b = −2.030; 95% CI −3.607 to −0.453; P = .02), depression (b = −1.841; 95% CI −3.569 to −0.113; P = .04), stress (b = −2.159; 95% CI −4.007 to −0.311; P = .03), and subjective well-being (b = 5.454; 95% CI 2.065 to 8.843; P = .008).

These significant interaction effects were followed up with simple effects testing to determine changes in outcomes for the control and intervention groups separately. Stress symptoms were significantly reduced in the intervention group (b = −2.070; 95% CI −3.743 to −0.397; P = .04; Cohen d = 0.338) but did not change significantly in the control group (b = 0.246; 95% CI −1.028 to 1.520; P = .75; Cohen d = 0.043). Improvement in depressive symptoms was borderline significant for the intervention condition (b = −1.361; 95% CI −2.752 to 0.030; P = .05; Cohen d = 0.267) but did not significantly change in the control group (b = 0.427; 95% CI −0.697 to 1.551; P = .27; Cohen d = 0.085). Subjective well-being worsened significantly in the control group (b = 3.894; 95% CI −5.920 to −1.868; P = .002; Cohen d = 0.428) but did not significantly change in the intervention condition (b = 1.501; 95% CI −1.540 to 4.542; P = .42; Cohen d = 0.135). Neither the control group (b = 1.089; 95% CI −0.64 to 2.242; P = .06; Cohen d = 0.210) nor the intervention group (b = −0.921; 95% CI −2.182 to 0.340; P = .11; Cohen d = 0.199) significantly changed in the level of anxiety by postintervention, although their symptom change trended in opposite directions (improvement for the intervention group and worsening for the control group), which accounts for the significant group × time interaction.

Among the secondary outcomes, the group × time interaction was only significant for secondary control (b = 2.522; 95% CI 0.552 to 4.492; P = .02). Post hoc testing revealed a significant reduction in secondary control for the control group (b = −2.558; 95% CI −3.786 to −1.330; P < .001; Cohen d = 0.463) but a nonsignificant change in secondary control for the intervention group (b = −0.030; 95% CI −1.550 to 1.490; P = .97; Cohen d = 0.005).

Changes From Postintervention to 3-Month Follow-Up (Intervention Group Only; Hypotheses 3 and 4)

Among the primary outcomes, significant improvements were observed from postintervention to the 3-month follow-up for depression (b = −1.824; 95% CI −3.466 to −0.182; P = .03; Cohen d = 0.360) and subjective well-being (b = 4.825; 95% CI 2.304 to 7.346; P < .001; Cohen d = 0.621) but nonsignificant changes in symptoms of anxiety (b = −0.123; 95% CI −1.442 to 1.196; P = .86; Cohen d = 0.030) and stress (b = −1.723; 95% CI −3.630 to 0.184; P = .08; Cohen d = 0.293).

Among the secondary outcomes, significant improvements in symptoms were observed for emotional well-being (b = 6.132; 95% CI 3.451 to 8.813; P < .001; Cohen d = 0.742), optimism (b = 0.776; 95% CI 0.208 to 1.344; P = .007; Cohen d = 0.443), self-esteem (b = −0.842; 95% CI 0.258 to 1.426; P = .005; Cohen d = 0.137).
d=0.468), support from family (b=2.154; 95% CI 0.872 to 3.436; P=.001; Cohen d=0.546), and support from significant others (b=2.662; 95% CI 1.300 to 4.024; P<.001; Cohen d=0.634).

**Modules Completed as Moderator (Hypothesis 5)**

In total, 58 of the 73 individuals allocated to the intervention arm viewed at least one module, although all 73 individuals were retained for analyses consistent with the principles of ITT. On average, participants in the intervention condition completed 2.55 out of the 5 modules (SD 1.05). Psychoeducation (56/58, 97%) and values modules (52/58, 90%) were the most commonly used modules, with less viewing of mindfulness (17/58, 29%), well-being (12/58, 21%), and behavioral activation modules (11/58, 19%).

The number of modules completed moderated the level of improvement in primary control from baseline to postintervention for the intervention group (b=1.420; 95% CI 0.422 to 2.418; P=.01; Cohen d=0.389), such that primary control improved further with every additional module completed. The number of modules completed did not moderate any of the other studied variables (all remaining P values were >.05 and Cohen d values <0.24).

**User Feedback (Hypothesis 6)**

The overall quality of the app was rated highly, with a mean score of 3.94 out of a maximum score of 5 (SD 0.58). Participants rated their subjective quality of the app slightly lower (mean 3.19, SD 0.85). Within the subjective quality subscale, participants expressed that they would not choose to pay for the app (mean 2.22, SD 1.14), which was the only item to be rated with a mean score below 2.5. The app was rated particularly positively for its functionality (mean 4.19, SD 0.75), information (mean 3.96, SD 0.63), and aesthetics (mean 3.95, SD 0.63). Although all subscales were rated highly, the engagement subscale achieved the lowest mean score (mean 3.68, SD 0.65). Within the engagement subscale, the items assessing customization and interactivity were rated the lowest (mean 3.31, SD 0.85; and mean 3.47, SD 0.82, respectively).

**Discussion**

**Principal Findings**

The purpose of this study was to evaluate the efficacy of a mobile app–based, self-directed psychological intervention for individuals providing care to family or friends with a physical or mental condition. The sample predominantly consisted of mothers of children with a disability with high levels of care burden and stress. The intervention group experienced improvements in the primary outcomes of stress, depression, anxiety, and subjective well-being across the intervention period despite using only a small number of the treatment modules offered, with further improvements in mental health and outlook observed over the 3- to 4-month follow-up period. Participants rated the intervention app highly for its usability and quality, with the potential to improve the app design further through the addition of greater personalization and flexibility. Given the limited number of studies that have investigated the potential of mobile health (mHealth) tools for caregiver populations, the results of this study have important implications for future work in this field.

We found that caregivers initially presented with challenging caring contexts and elevated levels of distress. Importantly, the study sample differed in several ways from national survey data on caregivers in Australia (collected by the SDAC [2]). Notably, participants in this study were more likely to be female, of younger age, experiencing a high care burden, and more likely to be caring for children with a disability, compared with participants in the SDAC study. Participant recruitment was extended to caregivers of all demographic types, suggesting that a self-selection bias occurred favoring a specific caregiving context. Differences between this study’s sample and the SDAC sample may indicate that younger female caregivers may be more help seeking and have greater familiarity with, or interest in, seeking help through technologies, such as mHealth, social media, and/or other digital health interventions, compared with caregivers more broadly [78]. Furthermore, the higher prevalence of parents of children with disabilities in this study’s sample than in the SDAC may suggest that the concept of an app-based mental health intervention has particular applicability to this caregiving context. A significant body of literature has shown that parents of children with disabilities, particularly autism spectrum disorder, experience highly elevated levels of depression and stress [79,80], with very few interventions targeting the mental health needs of this population and fewer again being offered through digital platforms [81]. Digital health initiatives may be particularly appealing to this demographic of caregivers, given the high levels of need, convenience, flexibility, and speed offered [82,83]. The high proportion of younger women caring for children in this study’s sample means that some caution is needed when generalizing our findings to caregivers more broadly. Further research with different subsets of caregivers (such as male caregivers; older caregivers; or those caring for spouses/partners, parents, or siblings) will help clarify the benefits of the StressLess app for these groups.

Intervention-related effects were observed despite the somewhat low usage across intervention modules. Although participants tended to not complete all modules provided by the app, the modules participants chose to complete appear to have been effective. This finding is consistent with the broader literature, which has found that the therapeutic techniques presented in each module are independently associated with improvements in mental health and well-being [27,28]. Participants in this study appear to have targeted their use to specific modules, which may be reflective of their high stress and time-limited context [84]. This finding suggests that flexible intervention designs may be particularly important with caregiver populations as they enable individuals to tailor programs to their needs. Structured mHealth interventions that require high levels of compliance from participants may not show the same levels of improvement as observed in this study, given the difficulties caregivers face in managing competing demands [84]. Further exploration of ways to reduce intervention-related workload while ensuring positive outcomes is needed. Testing the modules that are most efficacious may provide data for the StressLess app to recommend specific combinations of modules as most important. Augmenting longer modules, as per the StressLess
app, with microintervention content, may also help to provide immediate symptom relief when needed, but without unrealistic time commitments [76].

Although participants rated the quality of the StressLess intervention app highly, their feedback expressed a desire for greater personalization and flexibility in the app design. This suggests that caregivers may benefit from greater opportunities for customization and interactivity in the intervention app’s user experience. Evidence from the broader mHealth literature indicates that tailoring the user’s experience through personalized feedback, prompting, alerts, and reminders is more effective than providing static content to all users [85,86]. Future research could consider the utility of providing a tailored experience to app users, such that the program dynamically adapts to a participant’s context and usage. On the basis of mood assessments within the app and automatically detected usage patterns, the app could in the future send push notifications with recommendations to engage in specific modules at a given point in time [87,88]. Such tailoring, based on knowledge of a user’s past behavior, is common in consumer apps (eg, Netflix) and may provide similar benefits to users of mHealth interventions by providing support at the time of need, based on previous usage behavior [89,90]. Such systems would benefit from a participatory design to ensure that the intelligent health system adequately balances automated decision making with the user’s own input and that its design is also in awareness of privacy concerns that participants may have in disclosing personal data. Developing intelligent and adaptive mHealth interventions through emerging big data technologies, such as machine learning, may be a promising avenue for future research with this population [89,91-93]. This active prompting may also better approximate the structure and support provided in face-to-face therapy.

Limitations

This study has several limitations. First, as noted earlier, the sample is not broadly representative of caregivers in national studies [2]. This sampling bias may reflect the recruitment and intervention delivery methods used in this study through technology, such as social media and smartphones. Therefore, the results may not be generalizable to other caregiver contexts, particularly to caregivers who face barriers in accessing technology. Future research could aim to examine the effectiveness of mHealth interventions within different caring contexts. Second, given the nature of the intervention, blinding to condition was not possible. This may have impacted the results, as participants could reasonably predict the researchers’ hypotheses. Third, as the study was limited to individuals with an iOS-based phone, it is unclear whether usage patterns and user experiences will generalize to Android users. In Australia, market share is reasonably even for iOS- and Android-based smartphones [94,95], but this is not the case globally. At the very least, this impedes the uptake of the StressLess intervention. It may also signal different demographics that may relate to efficacy, an issue that needs further exploration in eHealth interventions. Fourth, although sample sizes were adequate as calculated through a priori power analysis, attrition across the study duration resulted in smaller numbers in the final assessment. Despite this, for the group attained, moderate effect sizes were identified in the final follow-up. We also note that for ethical reasons and given that the primary analyses were based on the postintervention time point, participants initially assigned to the waitlist control group were granted access to StressLess after the postintervention time point rather than the 3- to 4-month follow-up. As such, stability in outcome measures for the intervention group cannot be compared against changes that would occur for this period without intervention. Finally, the majority of measures used were completed by self-report, with no objective clinical measures of the primary and secondary intervention outcomes of stress, depression, anxiety, and subjective well-being. Nevertheless, both the Depression Anxiety and Stress Scale–21 and PWI have demonstrated sound psychometric properties [60,61] and have been applied in caregiver contexts in previous studies [76].

Conclusions

Overall, this study has important clinical implications for the design and effective treatment of mHealth interventions for caregivers experiencing stress. First, the results confirm prior studies showing that caregivers commonly report a need for support for their mental health and well-being, particularly in contexts with high levels of care burden [84]. This study’s sample primarily consisted of mothers caring for children with a disability with high levels of care burden and stress, consistent with the broader disability literature [22,96,97]. Second, caregivers experienced improvements in their mental health and well-being despite using only a small number of the modules offered, indicating that burdensome treatment designs may not be necessary in the caregiver context. Finally, caregivers expressed a preference for interventions that are personalized and flexible in their design, with advances in technology offering the potential for ubiquitous, tailored support. Taken together, the StressLess intervention demonstrates that mHealth apps can successfully improve health and well-being in caregivers, with further work needed to evaluate such interventions in other caregiver groups (ie, older or male caregivers) and to ascertain impacts longer term.

Acknowledgments

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Authors' Contributions

MFT, BR, DH, ST, and KL conceptualized and designed the study, coordinated and supervised data collection, carried out the analyses, contributed to the interpretation of the data, and wrote the manuscript. LC, TC, SK, RC, and CO conceptualized and designed the study and critically reviewed and revised the manuscript for important intellectual content. BR developed the app used in the trial. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest

The authors declare that they have no competing interests. Although BR made the app, there are no financial incentives to conflict with the aims of this manuscript, as the authors have made the app freely available to the public.

