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Viewpoint

Workshop on the Development and Evaluation of Digital Therapeutics for Health Behavior Change: Science, Methods, and Projects

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Abstract

The health care field has integrated advances into digital technology at an accelerating pace to improve health behavior, health care delivery, and cost-effectiveness of care. The realm of behavioral science has embraced this evolution of digital health, allowing for an exciting roadmap for advancing care by addressing the many challenges to the field via technological innovations. Digital therapeutics offer the potential to extend the reach of effective interventions at reduced cost and patient burden and to increase the potency of existing interventions. Intervention models have included the use of digital tools as supplements to standard care models, as tools that can replace a portion of *treatment as usual*, or as stand-alone tools accessed outside of care settings or direct to the consumer. To advance the potential public health impact of this promising line of research, multiple areas warrant further development and investigation. The Center for Technology and Behavioral Health (CTBH), a P30 *Center of Excellence* supported by the National Institute on Drug Abuse at the National Institutes of Health, is an interdisciplinary research center at Dartmouth College focused on the goal of harnessing existing and emerging technologies to effectively develop and deliver evidence-based interventions for substance use and co-occurring disorders. The CTBH launched a series of workshops to encourage and expand multidisciplinary collaborations among Dartmouth scientists and international CTBH affiliates engaged in research related to digital technology and behavioral health (eg, addiction science, behavioral health intervention, technology development, computer science and engineering, digital security, health economics, and implementation science). This paper summarizes a workshop conducted on the *Development and Evaluation of Digital Therapeutics for Behavior Change*, which addressed (1) principles of behavior change, (2) methods of identifying and testing the underlying mechanisms of behavior change, (3) conceptual frameworks for optimizing applications for mental health and addictive behavior, and (4) the diversity of experimental methods and designs that are essential to the successful development and testing of digital therapeutics. Examples were presented of

ongoing CTBH projects focused on identifying and improving the measurement of health behavior change mechanisms and the development and evaluation of digital therapeutics. In summary, the workshop showcased the myriad research targets that will be instrumental in promoting and accelerating progress in the field of digital health and health behavior change and illustrated how the CTBH provides a model of multidisciplinary leadership and collaboration that can facilitate innovative, science-based efforts to address the health behavior challenges afflicting our communities.

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KEYWORDS

digital health; behavioral health; mobile technology; mHealth; digital interventions; behavior change; behavioral science; addiction; mental health

Introduction

Over the last 25 years, scientists in the fields of addiction science and mental health have studied how to enhance treatment outcomes, how to improve the dissemination and implementation of effective treatments, and how to reach a greater proportion of the population experiencing behavioral health challenges. Barriers to success have included substandard screening and identification of cases, limited numbers of trained personnel, high burden associated with training, poor fidelity and integrity of treatment delivery, low pay for providers, high costs for delivering the most effective interventions, stigma and burden associated with seeking treatment, and limited individualization and personalization of treatment.

Broadly speaking, the health care field has integrated numerous advances in digital technology at an accelerating pace to improve health behavior, health care delivery, and cost-effectiveness of care. This area of science, often referred to as *digital health*, has been embraced within the realm of behavioral science, allowing for an exciting roadmap for advancing care by addressing the many challenges to the field via technological innovations [1-4]. Technology-delivered treatments, commonly referred to as *digital therapeutics*, offer the potential to extend the reach of evidence-based interventions at reduced cost and patient burden and to increase the potency of existing interventions. Delivering on these promises has substantial public health implications, given that the majority of people with behavioral health needs are not receiving treatment of any kind, and only the minority of those who do receive treatment are provided with an evidence-based intervention. Multiple studies have demonstrated that treatment models assisted by computer-, Web-, or smartphone-based delivery of evidence-based interventions improve access to care, reduce costs, and improve the efficiency of treatment delivery [1-4]. Intervention models have included the use of digital tools as supplements to standard care models, as tools that can replace a portion of *treatment as usual*, or as stand-alone tools accessed outside of care settings or direct to the consumer. Indeed, digital therapeutics have progressed to such an extent that the US Food and Drug Administration (FDA) recently launched an initiative to incorporate digital health into mainstream medical practice [5]. This significant step acknowledges the potential of and the growing evidence for digital therapeutics. The FDA has further defined a class of digital therapeutics as *mobile medical applications*, software apps that meet the definition of a medical device, that is, performing patient-specific analysis and providing patient-specific diagnosis or treatment recommendations, and at least one mobile app has received FDA permission for marketing [6,7].

However, to further advance the potential public health impact of this promising line of research, several areas warrant development and investigation. Although some digital therapeutics for health behavior problems have been deemed effective, effect sizes to date have been generally small to medium, and treatment mechanisms have been understudied. To address this problem, it is essential to focus more research on identifying and understanding specific mechanisms relevant to health behavior change. Importantly, direct comparisons between digital therapeutics and well-understood traditionally delivered interventions may provide the clues necessary for achieving this goal and developing more potent interventions [8]. Given their *on-demand* availability and opportunities for personalization, digital therapeutics may impact the rate and nature by which health behavior change occurs. An increased understanding of the active ingredients and mediators of outcome from such interventions can greatly enhance future efforts to optimize development efforts. Such progress could move the digital health field beyond direct adaptations of existing face-to-face interventions to better harness the dynamic potential of technology in collecting data about individuals in unprecedented ways (and in real time) and in intervening at the exact moments when individuals may be maximally motivated and receptive [9].

Optimization and acceleration of the development and evaluation of digital therapeutics also require advances in the measures and methods used to study treatment processes, mechanisms, and outcomes. Understanding how an intervention produces changes in cognitive, behavioral, or environmental factors that are then, in turn, causally related to health behavior change (eg, reduction in drug use) allows for the identification of more specific treatment targets, which, in turn, permit refinement and optimization of subsequent iterations of an intervention [8]. Continued development of more granular, objective, and valid measures of important mechanism constructs and processes and treatment outcome variables is also essential for the advancement of health behavior change research and development. Technological and data analytic advances offer exciting new approaches for obtaining and interpreting more meaningful and ecologically valid data that can be readily collected in the natural environment over substantial periods. Finally, the pace of science in the realm of digital health can greatly benefit from explicit methodological frameworks to guide research efforts and the application of innovative

experimental designs. Several novel and underused methodological approaches are relevant to developing and evaluating digital therapeutics that can supplement the findings from traditional randomized controlled trials (RCTs) [10-13]. Such approaches include flexible, rigorous, and efficient methods, which can help optimize interventions and bridge the gap between clinical trials and community care.

Center for Technology and Behavioral Health—Workshop

The Center for Technology and Behavioral Health (CTBH; a P30 *Center of Excellence* supported by the National Institute on Drug Abuse [NIDA] at the National Institutes of Health) is an interdisciplinary research center at Dartmouth College focused on the goal of harnessing existing and emerging technologies to effectively develop and deliver evidence-based interventions for substance use and co-occurring disorders [14]. In total, 3 primary cores, treatment development and evaluation (TDE), emerging technologies and data analytics, and dissemination and implementation, bring together a diverse team with expertise in addiction science, behavioral health intervention, technology development, computer science and engineering, digital security, health economics, and implementation science.

The TDE core of the CTBH organized a workshop, "Development and Evaluation of Digital Therapeutics for Behavior Change: Science, Methods, and CTBH Projects," which was recently held on the campus of Dartmouth College. This was one of the series of workshops launched by the CTBH to encourage and expand collaboration among Dartmouth scientists and international CTBH affiliates across the diverse disciplines that engage in research related to digital technology and behavioral health. The goals of the workshop were to (1) highlight key conceptual and scientific issues vital to the proliferation of research on digital therapeutics, (2) stimulate new collaborations and scientific developments, and (3) showcase the work of CTBH-TDE core investigators. The workshop theme was the *Science of Behavior Change.* More than 50 faculty, students, trainees, and staff attended this all-day meeting in person, and collaborative partners from a number of US institutions and ETH Zürich's Center for Digital Health Interventions attended remotely. This paper summarizes the workshop sessions, which addressed (1) principles of behavior change; (2) conceptual frameworks for optimizing applications in mental health, addictive behavior, and health behavior change; and (3) the diversity of experimental methods and designs that are essential to the successful development and testing of digital therapeutics for behavior change. Most sessions also provided examples of ongoing projects focused on identifying and improving the measurement of health behavior change mechanisms and the development and evaluation of digital therapeutics. Our goal here was to use the knowledge gleaned during this workshop to provide a broad overview of the wide-ranging research topics that must be addressed to advance the field of digital health and its impact on health behavior problems and to illustrate how our CTBH model can facilitate progress in meeting the vast health challenges facing behavioral health research and service delivery models.