Multimedia Appendix 1
Summary of the contents of the five modules of the StressLess intervention.
[DOCX File, 17 KB - mental_v7i7e17541_app1.docx ]

Multimedia Appendix 2
Summary of reliability estimates per group over time for outcome variables.
[DOCX File, 28 KB - mental_v7i7e17541_app2.docx ]

Multimedia Appendix 3
CONSORT-EHEALTH checklist (V. 1.6.1).
[PDF File (Adobe PDF File), 400 KB - mental_v7i7e17541_app3.pdf ]

References


Abbreviations

ABS: Australian Bureau of Statistics
CBT: cognitive behavioral therapy
CONSORT: Consolidated Standards of Reporting Trials
DV: dependent variable
eHealth: electronic health
EMA: ecological momentary assessment
ITT: intention-to-treat
mHealth: mobile health
PSCS: Primary and Secondary Control Scale
PWI: Personal Wellbeing Index
SDAC: Survey of Disability, Aging, and Carers
Remote Care for Caregivers of People With Psychosis: Mixed Methods Pilot Study

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Abstract

Background: A reduced availability of resources has hampered the implementation of family work in psychosis. Web-based support programs have the potential to increase access to high-quality, standardized resources. This pilot study tested the Norwegian version of the Relatives Education and Coping Toolkit (REACT), a web-based United Kingdom National Health Service program in combination with phone-based support by trained family therapists.

Objective: We investigated how the program was perceived by its users and identified the facilitators and barriers to its clinical implementation.

Methods: Relatives of people with psychosis were offered access to REACT and to weekly family therapist support (with 1 of 2 trained family therapists) for 26 weeks. Level of distress and level of expressed emotion data were collected at baseline and after 26 weeks using the Family Questionnaire and the Relatives Stress Scale. Both family therapists and a subset of the relatives were interviewed about their experiences after completing the program.

Results: During the program, relatives (n=19) had a median of 8 (range 4-11) consultations with the family therapists. Postintervention, there was a significant reduction in stress and in expressed emotions in the relatives of people with psychosis. Interviews with the relatives (n=7) and the family therapists (n=2) indicated the following themes as important—the intervention turned knowledge into action; the intervention strengthened the feeling of being involved and taken seriously by the health services; and management support and the ability for self-referral were important, while lack of reimbursement and clinician resistance to technology were barriers to implementation.

Conclusions: The service was found to offer a valued clinical benefit; however, strategies that aim to engage clinicians and increase organizational support toward new technology need to be developed.

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KEYWORDS

REACT; psychosis; family work; early intervention; psychoeducation; mental health service; innovation; eHealth

Introduction

The relatives of people with severe mental health problems often face considerable emotional, financial, and practical problems [1,2]. Despite providing the vast majority of care for people with severe mental health problems—and thus saving society, at large, considerable costs [3]—families often receive inadequate support from the mental health care system [4,5]. Recent reviews [6-8] have concluded that family work is an effective intervention both at early and later stages of psychosis. Psychoeducational single or multiple family groups are the gold
standard according to several national guidelines and best practice recommendations [9]; however, despite a generally high satisfaction with family groups, some research has shown that patients, relatives, and staff find the group format resource intensive and time consuming [10]—meeting in groups requires everyone to be at the same place at the same time for longer periods. Because the traditional multifamily group format includes the patient, because the patient may not consent to family participation, relatives are sometimes excluded.

Previous research [6] has emphasized the importance of providing support and psychoeducation to the families of individuals with psychosis; however, both the implementation of evidence-based practices and the availability of skilled psychoeducational family work staff remain limited [11]. A review [12] suggested that one reason could be that families have different needs and preferences when it comes to the timing, length, intensity, and content of the intervention. In addition, staff access to training, lack of available resources, and long distances between families and trained staff can all limit access to family support.

Web-based interventions have the potential to overcome several barriers. They are accessible across geographical areas; information, interventions, and timing can be tailored to meet the needs of the individual; and these interventions can address the needs of relatives without requiring consent from the patient. Web-based interventions have already been offered to the relatives of people with other conditions who need long-term follow-ups, including those with dementia, stroke, age-related illnesses, and brain injury [13-16]. In line with this, the protocol for the Altitudes study [17] describes a purpose-built online social networking program for caregivers of young people with psychosis. The program integrates expert and peer moderation with evidence-based psychoeducation within a single app [17]. Web-based solutions have the potential to be tailored to both needs and technology availability; however, as stated by a review [18] of web-based interventions for mental health disorders, more research is needed to conclude whether and how they ameliorate the burden of relatives.

Furthermore, the introduction of digital interventions requires change in behavior at several levels of health care services. Previous research [19,20] has shown that innovation implementation has proven to be difficult because of the multiple features of health care organizations, such as their task, workforce, leadership, and performance control and measurement systems. In-depth knowledge about how the implementation of technology is received as a method to enhance digital competencies in health care is required [21,22]. For a product or service to be engaging, it must be usable, accessible, desirable, and it must fulfill human-centered design criteria [23].

The Relatives Education and Coping Toolkit (REACT) is a guided self-management intervention for the relatives of people experiencing a recent onset of psychosis. It was developed by researchers at the Spectrum Centre for Mental Health Research in the United Kingdom, Lancaster University, and Lancashire Care National Health Services Foundation Trust) in close collaboration with relatives and patients. The aim of this intervention was to meet the clinical recommendations from the National Institute for Health and Care Excellence to offer education and support to all relatives of individuals with psychosis [24] or bipolar disorder [25]. Early testing has shown its ability to reduce stress and increase coping strategies [26].

REACT was initially developed in paper form and is supported by members of a clinical team via telephone or email. More recently, REACT has been developed into an online toolkit through which support is offered with a moderated peer forum and direct messages. The clinical efficacy and cost effectiveness of offering this online toolkit directly to relatives is currently being tested [27], and the barriers to the implementation of REACT within a clinical service in the UK are currently being evaluated [28].

The main objective was to explore how a blended approach consisting of web-based (a Norwegian version of REACT, REACT-NOR) and phone-based support from skilled family therapists would be received when offered to the relatives of people who had recently experienced their first psychotic episode. More precisely, we wanted to accomplish the following: (1) Investigate how the service was received by relatives and the family therapists. (2) Investigate the impact of the service on relatives’ levels of distress and expressed emotions. (3) Explore the critical facilitators and potential barriers to the implementation REACT-NOR into routine clinical care.

Methods

Setting and Participants

This study was a mixed methods pilot study. The original REACT was translated and designed to accommodate the Norwegian setting. The study was conducted at Vestfold Hospital Trust in Norway, which has a catchment area of 240,000 people and consists of mixed urban and rural areas. The REACT-NOR web program was supported by two nurses who had also been trained in psychoeducational family therapy working in the Hospital Trust. Our initial aim was to recruit the relatives of people experiencing their first episode of psychosis. Despite considerable efforts to promote the project through written communications and oral presentations within the departments involved in the study, many clinicians did not ask relatives to participate. Because of the study’s limited timeframe, we expanded the project to include the relatives of people with a longer history of psychosis and used social media to aid recruitment.

The project was disclosed and discussed with the regional ethics committee. The committee did not regard the project as medical or health professional research as understood by law; rather, the committee saw it as an assessment of a support tool for relatives, hence the project fell outside the provisions of the Health Research Act. The local data protection officer approved the project.

Procedure

Relatives of people experiencing psychosis were included from May 2016 until January 2017. They were either referred by the treating clinicians or self-referred after reading about the project on social media or in a newspaper. All participants were related...
to a person who was, at the time, in treatment for psychosis. After referral, the family therapists informed the relatives about the project and requested written informed consent. Each participant received access to REACT-NOR through a personal key consisting of a username and personal password.

**Intervention**

Since the aim of REACT is to support relatives, it does not require engagement with the person experiencing psychosis. REACT consists of 12 modules (Figure 1): (1) What is REACT? (2) What is psychosis? (3) How to handle positive symptoms; (4) How to handle negative symptoms; (5) How to handle crisis; (6) How to handle difficult behavior; (7) Coping with stress by thinking differently; (8) Coping with stress by acting differently; (9) Mental health services—How do I get the help I need? (10) Treatment options; (11) Resources; and (12) Terms and dictionary. The modules in REACT were based on psychoeducational family therapy and cognitive behavior therapy. Each module started with a psychoeducational theme, which was followed by cognitive behavior therapy–based tasks to help participants reflect on their own situation in view of what they had learned through REACT.

Figure 1. Screen capture image of the webpage with the introduction and a list of the different modules.

REACT-NOR included adjustments to reflect a Norwegian setting. The REACT dictionary was translated and customized, and the individuals in the illustrative case stories were given common Norwegian names. Relevant information about the mental health care services in Norway was added.

The program was available 24 hours a day/7 days a week, as a regular webpage. Participants could move back and forth and read relevant sections at their own pace; however, unlike the original, REACT-NOR did not provide the opportunity to interact online with the family therapists. In the original version, participants could receive support and perform the cognitive behavior therapy–based exercises online. This interactive platform could not be developed for REACT-NOR within the study’s limited budget. Instead, the participants were given a booklet containing the same cognitive behavior therapy–based exercises. The booklet was used actively during consultations with the family therapists. Support was offered by the family therapists on the phone for a maximum of 1 hour per week for 26 weeks to help participants navigate the program and to answer questions related to the program and exercises. To be proactive, the family therapists contacted the participants at least monthly if they had not responded to weekly appointment phone call or had not initiated contact themselves. Before entry into the study, each participant had a face-to-face consultation with their allocated family therapist.

**Support Staff**

The 2 family therapists responsible for the support work in Norway had extensive training in psychoeducational multi- and single-family groups and used their competence when they felt it was appropriate. They were also trained to deliver support for REACT-NOR through standardized training materials provided by the research team at Spectrum Centre for Mental Health Research and through online video consultation (Skype) with trained supporters from Spectrum Centre for Mental Health Research.

**Measures**

**Quantitative Data**

Expressed emotions and stress were assessed at baseline and at the end of the intervention using the Family Questionnaire [29] and the Norwegian version of the Relatives Stress Scale [30,31]. High levels of expressed emotions in relatives have been associated with higher avoidance coping, higher subjective burden, lower perceived patient interpersonal functioning, and worse outcomes [32,33]. The Family Questionnaire is a brief 20-item self-report questionnaire measuring the level of
expressed emotions using a 4-point Likert-scale (never/very rarely, rarely, often, very often). It includes 10 items for criticism and 10 items for emotional overinvolvement. Higher scores represent higher levels of expressed emotions. The Relatives Stress Scale [30,31] was originally developed to measure stress in the relatives of people with dementia. The Relatives Stress Scale consists of 15 items scored on a 5-point Likert scale (never, rarely, sometimes, often, very often/always). Higher scores indicate higher levels of emotional distress, social distress, and negative feelings related to caregiving.

**Digital Analytics**

We used Google universal analytics to analyze the use of the webpage. We collected a ranking of the most visited sections in the tool based on page views (the total number of pages that had been viewed, and repeated views of one page were counted) and a list of most read sections in the tool (the mean user time spent on a particular screen).

**Qualitative Data**

After the intervention, a subset (of the relatives, n=7) was invited to take part in qualitative interviews. The 2 family therapists were also interviewed. Two couples and the therapists were interviewed as pairs; other participants were interviewed individually. All interviews were conducted face-to-face at the office of the family therapists in Vestfold Hospital Trust. These interviews were digitally recorded and transcribed by LN. The number and selection of participants and the joint group format were chosen for pragmatic purposes; there were limited resources (2- to 3-hour drive for KLR and LN between Vestfold and Oslo), and all participants had to meet during the daytime. LN carried out the interviews with KLR as a co-moderator. All interviews were conducted within 2 months of the end of the project, and each one lasted approximately 60 to 70 minutes. The interview guide was designed to capture the variety of experiences in using the REACT-NOR including general impressions, areas of specific feedback, perceived impact, and the ability to engage both relatives and family therapists. The interview guide for the family therapists included questions about their opinions on facilitators and barriers to implementation of REACT-NOR in future clinical care.

**Researchers’ Perspectives**

LN is a psychiatric nurse, who, at the time of the interview, was employed by Oslo University Hospital. She has extensive clinical experience, is a trained psychoeducational family therapist, and holds a PhD in family work in first-episode psychosis. She has been collaborating with relatives and patients over many years both as a clinician and as a researcher. KLR is a psychiatrist and holds a PhD focusing on first-episode psychosis. She led the REACT-NOR pilot study and has extensive clinical experience, but no training in psychoeducational family therapy.

**Analysis**

The quantitative data were analyzed with two-sided paired t tests. The level of significance was set to \( P=0.05 \). When a single item was missing in one of the scales, the imputed mean for the group for that single item was used. The qualitative data were analyzed according to the principles of systematic text condensation [34,35]. Interviews were transcribed modified verbatim (meaning that instances of “hmmm” and half sentences that were not relevant to the research question such as comments on lack of parking spaces or the temperature of the coffee were not transcribed). Analysis was conducted in 4 steps: (1) LN read through the interviews to achieve an overall impression and to look for preliminary themes related to the REACT-NOR intervention. (2) The text was broken down into manageable units, and related meaning units were organized in code groups. (3) The meaning was condensed under each code group. (4) An analytic text about each category relevant for the study was developed. The transcripts were reviewed 3 or more times by LN, KLR, and KG to ensure that the data were accurately represented and interpreted. The quantitative and qualitative data were analyzed separately to distinguish contributions and to allow for different perspectives to emerge. Step 2 and step 3 were analyzed using NVivo (version 10; QSR International LLC).

**Results**

**Quantitative**

Using social media, we were rapidly able to recruit 19 relatives: 11 mothers, 6 fathers (including 1 stepfather), 1 sibling, and 1 spouse. Out of these, 6 were couples, and 1 was a sibling whose parents (mother and stepfather) were taking part in the project. The stepfather and the sibling withdrew during the study period because they felt it was enough to have 1 family member attending, and 1 mother found it difficult to engage in the program because her child was in the middle of a crisis and had a multitude of tasks demanding her attention; therefore, 10 mothers, 5 fathers, and 1 spouse completed the pilot. The median age was 54 (range 42-68) years, and the median duration of time spent caring for an ill relative was 12 (range 1-204) months. We lacked data on age and duration of caring time spent for 1 participant. For 1 participant, there was no baseline data for Relatives Stress Scale; this participant was excluded from the analysis. Imputation for a missing item was applied in 3 separate cases: 1 item missing for Relatives Stress Scale at baseline, 1 for Family Questionnaire at baseline, and 1 for Relatives Stress Scale at 26 weeks.

There was a significant reduction in the level of expressed emotions from baseline to postintervention (baseline: mean 45.6, SD 7.3; postintervention: mean 42.1, SD 7.0; \( t_{14}=2.3, P=0.03 \), with a parallel reduction in perceived level of stress (baseline: mean 24.6, SD 9.8; postintervention: mean 20.0, SD 8.6; \( t_{14}=2.6, P=0.02 \)). The median number of telephone consultations with the REACT-NOR support team was 8 (range 4-11), and the telephone consultations lasted from 5-60 minutes.

The analysis of digital data found a preference for themes related to how one would handle symptoms and control stress (Table 1).

---

**Table 1**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Management</td>
<td>Strategies to cope with the illness</td>
</tr>
<tr>
<td>Stress Reduction</td>
<td>Techniques to manage stress</td>
</tr>
<tr>
<td>Communication Support</td>
<td>Methods to improve family interaction</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 1. User patterns from the website (highest exposure on top).

<table>
<thead>
<tr>
<th>Most visited sections</th>
<th>Most read single pages</th>
<th>Mean time per page (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is psychosis?</td>
<td>How to control your stress level</td>
<td>5.22</td>
</tr>
<tr>
<td>How to handle negative symptoms</td>
<td>Negative symptoms—top 10 tips</td>
<td>4.46</td>
</tr>
<tr>
<td>How to handle crisis</td>
<td>Family work</td>
<td>4.09</td>
</tr>
<tr>
<td>How to handle positive symptoms</td>
<td>The most usual thought traps</td>
<td>4.01</td>
</tr>
<tr>
<td>Stress—thinking differently</td>
<td>How can I think differently?</td>
<td>3.34</td>
</tr>
<tr>
<td>How to handle difficult behavior</td>
<td>Set up a personal plan</td>
<td>3.13</td>
</tr>
<tr>
<td>Stress—how to do things differently</td>
<td>Good advice</td>
<td>3.08</td>
</tr>
<tr>
<td>What do we mean by mental health care?</td>
<td>Guide to “the fantastic seven golden rules”</td>
<td>2.50</td>
</tr>
<tr>
<td>Treatment options</td>
<td>Usual consequences of psychosis</td>
<td>2.45</td>
</tr>
</tbody>
</table>

Qualitative Interviews

Themes from the qualitative interviews were (1) the toolkit turns knowledge into action, (2) the service strengthened the feeling of being involved, and (3) factors important for engagement and implementation (Table 2).

Table 2. Themes and subthemes with exemplifying quotes.

<table>
<thead>
<tr>
<th>Main themes and subthemes</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The toolkit turns knowledge into action</td>
<td>“[You get],...both counseling and advice on how to best handle it. It is like asking for help in the store when you can’t find what you are looking for because you’re lost in a corner. And that’s easily done.” [mother]</td>
</tr>
<tr>
<td></td>
<td>“You can jump back and forth [in REACT-NOR] as you need, and I really did.” [mother]</td>
</tr>
<tr>
<td>The service strengthened the feeling of being involved</td>
<td>“...We hope that [NN] and NN will get well and that we won’t need any more help. But if something should happen, it is nice to know where you can look up more information so you can avoid the old traps.” [mother]</td>
</tr>
<tr>
<td></td>
<td>“...[as the patient refused the father to participate in the treatment]...This has been something he could accept for his own sake, so for him, it [participation without consent] was important.” [family therapist]</td>
</tr>
<tr>
<td></td>
<td>“...I feel it is an advantage that the supporter is a professional, yes...one with a professional background.” [mother]</td>
</tr>
<tr>
<td></td>
<td>“I had to ask [family therapist] if it seemed ok how I chose to do things...you have to get some support for how you handle the situation because I didn’t know if what I was doing was normal.” [mother]</td>
</tr>
<tr>
<td>Factors important for engagement and implementation</td>
<td>“[REACT]...has a nice layout and is easy to use; everybody gave me that feedback...” [family therapist]</td>
</tr>
<tr>
<td></td>
<td>“...It is important practice...and at the same time to get support from someone who knows the program.” [family therapist]</td>
</tr>
<tr>
<td></td>
<td>“...When I have met her here [at the hospital], I knew that that she is real. The conversations are kind of intimate, and you don’t want to share this with anyone.” [mother]</td>
</tr>
<tr>
<td></td>
<td>“People are generally positive, but it [the implementation of new interventions] is drowning in everything else that has to be remembered.” [family therapist]</td>
</tr>
<tr>
<td></td>
<td>“I think self-referral is much better...[Ordinary referral]...will make it less available and delay the start-up.” [family therapist]</td>
</tr>
<tr>
<td></td>
<td>“…[negative symptoms] could have been treated more thoroughly” [father]</td>
</tr>
</tbody>
</table>

For patient anonymity and privacy, this is a pseudonym.

The Toolkit Turns Knowledge Into Action

All participants approved of the toolkit and found it easy to understand. They reported an increase in knowledge on two levels: passive knowledge that dealt with theoretical knowledge of the disorder, its diagnosis, and treatment; and action-oriented knowledge gained through completing the tasks based on their personal situation. This knowledge made them feel more in control of the situation. This was in line with the findings in Table 1. The relatives acknowledged the need for both knowledge categories, but they favored the action-oriented category which gave them practical tools:
A bit like icing on the cake, yes...it linked stress and stress management to the disease, which comes and goes. Sometimes, everything is ok, and then, there is a new breakdown, and it’s like pressing a button. The situation reactivates my own fear, but then, I can look at the worksheet again. [mother]

Relatives appreciated the stepwise approach to psychoeducation, going from basic knowledge (with examples and illustrations) to in-depth knowledge; however, most relatives did not work through the toolkit systematically, but went back and forth according to their momentary needs. Service logos from Lancashire Care National Health Services Foundation Trust, Lancaster University, and Oslo University Hospital were visible in the program’s interface; this was important because it assured them that the information was trustworthy.

The Service Strengthened the Feeling of Being Involved

All interviewed relatives had felt ignored by the mental health care system and had felt personally responsible for initiating contact and providing relevant information about symptomatology or how the person had been before the onset of illness. From their perspective, this lack of engagement acted as a barrier to an understanding of both the patient and the situation. Furthermore, this was followed by a feeling of lack of acknowledgment for the impact the disease had on their own lives:

To be involved in the treatment makes me feel that someone sees me as a person. The main focus is the person being ill, and that is how it should be, but I feel a bit ill myself sometimes because it influences my entire life...there has been quite a few limitations in what I have achieved for myself. [mother]

The experiences of the relatives with REACT-NOR was in stark contrast to many of their previous experiences with health care services. They described useful and caring conversations, the feeling of being listened to, being allowed to verbalize their concerns and being able to discuss problem solving. REACT-NOR also provided them with a vocabulary that made it easier to communicate about the situation, not only with health professionals, but also with friends and family. Most relatives and the family therapists felt that a first face-to-face meeting was important; however, because 1 relative had to change family therapist support with REACT-NOR as important for their engagement. By talking to a family therapist, they received professional advice and support, and this was especially valued when they were feeling emotionally out of control and were worried if their reactions were normal or not:

...I think it is important to talk to someone who also knows the patient. Then, you know a little more about what it is all about, and you can relate to why you are in this stressful situation and why you react as you do to specific events... [mother]

Factors Important for Engagement and Implementation

Engagement

Both the family therapists and relatives underlined the user-friendliness of REACT-NOR and how important functioning technical solutions can be. All but the oldest participant preferred online worksheets to the booklet. Both family therapists preferred an online communication channel because this allowed them to answer questions more efficiently and to prepare for consultations; however, both family therapists and 1 relative had concerns about the self-censorship that might occur if you were to use an online messaging system:

It is even worse to write the questions online, to formulate the message, to get it right...I might extensively use the return tab; I cannot articulate this way. It is better like this...you take a phone call and just say how it is. [mother]

Several relatives had previously attended psychoeducational courses, but they had found it difficult to focus on themes that were not relevant to them at the time. A participant described their situation as being in an everlasting storm that made it difficult to remember the given information. The online format was favored because it was accessible and enabled the participants to read and reread information when needed. This was in line with the family therapists’ experience:

When working with specific chapters, one tries to support, but the relative’s concerns are often related to the sick person they are caring for and how they are coping and handling these challenges. [family therapist]

All relatives pointed at the blended approach which combined family therapist support with REACT-NOR as important for their engagement. By talking to a family therapist, they received professional advice and support, and this was especially valued when they were feeling emotionally out of control and were worried if their reactions were normal or not:

There is no single element that has worked...I took a pick of what I could get, but there was one important element; this was not a friend, not close family but someone able to put things in perspective, and that was exactly what I needed. [mother]

The family therapists felt that their knowledge complemented the program. Because of how the content was structured, with stepwise information and based on psychoeducation and cognitive behavior therapy, the family therapists found it easy to tailor the content to the needs of the participants. They felt that being an expert in family therapy made them more competent in meeting the relatives’ needs. One described this as follows:

http://mental.jmir.org/2020/7/e19497/
I use what I know, psychoeducation, normalization, Socratic questioning, asking, reframing and identification of problems...and I believe that we have succeeded. [family therapist]

Even though REACT-NOR was generally liked, there were specific themes identified in the interviews as missing and that may be relevant for engagement: (1) Having more concrete advice concerning cognitive deficits and negative symptoms because these issues were problematic for the relatives but drew little attention from the clinic; (2) a wider cultural approach to psychosis; (3) a wider range of examples of family patterns in the program than the typical nuclear family to increase representativeness and make the program more appealing to a broader group; (4) more information for siblings; (5) the family therapists missing a diagrammatic illustration of the stress/vulnerability model [36], which is widely used by family therapists in Norway; and (6) compulsory treatment being more thoroughly covered. For example:

It sounds so great you think that now he is under compulsory treatment, and then...almost everything is voluntarily anyway...[mother]

**Implementation**

The family therapists underlined the importance of management support from all levels of the organization. Introducing new ways of service delivery demands both flexibility and positive attitudes. The lack of referrals to the program was believed to be partly because of a general unfamiliarity with digital tools in mental health care. Clinicians quickly considered the relatives of the patients under their care as not suitable for the project, and some were concerned about overloading the relatives’ capacity, despite the lack of other options for structured family therapy. The family therapists suggested that this might be overcome by clear management support and the ability to self-refer. The family therapists also underlined the need for reimbursement and economic incentives as crucial to building management support. Norwegian specialist health care is reimbursed based on procedure codes, and implementation strategies must incorporate new policies for the reimbursement of remote care. Finally, the importance of having more than one family therapist at each site was considered crucial since working with new interventions makes one vulnerable because of a lack of people to share experiences with and from whom to receive support.

**Discussion**

**Principal Findings**

The main finding in this study was that relatives were able to receive care and be involved through a blended approach that combined a web-based intervention with support from skilled family therapists. We found some evidence of an improvement in the levels of stress ($t_{15}=2.6, P=.02$) and expressed emotions ($t_{15}=2.3, P=.03$). Our data confirmed that the relatives experienced REACT-NOR as a tool they could use to adjust their own behavior for both the patients and their own needs, which was in line with the results from the UK feasibility study for REACT [26]. We are not able to tease out the relative contribution of the REACT-NOR versus provision of professional support by family therapists on outcome; however, access to REACT-NOR was mentioned by both relatives and family therapists as a valuable and flexible tool that aided both information seeking and conversations. Both relatives and family therapists gave the impression that the blended approach optimized the intervention.

The ability to adjust timing and content according to their own needs was valued and was in contrast to how regular family education is offered in Norway—generally provided as a classroom teaching experience with a fixed set of themes. Family therapy is often limited because of lack of consent from the sick family member and resources. In this intervention, REACT-NOR provided relatives with both education and problem-solving skills, independent of the patient, and therefore, did not require their consent. Furthermore, the exclusive focus of the family therapists on the relatives’ needs was valued. Even though some relatives preferred that the family therapists knew the patient, the ability to feel free to receive care without concern about a breach of confidentiality was important. It may also explain the good working relationships despite the lack of regular face-to-face contact. These positive reports were similar to findings from previous research [37] which showed that relatives seemed to benefit from having the opportunity to tell their stories. Indeed, it has been reported that the relatives of people with schizophrenia are up to 10 times more likely to be socially isolated than people in the general population [38].