Science of Behavior Change

WA, the Director of the NIDA's Behavioral Therapy Development Program in the Clinical Research Grants Division, provided opening comments and highlighted NIDA's keen interest in research on behavior change and mechanisms of change in research on addictions. He emphasized how science that targets potential change mechanisms, such as self-regulation, stress, resilience, and intra- and interpersonal processes, can have a ubiquitous impact on our ability to provide more focused and parsimonious treatments, that is, personalized medicine. WA concluded with a discussion of how the integration of technology-based treatments can uniquely target and facilitate change in these mechanisms and thereby advance the development of effective interventions for substance use and associated psychiatric disorders.

As the workshop audience comprised a diverse group of multidisciplinary scientists who affiliate themselves with the CTBH, AB began with an overview of key principles of behavior change, from basic theories of learning (eg, Skinnerian principles of reinforcement) to current behavioral economic concepts that are highly relevant to identifying and targeting effective behavioral health change mechanisms. This presentation illustrated how understanding the basic elements of behavior change principles can be translated into personalized, effective treatment elements. As examples, AB described how novel translations of behavior analytic principles of reinforcement and the construct of temporal discounting have been applied to inform the development of innovative treatment strategies that can enhance treatment outcomes for substance use disorders and other health behavior problems [15-17]. He also shared other heuristic behavioral economic principles that are currently being transformed into tools designed to optimize health behavior change [17] and discussed the many ways that technology can be leveraged to facilitate and accelerate the creation and dissemination of effective behavior change interventions.

JD then initiated a series of presentations that underscored the importance of using diverse and innovative methodologies and experimental designs to advance research on digital technology–based treatments. He introduced and discussed the key role that single-case experimental designs (SCEDs) can play in stage 1 testing of technology-based interventions to promote health behavior [18,19]. He illustrated how SCEDs can rigorously and efficiently answer questions about the preliminary efficacy and acceptability of an intervention. He reviewed the essential methodological elements of SCEDs and used examples from his published research on technology-based methods to promote smoking cessation to illustrate these elements [20]. In addition, he discussed how SCEDs can be employed to evaluate potential mechanisms underlying intervention efficacy. Specifically, mechanisms can be assessed by obtaining a time series of changes in measures of the mechanism construct and the outcome and by experimentally manipulating the mechanism using SCEDs. JD concluded by

noting some of the practical and scientific advantages of SCEDs and how their use encourages data intimacy, scientific rigor, and innovation.

CS's presentation alerted the audience to several emerging research methods and designs that may be particularly useful in evaluating and understanding the impact of technology-based tools on health behavior and that can supplement the findings from RCTs (eg, the Multiphase Optimization Strategy and Sequential Multiple Assignment Randomized Trial [SMART]) [21-23]. CS focused on SMART designs, which involve random assignment of individuals to conditions more than once during a study, based on their response to conditions experienced earlier in the study. As SMART designs involve multiple randomizations over time, they test the impact of applying different intervention approaches at critical decision points based on intervention response. CS presented an example of a recently completed SMART trial for adolescent cannabis use [24]. Using a SMART design, this study tested the impact of an initial intervention (adding working memory training to contingency management [CM] for youth with cannabis use disorder at treatment onset) and an adaptive intervention (switching youth who did not show a positive response after the first month of the intervention to higher magnitude CM incentives) on clinical outcomes. CS summarized how the SMART design fits particularly well with digital interventions because rapid assessment of changing (dynamic) predictors of intervention response and adaptive changes in intermediate outcomes in response to interventions are facilitated by the technology. This effort may lead to technology-based tools that can be readily tailored to optimally meet the needs of an individual [25].

Mechanism of Action and Measurement

The workshop shifted focus with LM's presentation on targeting mechanisms of action with digital therapeutics, in this case, self-regulation. She first raised awareness of the ubiquitous contribution and challenges that health risk behavior and poor adherence to medical regimens impart on chronic disease development and its management. Self-regulation, a person's ability to manage cognitive, motivational, and emotional resources to act in accordance with his or her long-term goals, was introduced as an important causal mechanism of health behavior, and deficient self-regulation was proposed as a key target for interventions addressing health risk behavior in chronic diseases. LM outlined existing but disparate literature that highlights the clear promise of interventions that target self-regulation to improve health and the challenges that must be addressed if we are to most effectively address this transdisease process of self-regulation [12]. Examples were provided of how digital technology and data analytics have created unprecedented opportunities to assess and modify self-regulation and thus accelerate scientific understanding and application. Intensive and continuous individual data collection with mobile devices (or passive sensors and digital footprints of Web-based social media) can provide rich personal and environmental data in real time, which sophisticated data analytics can turn into meaningful insights about individual health and inform person-centered adaptive interventions.

LM discussed an ongoing National Institutes of Health funded *ontology of self-regulation* project that involves the development of optimal measures of self-regulation using the aforementioned digital technology and data analytic methods and evaluation of how the mechanism of self-regulation relates to behavior change across 2 clinical populations (heavy smokers and persons with binge eating disorder) [12]. Participants will use a mobile health self-regulation platform that provides science-based behavior change tools to promote improved self-regulation and health behavior and facilitate real-time data collection.

ES provided more detail on the first stage of this project, that is, the application of data analytics to the development of a momentary measure of self-regulation that can be used to effectively evaluate change constructs in naturalistic settings via mobile devices in trials using digital therapeutics to assess and treat health behavior problems. She described the iterative process and innovative data analytics involved in empirically extracting the most informative items derived from the multitude of items contained within the many existing self-regulation assessments to efficiently capture momentary self-regulation status with a brief measure in longitudinal studies. ES showed data from an initial piloting of this 20-item measure using ecological momentary assessment (3 times per day surveys for 2 weeks). Her team used multilevel factor analysis to select 12 items that represented 4 valid self-regulation subscales (perseverance, self-judgment, sensation seeking, and mindfulness). CTBH affiliates have included this momentary measure to assess changes in self-regulation in 4 clinical studies.

The next 2 presentations illustrated the novel advances in measurement that passive sensing can bring to the study of behavioral health by providing examples of how mobile sensing can be used to identify temporal fluctuations in high-risk emotional states (eg, depression and stress). AC described his ongoing project focused on the high rates of depression and anxiety among college students. His study used passive sensing features of a smartphone and a commodity wrist-worn wearable (Microsoft Band2; Microsoft, WA) to monitor multiple behavioral and physiological correlates of depression over time (eg, activity level, conversation frequency, and sleep duration) [26]. These devices monitored location, phone usage, light and sound detection, activity duration (steps), heart rate, skin temperature, and galvanic skin response over 10 weeks, and text messages prompted collection of weekly patient health questionnaire depression scores and other experience sampling responses. Data analytic models using all these data and pre-post surveys that assessed stress, anxiety, productivity, and other relevant behavior or emotions were combined to determine how the passive sensing measures related to the students' mental health functioning across the semester.

In an excellent example of cross-discipline collaboration, SL presented results from a proof-of-concept pilot study conducted with members of Dartmouth's Computer Science and Engineering Sciences Departments to evaluate the reliability and acceptability of a wearable sensor system (called the Amulet Sensor System, a wrist-worn device developed at Dartmouth) to passively identify stress in a college student population. The sensor system included a commodity chest strap heart rate monitor to collect heart rate variability data, an electrodermal

activity sensor to assess skin conductance data, and the *Amulet* that acted as a data hub for data from the heart rate monitor. The Amulet included an accelerometer and software to conduct an ecological momentary assessment of stress constructs as well as an *event mark* feature to benchmark high-stress periods. SL discussed results about the feasibility of using commodity products for passive detection of stress and the potential of passive sensing techniques as the first line of assessment to trigger just-in-time interventions [27]. The discussion highlighted the importance and roles of multidisciplinary team of scientists from the fields of behavioral health, computer science, and engineering in the development and evaluation of digital approaches to behavioral health.

Clinical Application

The workshop then shifted to a more clinical focus as EN discussed the problem of intervention adherence in clinical trials using digital health tools, an issue similar to that which occurs with traditional behavioral and pharmacological interventions. He provided examples about how some technology-based interventions can reduce dropout compared with traditional therapist-delivered interventions for substance use disorders but noted that both approaches still have high rates of attrition. EN highlighted that more attention to increased *production value*, that is, more consumer-friendly user interface and user design, or gamification, could help address this vital adherence issue with behavioral health populations. He provided 2 examples of efforts in this direction, one that included high-quality video demonstrations to enhance development of coping skills in the context of treating substance use disorders [28] and one that is using gamification within a digital therapeutic for treating opioid use disorder [29], but he stressed the need to empirically test the assumption that these innovations positively impact adherence. EN showed data illustrating how a digital therapeutic tool had improved adherence to a buprenorphine medication regimen in the treatment of opioid dependence [30] and concluded with a discussion of other ideas for how technology could enhance treatment adherence, for example, remote camera (smartphone) monitoring and confirmation, facial recognition software combined with pill ingestion, automated messaging, and motivational prompts.