There were, however, areas that were not sufficiently covered. Negative symptoms and cognitive deficits required more attention; these symptoms are some of the major reasons for disability in psychotic disorders [39], and the relatives are the ones facing the problems that the symptoms cause. Treatments such as cognitive remediation, vocational rehabilitation, and cognitive behavior therapy for psychosis [40-42] could have been described in more detail in the program. A wider approach, including a multicultural understanding of psychosis and examples of mixed family patterns in the stories presented in the program may be warranted. This might be especially important because recent research underlines the different cultural norms for caregiving and in caregiving experiences [43].

It was difficult to recruit relatives through typical hospital pathways. Previous research [22] has emphasized that some of the common factors hampering the implementation of new technology is a lack of knowledge about technology. According to a meta-review by Ross et al [44], clinicians fear the loss of autonomy, have concerns about liability, and have concerns about patient privacy and security being compromised, all of which act as barriers to implementation. Clinicians may also perceive technology as a threat to the patient–health professional relationship. Ross et al [44] suggested involving the eventual users of the program in its development and implementation, improving leadership, implementing friendly and context-aware user interfaces, and providing better education. In addition, demonstrating the benefits to health professionals by having them participate in evaluating the intervention may increase their acceptance of digital interventions. We would further suggest that implementation plans for new technology in health care consider the importance of management support.
care should include methods such as simulation training and visualization, to demonstrate how the therapy will be carried out.

The average reading time on each web page was low compared with regular services offered in a face-to-face setting; however, compared to the length of typical web-based interactions, an average time spent per page that lasts minutes, not seconds, suggests valued content [45]. More research is needed to explore how much time is needed for this type of intervention to work, highlighting the need for more knowledge about usage characteristics [46], ie, how relatives engage with the toolkit.

Furthermore, it has been suggested that the use and uptake of different types of health care services such as self-help versus professional support may be modulated by extent of the toll on mental health that are they are experiencing as a result of their situation [47]. In general, it would be difficult to tell if a decline in use or a low amount of time spent using a website or web-based intervention was as a result of ineffectiveness of the opposite (ie, that the user required less help as they improved). If the intervention provided useful strategies, relatives may have been prevented from experiencing further distress, and this may have reduced their need for help. Attrition and nonuse may thus reflect the health service’s capacity to offer flexible solutions and, as such, not necessarily reflect failure. Future research should take this into account and study attrition from eHealth separately [48].

Strengths and Limitations
The strengths of this study included the mixed method design, where we explored the perspectives of both the relatives and the clinicians; however, there were limitations. This was a small pilot study, and we were only able to include 2 family therapists. The results should be interpreted with caution regarding generalizability. The pre and postdesign with no control group did not allow us to say that the observed reduction in distress was caused by the intervention, and the sample may not have been representative, because they were chosen for pragmatic reasons. Furthermore, we were not able to recruit the relatives of people with ethnic backgrounds other than Norwegian. Change in recruitment procedure and wider inclusion criteria due to recruitment problems may have affected our results. We were not able to draw conclusions regarding relatives of patients with first-episode psychosis as we ended up with a mixed sample, and there may have been a selection bias towards female relatives who tend to be more active with regard to health information on social media such as Facebook [49].

Conclusions
We found REACT-NOR to be an interesting method for a blended approach for therapy for families dealing with psychosis. Most families do not receive family interventions because of a lack of resources, geographical distance, or lack of consent from the patient. Web-based programs such as REACT-NOR are a valid alternative. REACT was not designed to replace other approaches, but more research should be carried out to explore how it can be used as support in blended approaches.

Acknowledgments
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Conflicts of Interest
REACT was originally developed and tested with funding from the National Institute for Health Research in the United Kingdom. FL was the chief investigator on these grants.

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Abbreviations

- **REACT**: Relatives Education and Coping Toolkit
- **REACT-NOR**: Norwegian version of Relatives Education and Coping Toolkit

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Abstract

Background: A small number of studies have found that digital mental health interventions can be feasible and acceptable for young people experiencing first-episode psychosis; however, little research has examined how they might be blended with face-to-face approaches in order to enhance care. Blended treatment refers to the integration of digital and face-to-face mental health care. It has the potential to capitalize on the evidence-based features of both individual modalities, while also exceeding the sum of its parts. This integration could bridge the online–offline treatment divide and better reflect the interconnected, and often complementary, ways young people navigate their everyday digital and physical lives.

Objective: This study aimed to gain young people’s perspectives on the design and implementation of a blended model of care in first-episode psychosis treatment.

Methods: This qualitative study was underpinned by an end-user development framework and was based on semistructured interviews with 10 participants aged 19 to 28 (mean 23.4, SD 2.62). A thematic analysis was used to analyze the data.

Results: Three superordinate themes emerged relating to young people’s perspectives on the design and implementation of a blended model of care in first-episode psychosis treatment: (1) blended features, (2) cautions, and (3) therapeutic alliance.

Conclusions: We found that young people were very enthusiastic about the prospect of blended models of mental health care, in so far as it was used to enhance their experience of traditional face-to-face treatment but not to replace it overall. Aspects of blended treatment that could enhance clinical care were readily identified by young people as increasing accessibility, continuity, and consolidation; accessing posttherapy support; strengthening the relationship between young person and clinician; and tracking personal data that could be used to better inform clinical decision making. Future research is needed to investigate the efficacy of blended models of care by evaluating its impact on the therapeutic alliance, clinical and social outcomes, cost-effectiveness, and engagement.

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KEYWORDS

Blended Treatment; Psychotic Disorders; Digital Intervention; Adolescent; Young Adults; mHealth
Introduction

If you think about it, our online life is integrated with our physical life... It wouldn't really make sense not to try and integrate it. [Frieda, 23]

The term psychosis refers to a serious mental health condition characterized by impairments in thought, perception, mood, and behavior and often manifests in hallucinations and delusions [1]. First-episode psychosis refers to the initial onset of psychosis and typically emerges in late adolescence and early adulthood [2,3]. Due to its onset during this important developmental stage, first-episode psychosis can cause severe disruptions to a young person’s education, employment, and interpersonal relationships [4]. If left untreated, first-episode psychosis can have grave long-term psychological and functional consequences and is often associated with persistent comorbid mental and physical health conditions [4].

Receiving treatment in the first 5 years following a diagnosis of psychosis may be critical to maximizing psychological and functional recovery [5-8]. Therefore, the development of early intervention services in the youth mental health field has been integral to improving clinical outcomes for young people experiencing first-episode psychosis [6,7]. While these improvements are significant in the short to medium term, there is evidence that positive clinical gains decline over time once a young person is discharged from early intervention services [9]. Current research suggests that providing treatment for a prolonged period of time (ie, extended across a full 5-year period following diagnosis) could be effective in maintaining clinical gains and improving social functioning over the longer term [7,10,11].

The term digital intervention refers to the digital delivery of psychosocial support and information, symptom monitoring, clinical connection, and peer connection through the use of technology such as computers, smartphones, and wearables [12]. Digital interventions have the potential to provide efficient avenues to extend treatment for young people experiencing first-episode psychosis [3,13,14]. It is estimated that up to 89% of people aged 16 to 25 years access social media daily [15], which makes digital intervention particularly relevant to adolescent and young adult populations. Importantly, young people experiencing first-episode psychosis also endorse digital pathways as a valuable mode through which to access mental health support and information [13,15,16]. To date, however, uptake of and engagement with digital mental health interventions are low, and attrition rates for mental health interventions, in general, are high [13,17]. Furthermore, most online interventions are focused on initial or short-term engagement, and little is known about maintaining long-term engagement [18].

Some studies have found that digital mental health interventions can be feasible and acceptable for young people experiencing first-episode psychosis; however, not many have examined how they might be blended with face-to-face approaches in order to enhance care [19]. The term blended treatment refers to the integration of digital and face-to-face mental health care [20], which has the potential to capitalize on the evidence-based features of both individual modalities while exceeding the sum of its parts; this integration could bridge the online–offline treatment divide and better reflect the interconnected, and often complementary, ways young people navigate their everyday digital and physical lives.

In this study, face-to-face treatment refers to the specialist service provided by the Early Psychosis Prevention & Intervention Centre which is delivered at Orygen, a mental health service for young people aged 15 to 25 years who reside in the western and northwestern regions of metropolitan Melbourne, Australia. Specifically, the Early Psychosis Prevention & Intervention Centre provides recovery-oriented care for a period of up to 2 years to young people experiencing first-episode psychosis [21]. The service includes weekly case management, medication management, carer support, and psychosocial groups [21]. Alternatively, a digital intervention refers to the centralized online platform, Horyzons [3], that affords young people digital access to evidence-based therapy, an online social network, clinical support, and peer support. A blended model of care in this study, therefore, refers to an interconnected model of digital and face-to-face treatment. In this context, a young person may have access 24 hours a day/7 days a week to a digital platform that delivers personalized evidence-based therapy, social connection with other young people, peer moderation, and clinical moderation delivered by their face-to-face clinician, in addition to their regular case management service.

Initial uptake and sustained adherence to digital mental health interventions remain low [13,17]. This is problematic as young people may not receive the minimum dosage of digital treatment necessary in order to receive positive clinical effects [22]. Involving young people in the development of mental health services and digital interventions has been recognized as both a practical and ethical imperative in the mental health domain [23]. Involving end users, the young people that the service is intended for, in the design and implementation phase increases both usability and credibility [17], which may lead to higher levels of engagement overall [17].

To date, little is known about young people’s perspectives on blended models of face-to-face and digital treatment in first-episode psychosis or in mental health treatment in general. Therefore, this study aimed to gain young people’s perspectives on the design and implementation of a blended model of care in first-episode psychosis treatment.

Methods

Study Setting and Design

This qualitative study was underpinned by an end-user development framework [24] and based on semistructured interviews as part of a broader blended treatment research project at Orygen Digital, Orygen’s digital mental health arm. End-user development has traditionally been used in the human–computer interaction and software development fields to anticipate and flexibly address the needs of the intended user [24]. With the advent of digital intervention in the psychological...
end-user development is now widely used in psychological research as an effective framework to gather and incorporate relevant feedback into the design and implementation of an intervention in a cost-effective and timely way [24].

In this study, participants had the unique experience of completing a previous 18-month to 2-year face-to-face engagement period with the Early Psychosis Prevention & Intervention Centre, followed by participation in a long-term digital mental health intervention known as Horyzons. The Horyzons randomized controlled trial [3] randomly allocated participants, who were from 16 to 27 years of age, to either an intervention (n=85; access to the Horyzons platform in addition to treatment as usual) or a control condition (n=85; treatment as usual). The Horyzons platform was a multicomponent digital platform that included evidence-based online therapy (Figure 1), peer moderation, clinical moderation, and an interactive online social network (Figure 2). Young people assigned to the intervention were allocated a key moderator who supported the participant in completing relevant therapy modules, participating in group discussions, interacting on the social network, and engaging in individual web-based conversations with clinical and peer moderators. The platform is discussed in length in the Horyzons trial protocol paper [3]. The Horyzons randomized controlled trial was registered in the Australian New Zealand Clinical Trials Registry (ACTRN1261400009617).

Figure 1. How to flourish webpage.

Figure 2. Interactive online social network webpage.
Participants

Young people were eligible to participate in this study if they (1) were previous clients of the Early Psychosis Prevention & Intervention Centre in Melbourne, Australia and (2) had been allocated to the intervention arm of the Horyzons randomized controlled trial.

Young people who met the criteria (n=10) were randomly contacted via phone call or text and invited to participate in a semistructured qualitative interview exploring their perspectives on the design and implementation of a blended model of face-to-face and digital mental health treatment. All 10 consented and were interviewed for the study.

Data Collection

Ethics approval was obtained from the Melbourne Health Research and Ethics Committee in 2018 (HREC/13/MH/164). Data were collected from October 2018 to March 2019. Participants specified their preferred interview locations, and as such, interviews took place in a variety of locations which included the Orygen clinic, libraries, cafes, and participants’ homes. A semistructured interview guide was designed to explore participant perspectives of blended models of face-to-face and digital treatment for first-episode psychosis. The interview questions focused on perspectives on blended models of care, perspectives on how to deliver blended models of care, and perspectives on functions to include in a blended model of care. Author LV had previously established relationships with all of the participants as a research assistant on the Horyzons randomized controlled trial. Before the interview commenced, participants were provided with a plain language consent form and an information statement detailing the study, and they were given the opportunity to ask questions about the study. All interviews were audio-recorded and transcribed verbatim. All participants were reimbursed Aus $20 (approximately US $13.91) for their participation.