The following series of presentations described ongoing digital health projects of the CTBH faculty and affiliates. Each of them highlighted behavior change methods, experimental design features, and potential next steps in their development efforts. First, MB described the development and testing of a mobile intervention to deliver motivational education for smoking cessation tailored for young adults with serious mental illness. She discussed the importance of reducing and quitting smoking to prevent the disparate chronic diseases in this vulnerable population and how design features of digital therapeutics need to be tailored to the special needs of the clinical population to optimize potential efficacy [31]. Her initial pilot study demonstrated increased quit attempts and increased biologically verified smoking abstinence compared with 2 control groups [32].

Next, WT described an international project called *Detection and Integrated Care for Depression and Alcohol Use in Primary Care*, which is funded by the Research Partnerships for Scaling Up Mental Health Interventions in Low- and Middle-Income Countries (Scale-Up Hubs) program of the National Institute of Mental Health. The project seeks to build sustainable research capacity and science-based programs in Latin America while simultaneously creating new knowledge to inform science-based approaches to scaling up mental health implementation research [33,34]. In Latin America, the burden of mental health problems is high, and services for mental health care are low. Expanding access to mental health care in a way that can be quickly scaled and have a substantial impact on the population is a significant global challenge. This project involves training the Latin American primary care workforce to use digital technology to enhance screening and diagnosis and to deliver treatment for depression and substance use via a science-based mobile digital therapeutic tool.

The next set of presentations illustrated how social media can be leveraged for conducting digital epidemiological studies, developing and testing of digital therapeutics, and in-person recruitment for traditional clinical trials. JB reported on a particularly cost-effective means of using social media to recruit adult and adolescent populations with unique characteristics. He highlighted existing literature demonstrating that such methods can be used to recruit clinically relevant populations (eg, persons with depression or HIV, electronic cigarette users, and those with alcohol use problems). He then described a series of studies conducted at CTBH using Facebook advertising mechanisms to recruit large and diverse samples of individuals who use cannabis and discussed the rich clinical epidemiological datasets that were obtained [35,36]. Such studies have provided valuable insights into policy impact, cannabis use phenomenology, and cannabis use benefits and consequences. He further highlighted how social media can also be leveraged to locate individuals interested in receiving treatment and for developing and delivering interventions remotely. AK described her innovative project that used social media, that is, private Facebook groups, to recruit adolescents at risk for anxiety and to remotely elicit their feedback on the design of a digital anxiety intervention [37]. She discussed how the observed active engagement and participation of teens in the Web-based focus group suggest that social media platforms may be an effective tool to engage and elicit feedback from youth in the early stages of the intervention design process.

CS concluded the series of demonstration project presentations by describing her Web-delivered intervention (WebRx) for teens with type 1 diabetes (T1D) and their parents. Across several small iterative pilot studies, she developed a novel multicomponent intervention that targeted adherence to self-management behaviors necessary to manage T1D [38]. Adherence-focused strategies include incentives for youth for objectively defined and tracked adherence behaviors, incentives for parents for daily monitoring of youth adherence, and Web-based health coaching to promote effective use of diabetes device data, and digitally delivered working memory training for the teens. CS described results from an RCT that demonstrated the superiority of WebRx, which engendered

higher self-monitoring of blood glucose, better visual-spatial working memory and inhibition, lower hemoglobin A_{1c} levels than those receiving usual care, more frequent parent review of the adolescent's glucometer, and reduced family conflict [38]. The presentation concluded by focusing on how this highly disseminable intervention focused on promoting the effective use of technology and software to monitor and improve medical outcomes.

Conclusions and Future Directions

This workshop brought together a collaborative group of junior and senior scientists from a diverse array of disciplines, including clinical and experimental psychology, data science and analytics, psychiatry, computer science, and population health, all interested in the same goal, that is, advancing digital therapeutics to improve health behavior. The presentations and discussions illustrated how scientists across these disciplines can learn from each other and jointly expedite the potential of technological innovation for improving public health and health care and how the science of behavior change is essential for maximizing the impact of this endeavor. Workshop participants endorsed finding additional meaningful ways to bring these seemingly disparate groups of scientists together more frequently. Many acknowledged that this was necessary to accelerate this area of science because of the multitude of phenomena involved in optimizing health and health research, for example, complexity of behavior, behavior change, assessment, measurement, big data analytics, intervention design, experimental design, technology capabilities and limitations, motivation for change, adherence to treatment regimens, and for optimal communication, dissemination, implementation, and sustainability of effective discoveries.

Attendees expressed an eagerness to participate in future workshops or alternative interdisciplinary activities that would better connect them to their colleagues and promote more collaborative project proposals. This workshop, the second of a planned series of 3 CTBH workshops corresponding to the Center's 3 scientific cores [39], confirmed and clearly illustrated the value of these types of structured activities for fostering greater collaboration among our interdisciplinary faculty and scientists. Complimentary ideas for the future included more in-depth workshops focused on *deep dives* into specific topics, organization of cross-disciplinary student and trainee journal clubs, use of alternative formats for workshops with built in time for small interdisciplinary group discussion, and the continued development of CTBH pilot funding opportunities that require specified cross-discipline collaborations.

In summary, our workshop on the development and evaluation of digital therapeutics for health behavior change showcased the myriad research targets that will be instrumental in promoting and accelerating progress in the field of digital health and health behavior change. The CTBH at the Geisel School of Medicine at Dartmouth College provides a model of multidisciplinary leadership and collaboration that can facilitate innovative, science-based efforts to address the health behavior challenges afflicting our communities by engaging and guiding teams of scientists to conduct research that will provide the knowledge and tools to inform more effective public health programming.

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Conflicts of Interest

LM is affiliated with Square2 Systems, Inc; Healthsim, LLC; and Pear Therapeutics. These relationships are extensively managed by LM and her academic institution. Dr. Brunette had a research grant from Alkermes, Inc.

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Abbreviations

CM: contingency management
CTBH: Center for Technology and Behavioral Health
FDA: Food and Drug Administration
NIDA: National Institute on Drug Abuse
RCT: randomized controlled trial
SCEDs: single-case experimental designs
SMART: Sequential Multiple Assignment Randomized Trial
T1D: type 1 diabetes
TDE: treatment development and evaluation
WebRx: Web-delivered intervention

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Original Paper

Involving End Users in Adapting a Spanish Version of a Web-Based Mental Health Clinic for Young People in Colombia: Exploratory Study Using Participatory Design Methodologies

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Abstract

Background: Health information technologies (HITs) hold enormous promise for improving access to and providing better quality of mental health care. However, despite the spread of such technologies in high-income countries, these technologies have not yet been commonly adopted in low- and middle-income countries. People living in these parts of the world are at risk of experiencing physical, technological, and social health inequalities. A possible solution is to utilize the currently available HITs developed in other counties.

Objective: Using participatory design methodologies with Colombian end users (young people, their supportive others, and health professionals), this study aimed to conduct co-design workshops to culturally adapt a Web-based Mental Health eClinic (MHeC) for young people, perform one-on-one user-testing sessions to evaluate an alpha prototype of a Spanish version of the MHeC and adapt it to the Colombian context, and inform the development of a skeletal framework and alpha prototype for a Colombian version of the MHeC (MHeC-C).

Methods: This study involved the utilization of a research and development (R&D) cycle including 4 iterative phases: co-design workshops; knowledge translation; tailoring to language, culture, and place (or context); and one-on-one user-testing sessions.

Results: A total of 2 co-design workshops were held with 18 users—young people (n=7) and health professionals (n=11). Moreover, 10 users participated in one-on-one user-testing sessions—young people (n=5), supportive others (n=2), and health professionals (n=3). A total of 204 source documents were collected and 605 annotations were coded. A thematic analysis resulted in 6 themes (ie, opinions about the MHeC-C, Colombian context, functionality, content, user interface, and technology platforms). Participants liked the idea of having an MHeC designed and adapted for Colombian young people, and its 5 key elements were acceptable in this context (home page and triage system, self-report assessment, dashboard of results, booking and video-visit system, and personalized well-being plan). However, to be relevant in Colombia, participants stressed the need to develop additional functionality (eg, phone network backup; chat; geolocation; and integration with electronic medical records, apps, or electronic tools) as well as an adaptation of the self-report assessment. Importantly, the latter not only included language but also culture and context.

Conclusions: The application of an R&D cycle that also included processes for adaptation to Colombia (language, culture, and context) resulted in the development of an evidence-based, language-appropriate, culturally sensitive, and context-adapted HIT that is relevant, applicable, engaging, and usable in both the short and long term. The resultant R&D cycle allowed for the adaptation of an already available HIT (ie, MHeC) to the MHeC-C—a low-cost and scalable technology solution for low- and middle-income countries like Colombia, which has the potential to provide young people with accessible, available, affordable, and integrated mental health care at the right time.

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KEYWORDS

Colombia; telemedicine; medical informatics; eHealth; mental health; cultural characteristics; cultural competency; ethnic groups; quality of health care; community-based participatory research; primary health care; patient participation; patient preference; patient satisfaction; consumer health information; methods; research design

Introduction

Background

According to the World Bank, Colombia (48 million inhabitants) [1] is defined as a middle-income country—gross domestic product (GDP) of US $314 billion [2]. However, it is one of the most unequal countries in the world (with a 2017 Gini index of 49.7) [3]. Although the country has spent 7% of its GDP on health over the past 15 years [4], only 0.08% of that spending has gone to mental health, which is the lowest of all South American countries [5]. Furthermore, although the country has a high level of nationwide health coverage (95%) [6], this is still difficult to access for ethnic minorities and Colombia's poorest regions. This is particularly the case for rural regions where 15% of the population lives [1]. As the Colombian health system is disease centered, the continuity and the quality of care are jeopardized in these areas because of the difficulty in attracting qualified specialists [7]. In 2017, it was estimated that there were only 1003 psychiatrists in Colombia [7] and that 80% of the psychiatrists were situated within major cities, resulting in a treatment gap of more than 50% [8].

Colombia has a very young population (40% of the population is aged below 25 years and 18% of the population is aged between 15 and 24 years) [1]. According to the most recent Colombian National Mental Health Survey (NMHS; 2015), the lifetime prevalence rate of mental health disorders for adolescents aged 12 to 17 years was 7% (any disorder), and the rate of suicide attempts for this age group was 3% [8]. This survey grouped adults between 18 and 44 years; therefore, the lifetime prevalence of these disorders in young adults is not clear. In a survey conducted in Medellin in 2012, the lifetime prevalence rates for young people aged 13 to 29 years were as follows: depression, 7%; any anxiety disorder, 13%; and posttraumatic stress disorder, 4% [9]. However, there are only a few specialized child and adolescent psychiatrists in the country; most of them are located in urban areas [10,11]. Many Colombian adolescents access mental health services (outpatient and inpatient) through adult facilities, which may not be fully equipped to meet their unique needs (appropriate to the stage of illness and developmental period, youth friendly, stigma free, preventative, positive, flexible, accessible, and affordable), and this results in more alienation for this young population [12].

Given the nature of the Colombian health system and its geography, the internet holds promise in bypassing the barriers to accessing mental health care for the country's population. This is particularly the case as Colombia has universal internet access (broadband, satellite, or microwave) [13]. A recent information and communications technology use survey revealed that 64% of households have access to the internet and that 72% of the households have at least one smartphone. Furthermore, there are more than 1500 free Wi-Fi hotspots located at major public places in the country. Colombia was one of the first countries in Latin America to propose a specific telehealth legislation (law 1419 of 2010). Its main aim is to integrate health information technology (HIT) interventions into the local health system to provide health services across all levels: promotion, prevention, diagnostic, treatment, rehabilitation, and health education [14].

Telemedicine in Colombia has been successfully operating since 1998 [15]; presently, the country has more than 2500 registered telemedicine service centers, which are located in the major cities and towns [16]. The number of these centers is constantly growing as some of the most important academic institutions and hospitals (public and private) are committed to delivering clinical assessments (including most of the medical specialties) to rural areas and marginalized populations [14,16,17]. The delivery of asynchronous telemedicine, which involves delivering text messages to end users (more commonly containing questions) and to experts (teleconsultation), has been postulated as an effective method for providing reliable health information and open dialogue about sensitive topics such as sexuality, drug use, or health concerns in the country [18-21]. Although HITs in Colombia seem to have a positive impact, most of the interventions still require rigorous evaluation [17].

However, although telemedicine has seen success in Colombia, there are a number of barriers to its further and more integrated implementation into Colombian health care. There is still a certain degree of skepticism in the general population toward delivering health care in this way, and health professionals still have limited knowledge on how to work effectively with technology [14,22]. Notwithstanding progress in the legislation, current law still restricts the use of telemedicine in rural populations (thus limiting its use in medium and small towns) and limits the use of telemedicine as a tool to only when face-to-face contact is not available [14,22]. Other legal limitations include the need for health professionals to be on both sides of the assessment (institution of remission and institution of reference), meaning that an individual cannot

directly connect with local or international health professionals, and there are some concerns related to security, privacy, data sharing, and data integrity [14,22]. Innovative uses of HITs, such as mobile health, and ubiquitous health, are still unregulated.

These barriers contribute to lack of uptake, engagement, and adherence, as well as high dropout rates. These phenomena can be explained by Eysenbach's attrition law [23], which postulates that a substantial proportion of end users lose interest or experience some difficulties while using the technological intervention and thus stop using it. This might be because of the perception that the intervention is not creating any benefit, that it is responding to an overly specific need, or that it has usability problems [23]. Although academia-led HITs have the strength of incorporating evidence-based and best clinical practices into their design, it is common to sacrifice the intervention's usability over content because of limited funding [11,24]. For researchers, it is hard to compete with commercial products that provide highly intuitive and engaging experiences in their products, despite having unknown evidence-based or clinical value [11,24].

To ensure that end users of HITs can derive maximum value from such interventions, it is critically important to involve them in their design and development and to strike a balance between best clinical practice and user experience (including usability). Participatory design (PD) methodologies represent one such solution [25-27]. The process involves engaging end users and other stakeholders at all stages (from conception to completion) of the design, development, and testing of these technologies [26,28,29]. Through several iterative phases, the prototype is co-designed, codeveloped, and refined until it has value to the end users; meets their needs; and is appealing, engaging, acceptable, and usable [26,30,31]. As end users share equal responsibility with the researchers for the outcomes, the rationale behind the use of PD methodologies could result in better products that are more functional in real-life settings, thereby closing the translational research gap [26]. In recent years, it has become more common to see the use of these methodologies in the development of mental health interventions in English-speaking countries [26-28,30,32]. However, to our knowledge, these methodologies have not yet been used in Colombia or any other Latin American country in this field.

The University of Sydney's Brain and Mind Centre (BMC) is a leader in the development of evidence-based electronic health technologies [11,26,33-38]. Through a partnership with the Young and Well Cooperative Research Centre (2014-2016), the prototypic version of the Mental Health eClinic (MHeC) [26,36] was designed and developed. This Web-based tool aimed to deliver best-practice clinical services to people experiencing mental health problems, making clinical care accessible, affordable, and available to young people whenever and wherever they need it most. The original MHeC was then co-designed and culturally adapted, developed, and user tested (2015-2017) with Spanish-speaking young people currently living in Australia, resulting in the Spanish version of the Mental Health eClinic (MHeC-S) [31].

The original MHeC comprised 5 key elements: a home page with a visible triage system for those requiring urgent help, a comprehensive Web-based physical and mental health self-report assessment, a detailed dashboard of results (with colored icons and traffic light representations of results), a booking and videoconferencing system to enable video visits, and the generation of a personalized well-being plan that includes links to evidence-based apps and e-tools recommended by health professionals and suggested by young people [26]. These elements were well accepted by Spanish-speaking young people living in Australia [31]. Considering the potential of the MHeC-S to be configured and adapted for use in Spanish-speaking countries and in other multicultural countries with Spanish-speaking migrant populations, as well as Colombia's health and internet characteristics described above, we envisioned that a Colombian version of the MHeC (MHeC-C) could greatly benefit young Colombians who are actively seeking help.

Aims

Using a modified version of our already established research and development (R&D) cycle [26,31] with Colombian end users (young people aged 16 to 30 years, supportive others, and health professionals) as a framework, this study aimed to (1) conduct co-design workshops with end users to culturally adapt the MHeC for young people in Colombia, (2) perform one-on-one user-testing sessions with end users to evaluate the alpha prototype of the MHeC-S and how to adapt it to the Colombian context, and (3) inform the development of the skeletal framework and alpha prototype of the MHeC-C.