Data Analysis

Given the end-user development framework and exploratory nature of the study, thematic analysis was considered the most appropriate method of data analysis [25]. Author LV completed the analysis and was supervised in this process by senior author SB. SB and LV had regular face-to-face meetings in which codes, themes, and LV’s thematic interpretations were interrogated thoroughly by SB to ensure rigor. Any disparity between authors regarding the analysis was debated until a resolution was reached. There were no a priori themes; all themes were derived directly from the data during the analysis process. Familiarization with the data was achieved by reading and rereading participant transcripts. Initial codes were assigned to the transcript to signify meaning, and codes that were similar within and between transcripts were noted. Aligned with a thematic analysis framework, the codes within and between transcripts were grouped into preliminary themes and reviewed in relation to all other themes. Some themes were superordinate—that is, the theme represented a whole category—while other themes were subordinate to the larger themes—these became subthemes [25]. In accordance with Morse’s [26] recommendations to maintain rigor, thick and rich descriptions of the themes were written up, these rich descriptions were then further debated between authors LV and SB.

Results

Overview

Participants (n=10) aged 19 to 28 (mean 23.4, SD 2.62) years were included in the study; 70% (7/10) were female, and 30% (3/10) were male. Female participants were all cisgender. Of the male participants, 2 were cisgender and 1 was transgender (Table 1).

Three themes emerged relating to young people’s perspectives on the design and implementation of a blended model of care in first-episode psychosis treatment: (1) blended features, (2) cautions, and (3) therapeutic alliance (Figure 3).

Table 1. Alias, age, and gender of participants.

<table>
<thead>
<tr>
<th>Alias</th>
<th>Age</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tristan</td>
<td>25</td>
<td>Male</td>
</tr>
<tr>
<td>Justine</td>
<td>19</td>
<td>Female</td>
</tr>
<tr>
<td>Ling</td>
<td>25</td>
<td>Female</td>
</tr>
<tr>
<td>George</td>
<td>22</td>
<td>Male</td>
</tr>
<tr>
<td>Amita</td>
<td>22</td>
<td>Female</td>
</tr>
<tr>
<td>Caroline</td>
<td>26</td>
<td>Female</td>
</tr>
<tr>
<td>Milly</td>
<td>24</td>
<td>Female</td>
</tr>
<tr>
<td>Frieda</td>
<td>23</td>
<td>Female</td>
</tr>
<tr>
<td>Vinh</td>
<td>28</td>
<td>Male</td>
</tr>
<tr>
<td>Isla</td>
<td>20</td>
<td>Female</td>
</tr>
</tbody>
</table>

http://mental.jmir.org/2020/7/e18990/
Blended Features

**Accessibility, Continuity, and Consolidation**

Having multiple pathways to a case manager was identified by almost all participants as an important accessibility feature of a blended model of treatment. For instance, Tristan identified that access to his therapist through a digital platform would be useful when it was not “realistic” to get to a physical location or speak on the phone because of commitments such as travel or work. Similarly, Justine suggested that it would be beneficial to have access to her clinician through an online platform for those occasions when she could not attend her therapy appointment in person because

...maybe your mum can't drive you there or you can't take public transport 'cause you're not in the mindset. [Justine, 19]

In both Tristan and Justine’s scenarios, an alternate pathway to their clinician through a digital platform would safeguard against missed therapy sessions due to physical or psychological barriers.

Ling proposed that a digital platform could assist young people in moments when they are without a scheduled appointment with their clinician, but are in need of support. She suggested that, if faced with this common issue, young people could access resources and support via the platform instead. George reiterated that having resources and information available on a digital mental health platform would be useful because

...it provides people with quality information, rather than what they can possibly source themselves...so I guess it saves a lot of wasted time for that person, at least you're getting curated knowledge from a bunch of professionals rather than just what Google tells you. [George, 22]

Both Ling and Justine also noted that, in instances where young people were not able to speak with their clinician, they could connect with other young people online for peer support:

...there's many users that have been through what you have been through or are like going through the same thing, and you can talk to each other and connect to each other. [Ling, 25]

Tristan also observed that a digital therapeutic platform could be helpful for young people who were linked in with a mental health service, but were on the waitlist to see a clinician because

...sometimes you got to wait weeks to see a psychologist. [Tristan, 25]

He suggested that the platform could offer assistance during this time period because

...it's accessible and it's completely, like, anonymous. So, like, you have that information there in a time of need. [Tristan, 25]

Finally, he noted that there are times when young people can feel overwhelmed by the amount of therapeutic information or by the content of a therapy session. He suggested that a digital platform could be used to help consolidate the information, for instance,
Posttherapy Support

Multiple participants acknowledged feeling sad or “down” after a therapy session and identified that the platform could be used in the postsession period to combat negative feelings and feel connected to others on the therapeutic social network who may be having similar experiences. For instance,

...sometimes after a session, you talk about all your feelings and then you just have to go back to your life. It would be good to have an app in those moments, something to go back to... [Amita, 22]

Mood and Environment Tracking

The majority of participants identified that a digital function for tracking mood and environment could be useful in blended mental health treatment. One participant, however, noted that young people may purposively underreport mood.

Caroline identified that mood tracking apps had been useful to her in the past and proposed that pertinent measures could be identified in collaboration with her clinician, and the digital platform configured to track relevant data and make personalized suggestions based on her information. For example,

Hey, you’ve been feeling really irritable and hot, and you’re getting headaches. Maybe you’re dehydrated. Drink some water. [Amita, 22]

Caroline suggested that the ability to record the environment in addition to her mood would be helpful as she has noticed that her environment could have an impact on her mood and levels of paranoia. For instance,

I feel really suffocated here 'cause I don’t like being around people or like be in this type of situation. But, if I’m in an open space I feel more isolated but relaxed and calm, and I don’t feel paranoid as much. [Caroline, 26]

Caroline identified that if she could reflect on her user data with her clinician, she could make informed decisions about her environmental choices based on this information.

Alongside Caroline’s suggestion to record the environment as well as mood, George suggested that there could also be an option to record hashtags or keywords that are relevant to the young person’s thoughts and feelings. He noted that being made aware of correlations between particular mood trends and particular hashtags in order to better guide positive decision making could be an incentive to use the digital platform. Furthermore, he suggested that all user hashtags could be collated anonymously on the digital platform to generate a public cloud that could act to normalize young people’s thoughts and feelings to the broader group and be used to inspire conversational topics on the social network or in therapy sessions.

Milly advised that, in the early stages of her mental health care, she would underreport the depth of her low moods as she was afraid her treating team might increase her medication as a result. She said,

I didn’t want them to know that I was really down, ‘cause I didn’t want my meds to increase. That was the main thing. I didn’t like taking meds. [Milly, 24]

She identified that other young people might also underreport the extent of their symptoms on a mood or mental health tracker for similar reasons.

Cautions

Importance of Face-to-Face Contact

While participants expressed strong enthusiasm for a blended model of care, most were careful to communicate that they did not want a digital platform to replace the physical face-to-face experience of mental health treatment.

Tristan identified that he took information that was delivered to him face-to-face from a clinician more seriously than he took online advice because of the impact of the clinician’s tone of voice and body language. For Tristan, a digital platform could not embody these aspects of communication, and he acknowledged that if his Horyzons moderator had not, by complete chance, also been his face-to-face clinician then he may not have taken her digital therapy suggestions “as seriously” as he did. In a similar vein, both Isla and Ling shared that it can be harder to talk online and find the right words to express yourself, but it can be easier in person because “emotions just show on your face.” Isla also commented that purely online conversation could lead to miscommunication that would not be conducive to the therapeutic relationship, for instance, she said,

...like “hi” it can be processed in a polite way, and it can be processed in a rude way or [an] ignorant way, it really depends on what you see really. [Isla, 20]

Vinh and Justine suggested it can be challenging for young people to discuss new or sensitive information in person and identified that the young person could speak to their clinician via webchat, even in the same room, as a way to work up to speaking about the topic face-to-face.

Privacy

Amita acknowledged that young people are not always open and honest with their clinicians and suggested they may be less inclined to share openly on a digital platform if they knew it would be read directly by their treating clinicians. Similarly, Caroline asserted that she would no longer share openly on a digital platform if she was aware her clinician could see what she was posting and potentially change her course of treatment based on that information, particularly if it could result in a medication increase:

Yeah, maybe I wouldn’t be too open [long pause] now that I think about it yeah, I fully wouldn’t. [Caroline, 26]
Therapeutic Alliance

Young Person and Clinician

Both George and Tristan were two participants interviewed who were randomly allocated an online moderator for the Horyzons randomized controlled trial that by chance also aligned with their face-to-face clinician at the Early Psychosis Prevention & Intervention Centre. They both felt that their relationships with their clinicians developed at a faster rate because they were “exposed” to each other more—both online and face-to-face. Tristan expressed that he only completed tasks on the Horyzons platform because they were set for him by his face-to-face clinician. He believed, “you could pull away more easily” from a moderator if you had not previously met them face-to-face. Tristan observed that it would be “a game-changer” for young people’s mental health treatment if the moderator were also the young person’s face-to-face clinician.

Amita identified that she would like someone to talk to “...24 hours a day,” and she “literally, sometimes I literally just have to scream on the keyboard. [Amita, 22]

Tristan identified that having work set on the app between face-to-face therapy sessions would encourage him to complete it during the week due to a sense of accountability to his clinician, for instance,

Oh, I’m going to see her next week. Should probably get that done before she mentions it in my session. [Tristan, 25]

Ling identified “regularity” as a key factor in increasing her comfort levels with a clinician and identified increased time spent in a digital and face-to-face combination could contribute to this experience. George and Milly both advised that having digital access to their clinician outside of a face-to-face session through a digital platform could “strengthen” the relationship. Similarly, Justine suggested that a digital platform used in conjunction with face-to-face treatment would be a means to feel connected and supported by your clinician “even when they’re not there.”

Young Person and System

Amita suggested a chatbot could be useful in fulfilling therapeutic needs. Chatbots have been identified as effective and enjoyable emerging technology within the mental health landscape [27]. The digital tool refers to hardware or software that uses artificial intelligence to imitate human dialogue in a task-orientated interaction between itself and a person [27]. Amita identified that she would like someone to talk to “...24 [hours a day],” and she “literally, wouldn’t mind” if that need was serviced through a chatbot:

Like, sometimes people just have to say blah, blah, blah, blah and then they feel fine... Like, sometimes I literally just have to scream on the keyboard. [Amita, 22]

Furthermore, if the chatbot was an automated function, Amita noted that it would require less “effort” for her to speak to it than to a human clinician.

Discussion

Principal Findings

This qualitative study used an end-user design approach to explore young people’s perspectives on blended models of face-to-face and digital care in first-episode psychosis treatment. We found that perspectives could be grouped into three overarching themes and that these themes can be practically applied to the design and implementation of emerging blended models of mental health care.

We found that young people were very enthusiastic about the prospect of blended models of mental health care, in so far as it was used to enhance their experience of traditional face-to-face treatment but not to replace it overall. Aspects of blended treatment that could enhance clinical care were readily identified by young people as increasing accessibility, continuity, and consolidation; accessing posttherapy support; strengthening the relationship between young person and clinician; and tracking personal data that could be used to better inform clinical decision making. Overall, young people communicated that the digital experience could not embody the communication characteristics of face-to-face treatment. Tone, body language, and facial expressions were identified as important aspects of communication that young people felt would be lacking in a purely digital space. Previous research [28], however, has suggested that the benefit of online anonymity is particularly beneficial to some participant groups, and this benefit can work to counterbalance the loss of nonverbal communication. Furthermore, the potential that young people may underreport symptoms on mood tracking tools was identified. Concern centered on fears of clinicians and services responding to changes in clinical states in unwanted ways, such as changes to medications when reporting low mood. This has been reported in other studies [29,30], reflecting the importance of considering the role of, and response to, personal clinical information collected in daily life from users of clinical services.

Tracking mood, together with the environment and related keywords, was identified as a useful tool to guide positive decision making. Ecological momentary assessment is a method of recording momentary experiences using a mobile device in the context of daily life [31]. There has been recent interest in the use of information collected in daily life for clinical purposes. For example, one research group [32,33] explored the integration of ecological momentary assessment with standard psychological therapy for people with voice-hearing experiences. People tracked their voice-hearing experiences (and the context in which they occurred) over a week, allowing a clinician to analyze the patterns of occurrence. This was used to provide a formulation of the voices, which informed the selection of relevant intervention strategies. In our study, the use of tracking tools or ecological momentary assessment to identify mood patterns that could be subsequently shared with a clinician to the benefit of the young person’s therapy was identified as potentially useful. The incorporation of a digital tracking tool could support young people working collaboratively with their clinicians in identifying patterns of symptoms, environments, and relationships with other
determinants to inform treatment decisions and enable momentary interventions. This form of collaboration between young people and clinicians is aligned with autonomous and strength-based practice [34]. Importantly, in line with themes from our study, findings of qualitative research have suggested that this approach may fast-track treatment processes by enhancing the personalization of therapy, which would enable more individualized and targeted intervention strategies to be produced more efficiently based on the information gathered [35]. Additionally, an ongoing connection with a clinician, who has access to personal insights about the young person through their data, has the potential to enhance the therapeutic alliance.