Methods

Participants

Participants included community-based young people aged 16 to 30 years, health professionals, and supportive others with regular access to a mobile phone (iPhone or Android) and the internet. The recruitment strategy included the identification of potential participants through the reference groups and youth reference groups of our Colombian partner institutions (Pontificia Universidad Javeriana, Universidad de Antioquia, and Universidad Autónoma de Bucaramanga), posters and postcard advertisements displayed in common areas where the reference groups meet, Facebook advertisements, and a study-specific Facebook page.

The University of Sydney's Human Research Ethics Committee approved this study (protocol number 2014/689 for the co-design workshops and protocol number 2016/487 for the user-testing sessions); however, as requested by the Human Research Ethics Committee, local (Colombian) approvals were also obtained to ensure that the study complied with all the local regulations on research with humans. Participants were provided with relevant information about the study (participant information statement) before consenting and participating in the study. Young people were provided gift vouchers to thank them for their time and expertise when they attended co-design workshops and user-testing sessions.

Research and Development Cycle

The PD methodologies used in this study were based on the guidelines provided by the Young and Well Cooperative Research Centre [39] and were similar to the ones applied in our previous research [26,30,31]. The R&D cycle implemented in this study has been demonstrated to be an efficient method to obtain the most information from end users by engaging them in different activities. For this exploratory study, we conducted a modified version of our previously established R&D cycle (Figures 1 and 2) [26,31]. This study comprised 4 concurrently running phases: co-design workshops (phase 1), knowledge translation (phase 2), content tailoring (phase 3), and one-on-one user-testing sessions (phase 4). Considering that language and culture are the key aspects in the process of adaptation, we decided to incorporate language and culture as part of the framework the R&D cycle is based on. With that in mind, phase 3 (language translation and cultural adaptation) [31] of our previous MHeC-S's R&D cycle moved to be the cornerstone of the cycle used in this study, and phase 3 in this study only refers to the content tailoring process. Phases 5—rapid prototyping and user testing (alpha, a preliminary version that can be interacted with for user-testing purposes, and beta, a more refined version of the prototype that is much closer to the final product, prototypes)—and 6—real-world study, with a delta prototype that can be used directly by end users for feasibility testing—would be the subject of future research.

Figure 1. Previously established research and development cycle of the Spanish version of the Mental Health eClinic.

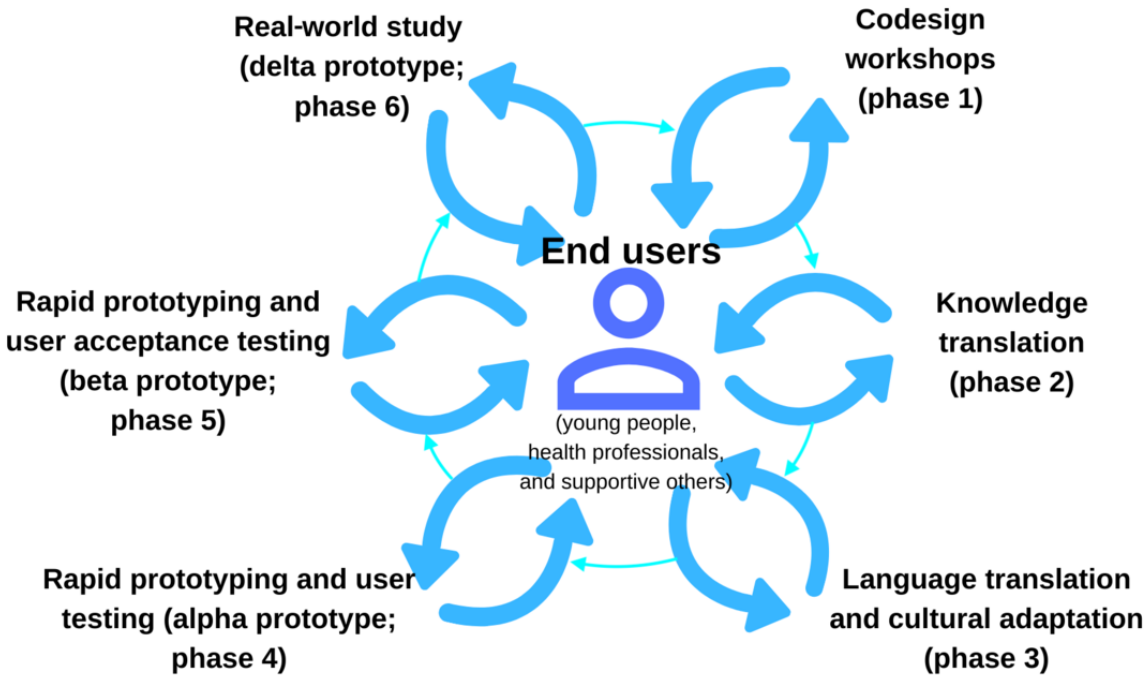
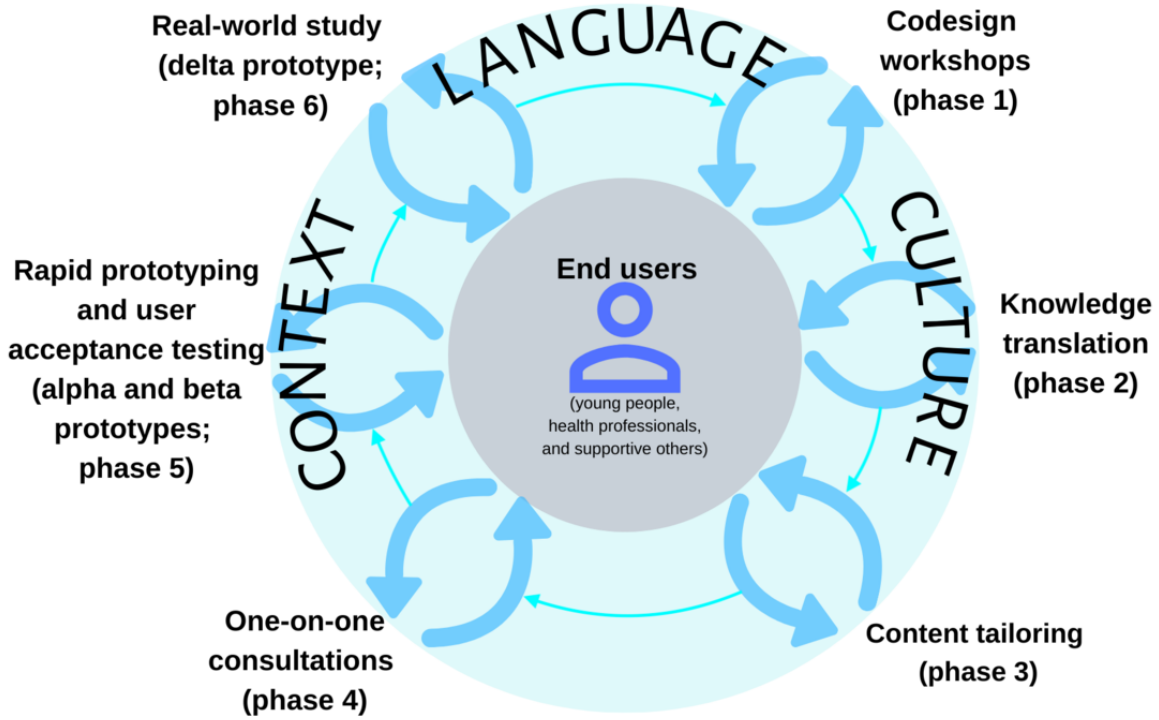


Figure 2. A language-appropriate, culturally sensitive, and contextually adapted framework as an intrinsic part of the research and development cycle.



Phase 1: Co-Design Workshops

We held 2 co-design workshops, one with young people and the other one with health professionals. The workshops were conducted in Bogota, Colombia, in 2015. The aim of these workshops was to identify how best to co-design the MHeC-C's alpha prototype and, broadly, how to adapt the MHeC to a Colombian setting and population. The half-day (4 hour) workshops comprised 3 stages: discovery, evaluation, and prototyping. At the end of each workshop, the information was analyzed and synthesized by a knowledge translation team (comprising 2 interns at The University of Sydney's BMC) for design testing in subsequent workshops. Digital technology was not used in any stage of the workshops.

Discovery

Workshop moderators facilitated participant discussion in relation to the following topics: defining the advantages and disadvantages of having an MHeC-C, defining the barriers of having an MHeC-C, and establishing how a prototype like this should look and function to meet the young persons' needs in the Colombian context. Handwritten notes were taken during the entire workshop.