The therapeutic alliance refers to the goal-directed, collaborative relationship between client and clinician and is the strongest predictor of client mental health outcomes [36,37]. According to Bordin [38], the alliance comprises three core conceptual elements which include bond, tasks, and goals [36]. One of the strongest findings identified in this study was the perception that a blended model of treatment had the potential to enhance the therapeutic relationship. Integrating a digital platform with the face-to-face experience was consistently endorsed as a means to strengthen the relationship between the young person and their clinician by providing greater consistency (ie, accessible sessions and more regular contact), collaboration (ie, joint decision making), accountability (ie, a sense of commitment to complete tasks on time), and the opportunity to consolidate information. This supports previous findings from Lederman et al [37], in which the experience of technology-mediated mental health therapy was examined and that, like Horyzons, included therapy pathways, a social network, clinical moderation, and peer moderation; Meridian was designed to support carers of young people experiencing mental illness. Lederman et al [37] found that the digital system could create an alliance-like experience for the users. Their research identified that it was likely that the combination of peer support workers, clinical moderators, and different core functions of the platform came together to “facilitate the formation of a state that mirrors therapeutic alliance [37].” The finding that a therapeutic relationship is possible beyond that of only the client–clinician experience is valuable knowledge to the digital mental health field, particularly because the therapeutic alliance is the strongest predictor of mental health outcomes [39].

In addition to the emerging possibility that the therapeutic alliance can develop beyond that of only the client–clinician relationship to incorporate a blended system (resembling client–technology–clinician), the notion of a digital therapeutic alliance between the user and the technology itself (ie, client–technology) is also a burgeoning area of research in the mental health field [27,37,40]. Among other technologies, chatbots are an avenue of such interest. Vaidyam et al [27] identified chatbots as an “effective” and “enjoyable” technology in the mental health setting. Chatbots were similarly acknowledged in this study, as a helpful venting tool and a plausible solution for a mental health service to provide sustainable 24-hour access. The concept of a digital therapeutic alliance between young people and technology or the digital platform itself is a notable avenue for further research.

For many young people who are native users of digital technology within their everyday lives [15] and are interested in receiving care via blended modalities, there is an important opportunity to assist them in strengthening connections with their therapist and offering ways to improve engagement with therapies. As the therapeutic alliance is considered one of the most important predictors of treatment efficacy regardless of the therapeutic approach [39], there is great potential in capitalizing on the ways to enhance this alliance through digital technologies or with digital technologies themselves [40]. The therapeutic alliance that develops through blended treatment has the potential to enhance engagement with both face-to-face and digital therapies through increasing therapeutic intensity and personalization, and by simultaneously addressing poor engagement and treatment continuity which are key issues in the digital health field [13,17].

Future Research

Future research is needed to investigate the efficacy of blended models of care by evaluating its impact on the therapeutic alliance, engagement, and treatment effects. Additionally, the formation of a digital therapeutic alliance between a user and a digital platform or other technology is an emerging area of research worthy of further exploration.

Limitations

Author LV had established relationships with all participants due to a prior role as a research assistant on the Horyzons randomized controlled trial and also completed all interviews in this study. While we found that the existing relationship could be conceptualized as a strength that possibly aided in creating a more open dialogue between interviewer and interviewees, a previous relationship generates an opportunity for participant bias as interviewees may, both consciously and unconsciously, provide answers that they believe will please the interviewer as opposed to what they may genuinely feel [41].

Conclusions

Young people were very enthusiastic about the prospect of blended models in first-episode psychosis mental health treatment. Aspects of blended treatment that could enhance clinical care were readily identified by young people as increasing accessibility, continuity, and consolidation; accessing posttherapy support; strengthening the relationship between young person and clinician; and tracking personal data that could be used to better inform clinical decision making. Tone, body language, and facial expressions, however, were identified as important aspects of communication that young people felt may be lacking in a purely digital space. Furthermore, the potential of underreporting symptoms through mood tracking was identified. Blended care was identified as an avenue through which the experience of mental health treatment could be enhanced. Future research is needed to investigate the efficacy of blended models of care by evaluating its impact on the therapeutic alliance, clinical and social outcomes, cost-effectiveness, and engagement.
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Authors’ Contributions

LV conducted participant interviews and data analysis. The analysis was supervised by SB. The study was cosupervised by MA and SB. All authors reviewed the final manuscript.

Conflicts of Interest

None declared.

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Digital Health Management During and Beyond the COVID-19 Pandemic: Opportunities, Barriers, and Recommendations

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\textbf{Abstract}

During the coronavirus disease (COVID-19) crisis, digital technologies have become a major route for accessing remote care. Therefore, the need to ensure that these tools are safe and effective has never been greater. We raise five calls to action to ensure the safety, availability, and long-term sustainability of these technologies: (1) due diligence: remove harmful health apps from app stores; (2) data insights: use relevant health data insights from high-quality digital tools to inform the greater response to COVID-19; (3) freely available resources: make high-quality digital health tools available without charge, where possible, and for as long as possible, especially to those who are most vulnerable; (4) digital transitioning: transform conventional offline mental health services to make them digitally available; and (5) population self-management: encourage governments and insurers to work with developers to look at how digital health management could be subsidized or funded. We believe this should be carried out at the population level, rather than at a prescription level.

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\textbf{KEYWORDS}
digital mental health; call to action; due diligence; data insights; COVID-19

\textbf{Introduction}

Although we maintain behaviors that limit the spread of the coronavirus disease (COVID-19), we must also ensure that measures are in place to prevent, or at least mitigate, the risks of individuals being harmed in other ways.

Before COVID-19, mental health and social services were already stretched. Depression is the second leading cause of disability worldwide, and by 2030, it is expected to be the leading contributor to the global burden of disease [1]. Efforts to contain the spread of COVID-19, including prolonged social distancing and self-isolation, may trigger or exacerbate social, mental, and physical health problems, such as anxiety.
relationship breakdowns, domestic violence, substance abuse or withdrawal, and obesity [2-4]. This could be especially serious for those with comorbid medical and psychological conditions [5].

During the COVID-19 crisis, digital technologies have become a major route for accessing mental health care. Therefore, the need to ensure that these tools are safe and effective has never been greater. We raise five calls to action to ensure the safety, availability, and long-term sustainability of these technologies: (1) due diligence: remove harmful health apps from app stores; (2) data insights: use relevant health data insights from high-quality digital tools to inform the greater response to COVID-19; (3) freely available resources: make high-quality digital health tools available without charge, where possible and for as long as possible, especially to those who are most vulnerable; (4) digital transitioning: transform conventional offline mental health services to make them digitally available; and (5) population self-management: encourage governments and insurers to work with developers to look at how digital health management could be subsidized or funded. We believe this should be carried out at the population level, rather than at a prescription level.

**Action 1: Due Diligence**

During this time of heightened health anxiety, poorly designed (or novelty) apps that give inaccurate or misleading information can do more harm than good, such as nudging inappropriate health-related behaviors, compromising access to necessary care, or having other negative unforeseen consequences. We call on app stores to take expert advice on which apps might undermine standard clinical practices and subsequently remove apps posing health risks. For example, there are “prank” blood pressure apps that give inaccurate, randomly generated readings to millions of users [6] and suicide and depression apps, which have been downloaded over 2 million times, that provide wrong or nonexistent information about suicide crisis helpline support [7].

**Action 2: Data Insights**

We must consider data insights from high-quality digital health tools wherever possible to support the greater response to COVID-19. For example, an international team is working with multiple digital service providers to document the scale and nature of the mental health impact of COVID-19 [8]. We briefly highlight some changes in user interactions that have already been observed by Wysa [9] and MeeTwo [10] (Textbox 1). Wysa is an artificial intelligence–enabled chat-based, self-management resource that has been downloaded almost 2 million times worldwide, and is the current top recommendation of the National Health Service (NHS) and the Organisation for the Review of Care and Health Apps [11] for mental health and wellness. MeeTwo is a fully-moderated, anonymous peer support app currently supporting 25,000 young people aged 11-25 throughout the United Kingdom and is part of the NHS Apps Library. Another more specialized app called distrACT [12], which offers information and support to people who self-harm and may feel suicidal that is also included in the NHS Apps Library, has not observed substantial changes in patterns of user interactions at the time of writing.
Textbox 1. Quantitative and qualitative observations provided by the anonymous artificial intelligence–enabled chatbot Wysa and the anonymous moderated peer-to-peer support network MeeTwo, which demonstrate a visible shift in demand and change in use patterns during COVID-19.

Wysa (quantitative insights)

- Wysa witnessed a 77% increase in new users during February and March 2020, as compared to the same period in 2019 [8].
- The proportion of users who referred to the coronavirus disease during therapist sessions increased week-by-week during March 2020, from 5% in the first week to 60% in the fourth week [8].

MeeTwo (quantitative insights)

- There were 27 suicidal posts between 8:30 AM and 8 PM on March 22, 2020 (48 hours after schools were closed), as compared to 406 suicidal posts in all of 2019 [8].
- There was a 95% increase in level 4 (severe risk) between March 20 and April 4, 2020, as compared to between December 20, 2019 and January 4, 2020 [8].
- There was a 116% increase in level 3 (high risk) posts between March 20 and April 4, 2020, as compared to between December 20, 2019, and January 4, 2020 [8].

Wysa (qualitative insights)

- Some of the causes of distress discussed in sessions included loss of access to a client’s therapists, medical support, or social worker due to lockdowns or social distancing; job loss during the coronavirus disease and not having health insurance coverage; loss of a loved one due to coronavirus disease–induced infection; fear of contracting the illness or loved ones contracting the illness; loss of sense of safety and security; loss of physical human support for clients with physical disabilities leading to more anxiety and fatigue; anxiety, hypervigilance, and loneliness from quarantining; increase in reporting of domestic violence incidents or abusive behavior due to quarantining, leading to less opportunities to access safe spaces or support; alcohol or nicotine withdrawals from lockdown impacting availability of addictive substances; and stigma around being a professional who comes in to contact directly or indirectly with a person who may have contracted the coronavirus disease [8].
- Clients have shared that they are in long waiting lines to get tested, that their own therapists or psychiatrists suddenly paused any upcoming appointments and are not available for consultations, which can all lead to panic as well as feelings of being abandoned by the system [8].

MeeTwo (qualitative insights)

- “My dad passed away due to the virus 2 days ago and honestly it just doesn't feel real yet” (April 1, 2020) [8].
- “camhs has passed me over to another service and because of covid-19 my counselling might have to be video calls at first and that makes me insanely uncomfortable. i hate calling people in my own family but a complete stranger??? no thank uuuu” (March 3, 2020) [8].
- “I love this app but I wish I had someone to talk to in real life, I have no friends and my parents just don’t understand and literally don’t say anything so?? I was ALMOST gonna get a therapist but then corona virus happened and I bet the waiting list is going to be over a year long when everything goes back to normal ugh” (April 2, 2020) [8].

Action 3: Freely Available Resources

The physical and mental demands on frontline care professionals puts them at increased risk of illnesses and death [13]. At this crucial time, we call for digital service providers to offer free tools and open access to services wherever possible. Some digital health providers have already made tools and resources freely available for health care workers, and some providers are offering certain resources freely for all of their users. This comes with a note of caution, however, as NHSX has received over 400 free platform offers, but many offerings are only for a short duration. A sudden removal of digital support can pose risks, such as creating dependency for patients, unclear expectations for care providers, or financial uncertainty. Therefore, we call on companies to strive to offer support for the full duration of need, which may extend beyond the immediate public health crisis. Furthermore, future approval of apps for health care use might take into consideration whether the digital tool could be made freely available during public health crises, and beyond, as needed.

Action 4: Digital Transitioning

COVID-19 has led to nonessential staff working from home. NHSX recently published guidance to relax the rules around using digital communication tools to maintain therapeutic connections with patients. We call for training in digital health support to be incorporated into the curriculum for health professionals. We also call for conventional supportive services to be made available digitally, for example, sustaining services like Improving Access to Psychological Therapies (IAPT) given its reduced capacity, partly due to the redeployment of staff to newly established crisis care lines. As an example of this digital transitioning process, the Central and North West London Mental Health NHS Trust has established a protocol of good practice to transition from face-to-face art therapies to tele-art psychotherapies that also monitor physical care as part of the therapy [14].

Action 5: Population Self-Management

We need more reimbursements or subsidizations for cost-effective preventive and self-management interventions for mental health at the population level rather than at a...
prescription level. A triage phone call to IAPT services costs approximately £100 (approximately US $125). Before COVID-19, two-thirds of callers were reported as inappropriate referrals [15]. Technologies that can support self-management and self-assessment could save governments money while directing expensive medical resources to those who need them most.

To summarize, we have identified some pressing issues, with actions that could address them; however, these are by no means comprehensive and come with uncertainties and risk (eg, gaining consensus as to what constitutes a list of acceptable apps, maintaining data security, and obtaining patient consent). Other effective and safe digital services could also be rapidly implemented (eg, virtual visiting for loved ones, especially for end-of-life patients). We also encourage stakeholders to consider the importance of managing screen time (eg, using voice recognition). Digital health is a priority area for widening reach and providing timely assistance. At a time of immense strain, we must supplement health care systems with digital health management support, and we must strive to reduce the risks that create additional burdens.