Evaluation

Participants were then presented with screenshots of existing mental health websites and wireframes or mock-ups of the early versions of the MHeC and the MHeC-S for their critical evaluation. These items contained a variety of features of interest, such as the 5 key elements of the MHeC and other relevant apps and e-tools related to mental health or well-being. Marker pens were provided for participants to annotate their observations.

Prototyping

Finally, participants were asked to hand-draw their ideas, specifications, and requirements for an MHeC-C. Sketchbooks and marker pens were provided for this activity.

Phase 2: Knowledge Translation Process

The knowledge translation process comprised analyzing the visual artifacts (mock-ups and end-user sketches) produced in the design-testing and sketching stages and tallying requested MHeC-C features from the notes taken in phase 1 (co-design workshops). Observations that were repeated 3 or more times were considered for inclusion in phase 4 or in the development of wireframes. The discrepancies that arose during this process were discussed between the knowledge translation team and 2 mental health researchers and Colombian psychiatrists (LOP and ANM) until reaching consensus in the second session.

Phase 3: Content Tailoring

LOP and ANM reviewed the general content of the MHeC-S alpha prototype to detect language subtleties. A literature review of published (identified via PubMed, Google Scholar, Scientific Electronic Library Online, and Latin American & Caribbean Health Sciences Literature) and gray literature (identified via Google Advanced search) was undertaken by LOP to identify relevant measures for this population, as well as those instruments already translated, validated, and used in Colombia. Recognizing that some questionnaires might have several versions, the following process was established to select instruments: (1) selection of official and published translations and (2) selection of published Colombian versions of the official translations. When more than 1 version or source was available, the 2 Colombian psychiatrists (LOP and ANM) selected the most appropriate version or source to be included through discussion and consensus. If the questionnaires were not publicly available or there were no self-report versions for the topics to

be assessed, expert recommendation (discussion and consensus among 3 Colombian psychiatrists LOP, ANM, and AC) was utilized.

Phase 4: Remote One-on-One User-Testing Sessions

Phase 4 involved in-depth one-on-one user-testing sessions with new end users (young people, health professionals, and supportive others). The sessions were held remotely using GoToMeeting and its shared screen capacity (GoToMeeting by LogMeIn, Boston, Massachusetts, United States, is a screen sharing software that allows users to display the entire screen, multiple monitors, or specific apps at any time) [40], using laptops, tablets, and mobile phones. In each 90-min one-on-one user-testing session, a researcher guided an end user into the already available alpha prototype of the MHeC-S. Using a think-aloud protocol [41], participants provided their observations as they were shown the navigation through the prototype. These sessions also explored the utility and the end users' inclination to use an MHeC in Colombia, overall comments, and the process of naming the prototype. Handwritten notes were taken during all sessions.

Data Analysis

All source documents (phase 1, co-design workshop notes and artifacts, and phase 4, user-testing notes) were uploaded to NVivo 11 for Mac (QSR International) and analyzed using thematic analysis techniques [42,43]. Importantly, source documents were analyzed at the end of each phase to explore preliminary findings and inform subsequent phases. The thematic analysis framework involved both inductive and deductive coding, with the deductive codes being 5 previously identified themes [31]: help-seeking barriers, technology platform, functionality, content, and user interface [26]. A total of 2 Colombian psychiatrists (LOP and ANM) coded the material, and 1 researcher analyzed the information (LOP). Data collection and qualitative analysis were conducted in Spanish by LOP and ANM. To facilitate the reporting of results, translated quotes from the source documents are included below, and Multimedia Appendix 1 lists the original quotes in Spanish.

Results

Co-Design Workshops and User-Testing Sessions

In June 2015, we conducted 1 half-day co-design workshop with young people in Colombia and 1 half-day co-design workshop with Colombian health professionals. In total, we conducted 2 knowledge translation sessions: one after the co-design workshops (phase 1) and the other at the end of the one-on-one user-testing sessions (phase 4). We conducted 10 remote one-on-one user-testing sessions in August 2017. The language and cultural adaptation process started in June 2015 and finished in November 2017.

Participant Characteristics

A total of 7 young people participated in the co-design workshops; 5 were female, and their ages ranged from 18 to 22 years (median age 19.5 years). A total of 11 health professionals participated in the workshops; 5 were female, and their ages ranged from 20 to 29 years (median age 27 years). Of the health professionals, 2 were medical students and the rest were psychiatry registrars (Table 1).

A total of 10 participants participated in the one-on-one user-testing sessions: 5 young people with ages ranging from 17 to 24 years (median age 22 years), 3 health professionals with ages ranging from 29 to 36 years (median age 29 years; all of them were psychiatrists), and 2 supportive others with ages ranging from 19 to 24 years (median age 21.5 years). Of these participants, 7 were female (Table 1).

Table 1. Participants' characteristics.

Characteristics	Co-design workshops with young people (n=7)	Co-design workshops with health professionals (n=11)	One-on-one user-testing sessions (n=10)
Demographics			
Female, n (%)	5 (71)	5 (45)	7 (70)
Age (years), median (IQR)[a]	20 (2)	27 (1.5)	23 (6.5)
Education			
Secondary, n (%)	7 (100)	2 (18)	6 (60)
Tertiary, n (%)	0 (0)	9 (82)	4 (40)

[a]IQR: interquartile range.

Coding Framework

During the co-design workshops, a total of 194 source documents were developed and analyzed (2 sets of workshop notes and 192 artifacts produced by participants). A total of 312 annotations were coded: 106 annotations in the content theme, 151 annotations in the functionality theme, and 47 annotations in the user interface theme. Moreover, 2 new themes emerged in this phase: opinions about the MHeC-C (4 annotations) and Colombian context considerations (4 annotations). There were no annotations in the help-seeking or the technology platform themes in this stage.

During the one-on-one user-testing sessions, 10 sets of notes were generated. A total of 293 annotations were coded: 132 annotations in the functionality theme, 58 annotations in the user interface theme, 42 annotations in the content theme, 23 annotations in the opinions about the MHeC-C theme, 20 annotations in the Colombian context considerations theme, and 18 annotations in the technology platform theme. There

were no annotations in the help-seeking theme; consequently, it was removed from the coding framework analysis.

For the purposes of this paper, we report the data aggregated from the co-design workshops and the one-on-one user-testing sessions, specifying in which session the information was collected where relevant.

Opinions About the Colombian Version of the Mental Health Electronic Clinic

All participants (28/28) liked the idea of having an MHeC specially designed for and adapted to a Colombian context. As possible advantages, they suggested it would reduce costs even if the initial investment would be considerable, and in the long run, individuals would save time and money and the need for physical infrastructure would be less. All young people (12/12), all health professionals (14/14), and supportive others (2/2) agreed that a prototype like this would expand access to health professionals (especially in rural areas), facilitate monitoring, and reduce loss to follow-up. This would ultimately increase satisfaction, convenience, and engagement with the health system, as individuals would have more flexibility with their time and no location barriers. In addition, all health professionals (14/14) felt the prototype would improve the health service network, as it would provide specialized assessments, regardless of the individuals' location, and support for rural professionals. Integrating the MHeC-C with electronic medical records, laboratory results, and pharmacological records would increase treatment adherence and provide more objective information that would translate to better monitoring and health outcomes. Some health professionals from the co-design workshops (7/11) also believed that this prototype could be safer in cases of assessing individuals with violent behaviors, whereas the rest (6/11) believed that they would feel safer if the MHeC-C was part of the already established health network.

However, regarding disadvantages and barriers, all participants (28/28) mentioned that in some places, the internet connection is not reliable, so the prototype needs to be backed up with a phone network. Among barriers of using an MHeC-C, all young people (12/12) mentioned difficulties while accessing the internet, as most young people do not pay for mobile data and therefore require internet access at their homes and schools, or they require free Wi-Fi networks. All health professionals (14/14) recognized that the MHeC-C could have limited utility in acute cases or in cases where performing physical (neurological) assessments would be required.

Colombian Context Considerations

Overall, health professionals (14/14) believed that the MHeC-C should be led by a partnership between a university and a health service provider and have strong networks with the community and other relevant organizations. A partnership with local governments and stakeholders would be necessary but especially relevant in rural settings to increase trust and, as such, increase the acceptability of the prototype. For people to be able to use the MHeC-C, it needs to be recommended by clinicians, health services, and school and university well-being centers, which should be complemented with publicity and media coverage (eg, radio, television, social networks, magazines, and newspapers). As most young people are not economically independent, it would be important for the MHeC-C to be embedded in the public health care system.

In relation to the branding and name of the MHeC-C, young participants (12/12) considered that the combination of terms *mental health* and *clinic* would be less appealing for them, as they might feel that the MHeC-C only deals with severe cases and might not be appropriate for them and that it would consequently be more stigmatizing.