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Authors' Contributions

BI formulated the notion to write about this topic and invited all coauthors to join, all of whom have made important contributions in the form of literature searches, idea generation, writing, and editing.

Conflicts of Interest

BI is an advisor for Wysa. RO has no conflicts of interest. ES is a clinical safety officer at Wysa. SJ is a lead psychologist at Wysa. VS is a research and compliance officer at Wysa. MK is a data scientist at Wysa. KS is the director of Expert Self Care Ltd (distrACT app). SG and KC are cofounders of MeeTwo. SV has received funding from iqvia for toolbox development. BM has no conflicts of interest.

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Commentary

An Integrated Blueprint for Digital Mental Health Services Amidst COVID-19

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Abstract

In-person traditional approaches to mental health care services are facing difficulties amidst the coronavirus disease (COVID-19) crisis. The recent implementation of social distancing has redirected attention to nontraditional mental health care delivery to overcome hindrances to essential services. Telehealth has been established for several decades but has only been able to play a small role in health service delivery. Mobile and teledigital health solutions for mental health are well poised to respond to the upsurge in COVID-19 cases. Screening and tracking with real-time automation and machine learning are useful for both assisting psychological first-aid resources and targeting interventions. However, rigorous evaluation of these new opportunities is needed in terms of quality of interventions, effectiveness, and confidentiality. Service delivery could be broadened to include trained, unlicensed professionals, who may help health care services in delivering evidence-based strategies. Digital mental health services emerged during the pandemic as complementary ways of assisting community members with stress and transitioning to new ways of living and working. As part of a hybrid model of care, technologies (mobile and online platforms) require consolidated and consistent guidelines as well as consensus, expert, and position statements on the screening and tracking (with real-time automation and machine learning) of mental health in general populations as well as considerations and initiatives for underserved and vulnerable subpopulations.

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KEYWORDS
digital mental health; mental well-being online assessments; machine learning; automation; COVID-19; well-being services

Introduction

It has been proposed that using digital health technology can strengthen our health systems [1]. Coupled with high-quality mental health research, digital innovations can aim at resolving “the potential crisis in the provision of health services to helping preserve and reconstruct a post-pandemic society” [2]. Digital mental health services delivered online and through smartphone technologies can be useful for targeted psychological interventions in communities affected by coronavirus disease (COVID-19) [3]. These provisions may fill the critical gap that practitioners are facing because of higher demand for mental health care services and the limitations of face-to-face consultations [4,5]. In this regard, the COVID-19 crisis could accelerate the use of mobile and teledigital health or at least challenge the usual standard of care [6].
Mental Well-Being Online Assessments and Automated Analysis Via Machine Learning

Data collection and analysis must be large-scale and of high quality to address mental health needs under the current pandemic. An example of an innovative, tailored, and practical technology applied in research methods is the machine learning induction of models. This technology was applied in a study by Wshah et al [7] to predict the probability of posttraumatic stress disorder (PTSD) symptoms in patients 1 month after trauma using self-reported symptoms from data collected via smartphones. The results suggest that simple smartphone-based patient surveys, coupled with automated analysis using machine learning–trained models, can identify those at risk for developing PTSD symptoms, and thus target them for early intervention.

It has long been acknowledged by mental health practitioners that there is a need to activate all possible opportunities to offer help, including through teleassistance, to patients [8]. At-home, mental health treatments are mostly limited to telehealth, where providers remotely communicate with patients over the phone or using video [9]. Telemental health services are perfectly suited to pandemic situations, with people being given access to mental health assistance without increasing the risk of contracting infections [10]. In times of crisis, the mental health of people needs to be supported in any way possible [11]. The call for innovative and expansive solutions and broad-scale collaboration in mental health prevention and intervention delivery includes support for technology [12]. Screening for and tracking of stress and adjustment issues in the general population via simple online/smartphone-compatible surveys, coupled with automated real-time analysis using machine learning–trained models, can deliver faster and better mental health care.

COVID-19 Mental Health Crisis: A Booster for Digital Interventions

Reliable, valid, and replicable mental health screening and tracking tools via machine learning have the potential to provide an integrated blueprint for the COVID-19 mental health response. The possibility of an integrated offering requires a strategy that brings together different areas of expertise (i.e., psychology, psychiatry, emergency and general health care, human welfare, and digital innovation). There is a range of ground-breaking developments happening, with automation taking hold rapidly and consensus to broaden horizons beyond telehealth to deliver digital assets [5,13,14]. A willingness to learn, the capacity to adapt to changes, collaboration, and well-connected management can help to resolve the organizational problems that continue to hamper the large-scale development and implementation of new technologies. The tragic impact of the COVID-19 pandemic may act as a booster for a rapid growth in activities related to digital interventions.

However, the adoption of digital interventions was recommended well before the onset of the pandemic and suggested as a complementary service that functions alongside traditional treatments, rather than be their replacement [15]. An important caveat is the possible lack of access for vulnerable people needing health care [1]. The consequences of COVID-19 have emphasized the urgent need to counteract the psychological impact of the pandemic by facilitating access to psychiatric diagnosis and treatment [16] while maintaining social distancing.

Mental health services could be broadened by training unlicensed professionals such as those who work in academia as researchers or in other areas of psychology, psychiatry, or mental health that don’t require direct clinical contact with patients. Self-help interventions can be delivered through a variety of media; these have proven effective for a range of mental health problems [17] and could be further explored for whether adjustment to a remote care set-up is linked to a (more) fertile mindset to solve issues.

Evaluation of Digital Interventions Required for Quality Assurance

Quality assurance remains problematic for online psychological services in low- and middle-income countries [18] and vulnerable populations [14]. There are no current systems known to be in place to evaluate digital mental health innovations with respect to underserved populations. International standards on service quality are essential, as are accessibility, sustainability, equity, and ethics [4,19]. Rigorous evaluations are needed to answer questions related to utility, effectiveness, confidentiality, and quality of interventions [20,21].

Conclusion

The global potential of digital mental health in improving the accessibility and quality of mental health service provision was boosted during the COVID-19 pandemic. A recent paper by Torous et al [14] focused on the requirements for increased efforts around safety, evidence, engagement, outcomes, and implementation to increase the scalability of and access to quality digital mental health care and proposed funding, research, policy changes, training, and equity as investments that will yield ongoing returns. In response, Whelan et al [4] emphasized the need for ongoing evaluation to ensure national evidence standards, digital training for mental health professionals, and assessment of how digital health innovations can be safely and sustainably embedded in care pathways with reference to the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework [22].

In adopting, scaling up, spreading, and sustaining digital mental health innovations in the midst of the COVID-19 pandemic and on a long-term basis, we recommend coordinating organizational and system framework assessments with evidence-based, online/smartphone-compatible screening and tracking tools deployed with real-time automation by machine learning–trained models. The results should be presented on sustainable, connected, and geocoded digital platforms, which may be supported by unlicensed professionals in order to expand and maintain patient engagement and increase options for prevention and intervention. A patient is thereby presented with recommendations for mental health care services including...
options for self-care and practitioner-led care with focus on value and capabilities. We also recommend suitably qualified content on mental health to be disseminated and accessed via digital workspaces with dashboards to build efficiency, consistency, and transparency from a single, global location.

Scalable screening and tracking tools should be implemented in a hybrid model of care combining face-to-face, telehealth, and digital-health approaches. Machine-readable paper copies or non–smartphone-based messaging could be adapted as solutions where there is a lack of access to the technological resources required for engagement in digital mental health services. An added value of digital mental health is that it may be designed for automated thematic and metadata review, traceability for quality assurance, and assignment of responsibility for identified cases of mental ill health. Existing telepsychiatry guidelines (including other relevant digital technologies) should be considered \[23\] for a consistent and consolidated knowledge management strategy for integrated services. Consensus, expert, and position statements are required from psychiatrists, psychologists, and academic researchers on the individual, cultural, and environmental factors that affect the well-being of the patient with suggestions for brief, valid and reliable screening and tracking surveys for the prevention and treatment of mental health symptoms and disorders. A general population version is needed with specifications for vulnerable subpopulations such as children, college students, domestic violence victims, frontline heath care workers, low socioeconomic groups, athletes, people with mental health disorders, and the elderly.

### Conflicts of Interest

None declared.

### References


Abbreviations

COVID-19: coronavirus disease
NASSS: nonadoption, abandonment, scale-up, spread, and sustainability
PTSD: posttraumatic stress disorder
Strategies to Increase Peer Support Specialists’ Capacity to Use Digital Technology in the Era of COVID-19: Pre-Post Study

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Abstract

Background: Prior to the outbreak of coronavirus disease (COVID-19), telemental health to support mental health services was primarily designed for individuals with professional clinical degrees, such as psychologists, psychiatrists, registered nurses, and licensed clinical social workers. For the first time in history, peer support specialists are offering Medicaid-reimbursable telemental health services during the COVID-19 crisis; however, little effort has been made to train peer support specialists on telemental health practice and delivery.

Objective: The aim of this study was to explore the impact of the Digital Peer Support Certification on peer support specialists’ capacity to use digital peer support technology.

Methods: The Digital Peer Support Certification was co-produced with peer support specialists and included an education and simulation training session, synchronous and asynchronous support services, and audit and feedback. Participants included 9 certified peer support specialists between the ages of 25 and 54 years (mean 39 years) who were employed as peer support specialists for 1 to 11 years (mean 4.25 years) and had access to a work-funded smartphone device and data plan. A pre-post design was implemented to examine the impact of the Digital Peer Support Certification on peer support specialists’ capacity to use technology over a 3-month timeframe. Data were collected at baseline, 1 month, 2 months, and 3 months.

Results: Overall, an upward trend in peer support specialists’ capacity to offer digital peer support occurred during the 3-month certification period.

Conclusions: The Digital Peer Support Certification shows promising evidence of increasing the capacity of peer support specialists to use specific digital peer support technology features. Our findings also highlighted that this capacity was less likely to increase with training alone and that a combinational knowledge translation approach that includes both training and management will be more successful.

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KEYWORDS
COVID-19; peer support; telemental health; mental health; training
Introduction

Digital peer support has potential to expand the reach of peer support services, improve the impact of peer support without the need for in-person sessions, and increase engagement among mental health service users [1-3]. Digital peer support is defined as live or automated peer support services delivered through technology mediums [4]. Peer support services are recovery and wellness support services provided by an individual with a lived experience of recovery from a mental health condition [5]. Most existing telehealth training is designed for individuals who have professional clinical degrees and licensures, such as psychiatrists, psychologists, registered nurses, and social workers [6,7]. These training sessions are short in duration [6], build on already existing skill sets, and focus on rapid attainment of skills and concepts [6]. Digital peer support is quickly expanding worldwide in the wake of the COVID-19 pandemic [3]; therefore, telemental health training developed for peer support specialists is currently needed.

Academic training programs for clinicians (eg, psychiatrists, psychologists, registered nurses, and licensed clinical social workers) frequently address methods and best practices for implementing telemental health services [7]. Within these traditional clinical roles, clinicians are encouraged to explore telemental health services through formal education standards and licensure requirements, continuing education credits, national training centers, professional associations, incentives for clinicians to use telehealth modalities [8], and reimbursement for telemental health services in private and public health systems [9]. Peer support specialists are increasingly reporting the desire and need to use technology to deliver peer support [10]. As peer telemental health is now reimbursable by Medicaid during the COVID-19 emergency crisis, standardized training on digital peer support services is greatly needed.

Using the framework for an Academic-Peer Partnership [11], we developed the Digital Peer Support Certification, which is designed specifically for peer support specialists (both Medicaid-billable peer specialists in traditional clinical services and peer specialists working for peer-run organizations) who deliver peer support via technology mediums in any country worldwide. This study examined the extent to which implementation of the Digital Peer Support Certification over three consecutive months impacted peer support specialists’ capacity to use a digital peer support smartphone app and care management dashboard, PeerTECH [1-3].

Methods

Study Design and Participants

A pre-post design was used to examine the 3-month Digital Peer Support Certification program offered through a community mental health center. Data were collected at baseline, 1 month, 2 months, and 3 months. This study was conducted between November 2019 and April 2020 in a community mental health center in an urban setting. The Dartmouth College institutional review board approved this study.

The participants included 9 certified peer support specialists between the ages of 25 to 54 years (mean 39). All the participants were trained and accredited as certified peer support specialists by the state of Massachusetts and were all employed for a mean of 4.25 years (range 1 to 11 years). All peer specialists personally owned or had access to a personal smartphone.