Functionality

As defined by Valdez et al in their culturally informed design framework [44], functionality indicates the actions that can be performed in the prototype. All participants (28/28) agreed that the 5 key elements of the MHeC-C were acceptable in this context. In general, participants agreed that the MHeC-C should be compliant with international cybersecurity standards to ensure privacy and data protection.

Element 1: Home Page and Triage System

All participants (28/28) agreed that to gain trust and increase credibility, the MHeC-C's webpage domain should be *.com*, *.co*, or *.org*. Alternatively, the MHeC-C could be imbedded in universities' official websites, as they believe universities should have a lead role in the development and maintenance of this kind of prototype. The logos of the principal institutions as well as partner organizations should be displayed at this stage. Participants also agreed with providing a small description of the MHeC-C, delivered with images, videos, and testimonials from young people and health professionals. Both young people and health professionals agreed that the initial home page could be the same for both groups; however, after registration and log-in processes, the prototype would change to address both user types' different needs.

All participants liked the triage functionality and recognized the importance of promptly referring someone to the emergency help services. In the same line, the *Need Help Now* button was identified as an important resource for people in crisis who were unaware of the emergency lines. Participants highlighted the importance of this button to be associated with a geolocation system, as in Colombia, emergency (psychological) numbers change according to their location. A health professional explained the following:

> *...the general emergency line is the same 123, but the psychological emergency line changes, for example in Bogota it is 106 and in Cartagena it is 125...* [Health professional, quote A]

As Web-based services are scarce in Colombia, it was proposed to have a 24/7, moderated Web-based chat that would provide support and counseling to individuals seeking help. For young people, this functionality would be situated under the *Need Help Now* button. Health professionals believed that a functionality like this would also be useful for them to provide guidance and supervision to other less experienced health professionals (eg, general practitioners in their social compulsory service) or to those located in rural areas. The chat functionality for health professionals would work only for health services and professionals attached to the MHeC-C. In case the internet

connection is intermittent or lost, the chat functionality should also have a phone support service that would be enabled to continue with the conversation (Figure 3).

Participants acknowledged the difficulty of having health professionals available at all times to chat; therefore, they proposed that the chat should work only during extended hours (from 6 am to 12 am), and in off-time hours, they should have the option to leave a question to be answered later. At the same time, young people recognized the importance of having carefully moderated blogs, forums, or group chats with a selection of helpful topics to find support and learn from other people's experiences. Figures 4 and 5 represent the proposed home page for future developments.

Figure 3. Hand-drawn sketch by end users during a participatory design workshop representing the chat functionality and the phone support service.

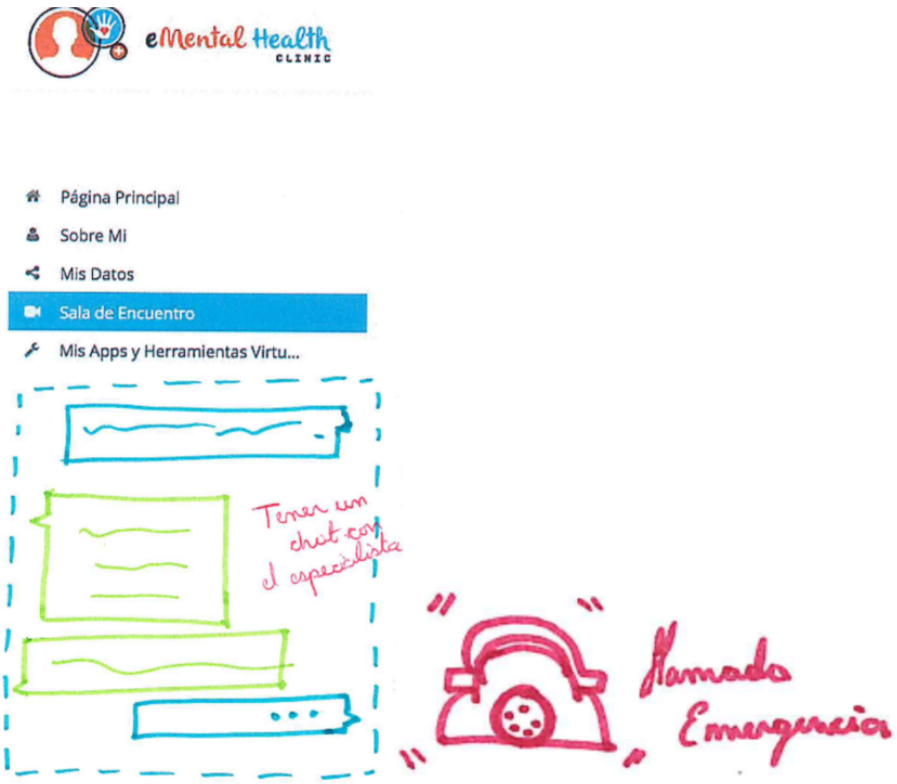


Figure 4. Hand-drawn sketch by end users during a participatory workshop representing the home page.

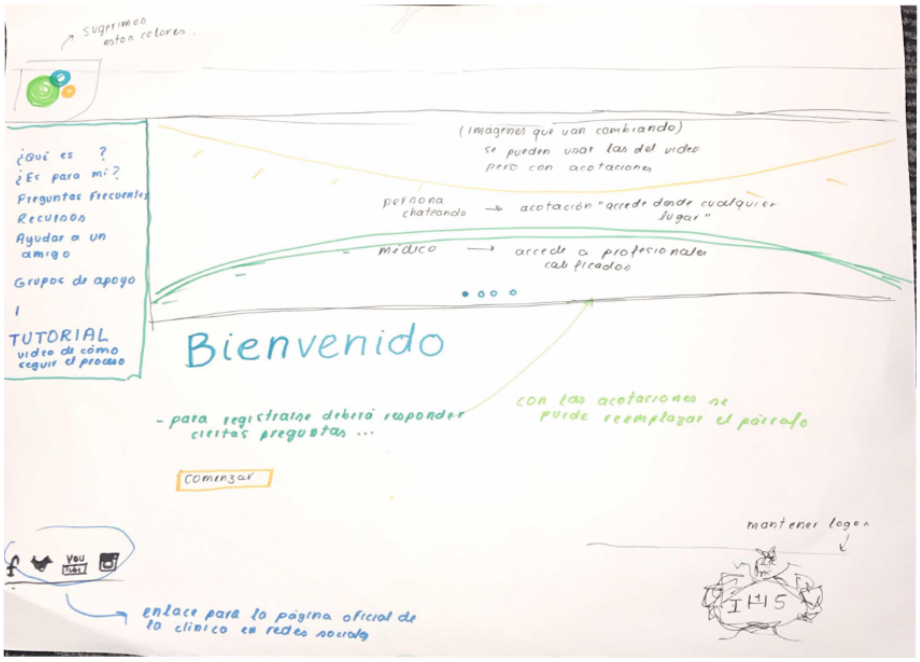


Figure 5. Screenshot of the skeletal framework of the home page of the Colombian version of the Mental Health eClinic.

Element 2: Web-Based Physical and Mental Health Self-Report Assessment

All participants agreed with the need to assess young people's physical and mental health. The already established features of this element were accepted among the end users: modular display of question sets, capacity of pausing and resuming later, and rule-based decision algorithms that enable a personalized assessment of the young person. Again, participants mentioned the possibility of using geolocation to automatically collect data about the participants and personalize the assessment. A health professional explained the following:

> *...it would be very useful to geolocate the person, this means the prototype would be able to know where they are so they don't have to waste time filling their addresses. Also, as Colombia is so diverse, we know that the regions have different needs so the questions could be specific to those needs. For example, in regions affected with violence, assessing this topic in-depth would be crucial. Another example would be assessing thoroughly the social determinants of health if the person lives in a poor area or is identified with a low socioeconomic status...* [Health professional, quote B]

The types of questions in the prototype (Likert-type scale questions and 2-way close-ended questions) were also acceptable to participants. However, health professionals (11/14) suggested adding visual responses, such as the pain visual analog scale [45], and including 1 open-text question with the aim of assessing the individual's reason for accessing the MHeC-C over traditional face-to-face services.

Element 3: Dashboard of Results and Progress Report

There was a discrepancy in the end users' opinion on the immediate display of the dashboard of results after completion of the Web-based self-report assessment. All young people (12/12) and some health professionals (6/14) agreed that the prototype should display the results immediately. Other health professionals (8/14) were concerned with the pertinence of the results, as a young person could potentially experience some distress while viewing their results, especially for those living in rural areas. As a potential solution to this, participants suggested giving individuals the option to pick if they want to see their results immediately or wait to review their results with a health professional.