Digital Peer Support Certification

The 3-month Digital Peer Support Certification was co-designed with academic partners and peer support specialists using the Academic-Peer Partnership [11]. In an earlier quantitative study (under review), our co-production team conducted an online survey with 267 peer support specialists to identify factors that can either prevent or enable digital technology engagement. Based on our findings, we co-designed specific digital peer support training content to meet the specialists’ needs. The Digital Peer Support Certification includes training on digital communication skills; technology literacy (ie, important digital terms such as PEERbots and digital phenotyping); technology usage skills with the PeerTECH system (eg, downloading apps, sending SMS text messages, entering goals, saving information, completing repeated surveys such as ecological momentary assessments on a smartphone app, increasing the volume on a smartphone, watching videos in the library, and offering digital peer support services); available digital peer support technologies; organizational policies and compliance issues; separating work and personal life; digital crisis intervention; and privacy and confidentiality. The Digital Peer Support Certification includes an education and simulation training session, synchronous and asynchronous support services, and audit and feedback. To ease uptake, the format, structure, and vocabulary were designed to be aligned with national peer support specialist practice standards [12]. Next, we will delineate each component of the certification program.

Education and Simulation Training Session

The education and simulated training session lasted 16 hours over two consecutive days and was led by the principal investigator, KLF. Facilitated interactive group discussions were paired with a printed standardized workbook. A standardized workbook was provided to all peer support specialists. All standardized workbook text was written at a fourth grade level and incorporated recovery principles consistent with peer support specialist practice standards [11,13]. The training was consistent with person-first language, involved sharing lived experiences of using technology in a group environment, and included simulation-based training on the PeerTECH smartphone app and the PeerTECH dashboard on a desktop computer. To promote learning of new knowledge and mastery of skills, reinforcement, summation, and teach-back techniques were incorporated into the education and simulation training session.

Audit and Feedback

As peer support practice standards are based on experiential learning and sharing of experiences [12], experiential learning was encouraged and an audit and feedback process was incorporated into the second phase of the Digital Peer Support
Certification. After the two-day training session, the peer support specialists applied their newly obtained technology skills for 1 month as part of PeerTECH, a 12-week digital peer support program that incorporates a smartphone app for service users and a care management dashboard to deliver peer support to service users via a smartphone app [1]. Audit and feedback is a quality improvement management tool that incorporates a summary of performance over a specific time period designed to provide constructive feedback to people so they can modify their performance [14-16]. Audit and feedback is used in all health care settings and most commonly involves clinical health professionals rather than peer support specialists [14-16].

The audit and feedback criteria were developed by two authors KLF and RW a priori. These criteria included capacity to complete peer support specialists’ technology-based PeerTECH tasks, including signing in to the dashboard with a username and password; writing an SMS text message in the dashboard and sending it to the smartphone app; and assisting service users in completing technology-based PeerTECH tasks, including entering goals on the smartphone app, signing in to the smartphone app with a username and password, completing surveys on the app, and sending SMS text messages. The audit and feedback process was performed in a group setting at 1 month during a 1.5-hour meeting and individually at 2 months with each peer support specialist via telephone and email; feedback sessions were also offered upon request. However, no additional feedback sessions were requested. The audit and feedback sessions aimed to promote digital peer support technology capacity using positive behavioral approaches [17,18]. We adopted a nonaversive behavioral approach to working with peer support specialists during the feedback sessions [19]. Nonaversive behavioral support focuses on affirmation of practices designed to educate and promote additional positive changes [20].

The principal investigator met with all peer support specialists in a group setting at baseline and after 1 month, then contacted the specialists individually at 2 months via telephone or email. Prior to the 1.5-hour group meeting at 1 month and the 15-minute individual meeting at 2 months, the principal investigator completed a technology audit and audio observations through audio recordings of PeerTECH sessions. Upon completion of both audits, descriptive statistics were calculated and prepared for the feedback meetings with the peer support specialists.

**Synchronous and Asynchronous Support**

Synchronous and asynchronous support were provided as needed. As such, the principal investigator and a research assistant offered telephone support (synchronous) and email support (asynchronous) from Monday to Friday between the hours of 9 AM and 5 PM. The components of the Digital Peer Support Certification are summarized in Figure 1.

**Capacity to Use Digital Peer Support Technology**

Capacity to use digital peer support was defined as the peer support specialists’ ability to use the PeerTECH system (ie, smartphone app and dashboard) through an in-person task analysis and a real-world task analysis. Task analysis is a user-centered design approach that is implemented to assess whether an individual can complete a task via a technology medium [21]. The tasks were defined based on tasks users are required to perform to operate the PeerTECH system, including signing in to the dashboard with a username and password; writing a text message in the dashboard and sending it to the smartphone app; and assisting service users in completing technology-based PeerTECH tasks, including entering goals on the smartphone app, signing in to the smartphone app with a username and password, completing surveys on the app, and
sending SMS text messages. Real-world task analysis included SMS text message exchanges, entering service user goals, completion of surveys by service users, and frequency of contacting the help desk. Peer support specialists were required to send 2 text messages each week to service users and were also instructed to include at least one goal in the smartphone app.

Data Analysis

Data from the PeerTECH system were imported into SPSS [22] (IBM Corporation) for analysis. The mean adherence from audit data from month 0 to month 1 was calculated to represent the peer support specialists’ capacity at the beginning of the certification process. The midpoint included month 1 to month 2. The mean capacity audit data from month 2 to month 3 were calculated to represent the end of the certification process for the capacity comparisons. To explore changes in the capacity to use the technology, data were calculated for SMS text message exchanges, entering service user goals, surveys completed by service users, and frequency of contacting the help desk.

Table 1. Changes in peer support specialists’ capacity to use digital peer support technology from baseline to the midpoint and end of the Digital Peer Support Certification.

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Baseline (1 month)</th>
<th>Midpoint (2 months)</th>
<th>Change (%)</th>
<th>End of Digital Peer Support Certification program (3 months)</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveys completed</td>
<td>0</td>
<td>202</td>
<td>Infinity</td>
<td>397</td>
<td>96.5</td>
</tr>
<tr>
<td>Texts sent by peer specialists</td>
<td>2</td>
<td>19</td>
<td>850</td>
<td>89</td>
<td>368.4</td>
</tr>
<tr>
<td>Texts sent by service users</td>
<td>5</td>
<td>42</td>
<td>740</td>
<td>67</td>
<td>59.5</td>
</tr>
<tr>
<td>Goals entered by peer specialists</td>
<td>0</td>
<td>10</td>
<td>Infinity</td>
<td>16</td>
<td>60</td>
</tr>
</tbody>
</table>

*aService users were prompted to complete one 3-item survey on a smartphone each day for 90 days.

Midpoint (Month 1 to Month 2)

The mean capacity from audit data for month 1 to month 2 was calculated to represent the peer support specialists’ midpoint capacity. During a 4-hour group meeting with the principal investigator, peer support specialists and their respective supervisors met to discuss PeerTECH. Between baseline and midpoint, the same 27 service users were enrolled in the study.

Between baseline and midpoint, 1/9 peer support specialists (11%) needed password assistance a total of one time (ie, they forgot their password). None of the peer support specialists required a password reset between the midpoint and end of the Digital Peer Support Certification. Service users did not contact the help desk for forgotten passwords during this time. A summary of the midpoint results for goals entered, surveys completed by service users, and SMS text messages sent is detailed in Table 1.

End of Digital Peer Support Certification (Month 2 to Month 3)

The mean capacity from audit data for month 2 to month 3 was calculated to represent the midpoint capacity. The principal investigator met with peer support specialists by telephone individually, audited their work, and sent emails in PeerTECH with information related to their work. Between midpoint and end of the Digital Peer Support Certification, 1/9 peer support specialists (11%) needed password assistance a total of 1 times (ie, they forgot their password). None of the peer support specialists required a password reset between the midpoint and end of the Digital Peer Support Certification. Service users did not contact the help desk for forgotten passwords for service users during this time. Table 1 presents information on the changes in the peer support specialists’ capacity to use digital peer support technology over three months.

Discussion

Principal Findings

This study examined the extent to which an education and simulation training session, synchronous and asynchronous technology support services, and audit and feedback over three months impacted peer support specialists’ capacity to use digital peer support technology. The peer support specialists’ capacity was less likely to change with training alone (ie, education paired with simulation-based training); this indicates that a combinational knowledge translation approach that includes training and management may be more likely to improve capacity. As the need for digital mental health services has expanded due to stay-at-home measures related to the
COVID-19 pandemic, peer support specialists may play a significant role in digitally supporting the needs of people by providing support services to augment traditional mental health treatment.

The combination of training and management approaches is an effective knowledge translation intervention to increase peer support specialists’ capacity to use digital peer support technologies. The Digital Peer Support Certification received support from clinical staff, peer support specialists, and organizations as well as financial support from funders. As such, implementation of the Digital Peer Support Certification supported adoption of digital peer support technology and flexibility in uptake by peer support specialists. The improvements in the peer support specialists’ capacity were likely due to a combination of the following attributes of the Digital Peer Support Certification: non–time-dependent team learning; nonaversive feedback; inclusion of peer support specialist practice standards; and reasonable accommodations for support. Future studies can build on the Digital Peer Support Certification success through employing these components. Next, we will discuss each component in detail.

**Team Learning**

Team learning within an organization is a key mechanism in promoting uptake of new technologies and new practices [23,24]. Team learning is defined as the collective effort of individuals to achieve a common goal [25]. In the learning organization context, team members commonly ask questions, share knowledge, and complement each other’s skills [25]. Team learning as part of the Digital Peer Support Certification included printed educational materials paired with group simulation-based training. Research indicates that the impact of printed educational materials on improvements in service delivery is generally small [26]. As such, we combined printed educational materials with simulation-based training. Education paired with simulation-based training offered a risk-free opportunity to practice skills; however, this approach demonstrated only a small change in the peer support specialists’ capacity to use technology. Rather, continuous real-world experience in combination with education and simulation-based training produced the greatest change in capacity, as evidenced by the increase in technology capacity over time. For adult learners, learning occurs through practice in the real world [27]. Our findings indicate that continuous real-world experience may have a greater impact on increasing the capacity to offer digital peer support than education alone paired with simulation-based training.

**Nonaversive Feedback and Peer Support Practice Standards**

Feedback that is perceived as supportive rather than punitive is more likely to positively influence behavior [18,28]. Nonaversive behavioral support is consistent with the values and philosophy of peer support services related to dignity and respect [20]. As such, through supportive feedback, the facilitator (the principal investigator) encouraged peer support specialists to share their experiences and expertise while using the smartphone app and to guide others toward solutions. Peer support practice standards value the experiences and expertise of similar people [12].

**Reasonable Accommodations**

The peer support specialists who participated in the study were offered reasonable accommodations for technology support, which is a service regulated and endorsed by the Americans with Disabilities Act (ADA) [29]. Most employers are obligated to provide reasonable accommodations to a person with a disability (eg, a diagnosis of a serious mental illness) that substantially limits a major life activity or bodily function [29]. According to the ADA, a reasonable accommodation is defined as a “change or adjustment to a job or work environment that permits a qualified applicant or employee with a disability to participate in the job application process, to perform the essential functions of a job, or to enjoy benefits and privileges of employment equal to those enjoyed by employees without disabilities” [30]. For example, training materials are considered to be a type of employment opportunity. As such, Digital Peer Support Certification offers flexible options for support. From ongoing training and professional development to synchronous and asynchronous support services and a 24/7 help desk, this program aims to provide a broad range of reasonable accommodations.

**Limitations of the Study**

This study is not without limitations. First, not all peer support specialists attended the audit and feedback sessions. Second, the small sample of peer support specialists may limit the generalizability of the results. Further, in this sample, all peer support specialists owned and used technology prior to using PeerTECH. Thus, all peer support specialists possessed a baseline level of technology capacity, which is consistent with the scientific literature [31]. However, 7 service users borrowed a smartphone; thus, these users had lower initial technology capacity. Low initial technology adoption may have impacted the service users’ rates of technology use. Stratified sampling by technology adoption in future studies may address this potential limitation. Finally, it is not known which learning mechanism produced the greatest effect: the education and simulation training session, the synchronous and asynchronous support services, or the audit and feedback. Future research should control for a time and examine the effects of individual and interactive learning mechanisms to optimize mastery of technology skills by peer support specialists.

**Conclusions**

The Digital Peer Support Certification may be an initial step to standardized telehealth training and competencies in the delivery of digital peer support. As people shelter in place and practice social distancing due to COVID-19, a peer support specialist workforce with proper training may play a powerful role in digitally supporting the needs of people in the community. Although the field of digital peer support is in its infancy [32], the expansion of digital peer support through wide-scale Medicaid reimbursements and standards training will potentially have applications in improving the health and wellness of service users during the COVID-19 pandemic. The Digital Peer Support Certification shows promising evidence of increasing the
capacity of peer support specialists to use specific digital peer support technology features (eg, SMS text messaging, ecological momentary assessments on smartphone apps, and goal setting). Our findings also highlighted that this capacity was less likely to change with training alone (ie, education paired with simulation-based training); this finding suggests that a combinational knowledge translation approach that includes training and management will be more successful.

Acknowledgments
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Conflicts of Interest
KLF offers consulting services through Social Wellness. ALM receives support from Social Wellness LLC.

References


Abbreviations

ADA: Americans with Disabilities Act
COVID-19: coronavirus disease

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