Participants agreed with the traffic light representations and colored icons. Simple bar and line graphs were preferred to represent progress and track data over time. Health professionals considered that the dashboard of results was useful to inform their practice, making the assessments more efficient and specific as well as enabling them to deliver the interventions earlier and monitor the individual's progress over time. In addition, health professionals believed that the results of the assessment and the dashboard were useful research tools. In relation to the dashboard's language, lay terms were preferred over medical terminology. The option of displaying a simple explanation of the term (only when medical terms are needed)

when participants click on the word or hover over it was widely accepted among the participants.

Element 4: Booking System and Video Visit

Before booking a video visit, participants wanted to view the profiles of the health professionals attached to the MHeC-C so that they could choose the professional they want to see. A young person explained the following:

> *...I would like to know more who I'm going to see, so I can decide if I see a man or a woman or see what are their areas of expertise...* [Young person, quote C]

In addition, it was proposed to have calendar functionality so that young people could book appointments according to the health professionals' availability. This functionality should also reflect other relevant calendars, such as the health professional's calendar, and the administrative staff so they can use it for other purposes such as billing.

Health professionals considered the video visit to be a useful tool for providing supervision, training, and consultation to colleagues located in rural areas. A health professional explained the following:

> *...doctors in their social compulsory service (located in rural areas) might need support from specialists, it would be very useful to use the video visit system to help them assessing difficult cases or to provide supervision...* [Health professional, quote D]

In addition, as some health services still have paper-based medical records, having an electronic medical record attached to the MHeC-C would be ideal so that all the individuals' information could be stored in the same place.

Given that health professionals would have detailed and accurate self-report information before the video visit (dashboard of results), all participants agreed that around 20 mins would be enough time to assess a young person and provide recommendations. Health professionals would also like the possibility to extend video-visit time with complex cases. Should a video-visit appointment run late, health professionals also suggested that the MHeC-C should send a notification to people waiting for subsequent appointments.

Element 5: Personalized Well-Being Plan Includes Links to Evidence-Based, Young Person–Suggested and Health Professional–Recommended Apps and E-Tools

Participants accepted the activation of a personalized well-being plan and recommendations according to their results. Young people and health professionals believed that these recommendations could be delivered as apps, videos, or printable material. Health professionals suggested the MHeC-C could be connected to the website *mental punto de apoyo* [46,47], as this informational website has a wide variety of information for individuals, supportive others, and health professionals; as well as, psychoeducational and training material; and community blogs.

The issue about shortage of Spanish-language apps and e-tools was also raised. Health professionals believed that developing such apps to track variables such as mood, sleep, physical activity, and nutrition as well as interventional apps that contain cognitive behavioral therapy strategies and mindfulness would be necessary. In general, participants believed these apps and e-tools need to be in Spanish, as the chances of using an English-based app are minimal. The need to create videos with general information, as well as relaxation and breathing exercises, was also mentioned.

Content

General Content

Content refers to the message that is transmitted [44]. Participants from the one-on-one user-testing sessions had the opportunity to explore the alpha prototype of the MHeC-S. These participants (10/10) found that some pieces of general content already available were relevant for them but needed minor tweaks to fit the context, such as general information about the MHeC-S, breathing exercises, frequently asked questions, and how to help a friend. Other content including health services information, terms and conditions, and information about partner organizations needed major changes to be relevant in Colombia. Again, the scarcity of Spanish-language apps and e-tools was highlighted, as they are the cornerstone of the personalized well-being plan.

Cultural Adaptation of the Self-Report Assessment

The original Spanish-language self-report assessment included 20 modules (Table 2) with smart skips built in so that it was tailored to each individual and took the minimum possible amount of time to complete (approximately 45 min) [31].

Of the 20 modules, 19 modules were considered relevant by the participants and 1 module (cultural adaptation and adjustment disorder) was considered unnecessary. Health professionals (3/3) and supportive others (2/2) from the one-on-one user-testing sessions suggested including further topics to be assessed. As *family* is very important in the Colombian culture, it was suggested to assess family structure and support network. Religion and spirituality were also considered as important factors to be assessed, as they might influence an individual's mental health, act as support, or define some treatments. Owing to the country's characteristics, it was also considered necessary to evaluate social risk by screening economic stability, neighborhood and physical environment, food security, and access to the health care system [83]. As Colombia has been severely affected by violence, participants also suggested to evaluate violence exposure, trauma, and resilience.

Table 2. Self-report assessments in the Spanish version of the Mental Health eClinic and the Colombian version of the Mental Health eClinic.

Module and questionnaires	Self-report assessments		
	MHeC-S[a] and MHeC-C[b]	MHeC-S only	MHeC-C only
Main reason for visiting	Short open-text question	—[c]	—
General demographics		Items adapted to Spanish from the Second Australian Young and Well National Survey [48] and the 2-step method to measure transgender identity [49]	Items adapted to Spanish from the Second Australian Young and Well National Survey [48] and the 2-step method to measure transgender identity [49]. Religion, spirituality, socioeconomical status, food insecurity, sanitation, access to drinking water, electricity, housing, assets, and health care selected items from the NMHS[d] [50]
Social and occupational function	World Health Organization Disability Assessment Schedule 2.0 [51] and an adapted version of the self-report version of the Social and Occupational Functioning Assessment Scale [52]	—	—
Psychological distress	10-item Kessler Psychological Distress Scale [53]	—	—
Depressed mood	QIDS-SR-16[e] [54,55]	—	—
Anxiety	Generalized Anxiety Disorder Assessment-7 [56]	—	—
Mania-like experiences	Items derived from the Altman Self-Rating Mania Scale [57]	—	—
Psychosis-like experiences	Items derived from the Community Assessment of Psychic Experiences-Positive Symptoms Scale [58,59]	—	—
Traumatic experiences		Primary Care PTSD[f] Screen [60] and the PTSD Checklist-Civilian Version [61]	Attitudes and experiences to violence (domestic violence, organized crime, displacement, and armed conflict) from the NMHS. Selected items from the Adverse Childhood Experiences [62]. Primary Care PTSD Screen [60] and the PTSD Checklist-Civilian Version [61]
Self-harm behaviors and suicidal ideation	Suicide Behaviors Questionnaire-Revised [63]	—	—
Tobacco, alcohol, and substance use	Items adapted from Alcohol Use Disorders Identification Test [64]; Alcohol, Smoking, and Substance Involvement Screening Test [65]; and Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers questionnaire [66]. Items adapted to Spanish from the Drinking Motives Questionnaire [67], Fagerström Test for Nicotine Dependence [68], and selected items adapted to Spanish from the National Drug Strategy Household Survey [69]	—	—
Physical activity	International Physical Activity Questionnaire [70,71]	—	—
Sleep behaviors	Sleep-related items from the QIDS-SR-16		
General mental health conditions	Spanish version of the World Mental Health Composite International Diagnostic Interview used in the National Comorbidity Survey Replication Adolescent Supplement [72,73]	—	—

Module and questionnaires	Self-report assessments		
	MHeC-S[a] and MHeC-C[b]	MHeC-S only	MHeC-C only
Overall heath and somatic distress	Items adapted to Spanish from the Somatic and Psychological Health Report [74], self-perceived health status, and general body measurements	—	—
Medical, mental health, and family history	Multiple-choice questions	—	—
Cognitive concerns and empathy	Items derived from the Subjective Scale to Investigate Cognition in Schizophrenia [75], adapted to Spanish, and the empathy quotient [76]	—	—
Eating behaviors and body image	Items derived from the Eating Disorder Examination [77], adapted to Spanish	—	—
Social connectedness and support (and family structure for Columbian version)	—	Items derived from the Perceived Social Support/Conflict Measure [78], plus 5 items measuring relationships with peers [79], adapted to Spanish	Items derived from the Perceived Social Support/Conflict Measure [78], plus 5 items measuring relationships with peers [79], adapted to Spanish, and family APGAR [50,80]
Cultural adaptation and adjustment disorder	—	The Brief Sociocultural Adaptation Scale, the Brief Psychological Adaptation Scale, the Brief Perceived Cultural Distance Scale, and the Brief Acculturation Orientation Scale [81]	—
Resilience	—	—	Connor-Davidson Resilience Scale (CD-RISC 10) [82]
Cultural adaptation and adjustment disorder (optional, consider in the case of migrant populations)	—	—	The Brief Sociocultural Adaptation Scale, the Brief Psychological Adaptation Scale, the Brief Perceived Cultural Distance Scale, and the Brief Acculturation Orientation Scale [81]

[a]MHeC-S: Spanish version of the Mental Health eClinic.

[b]MHeC-C: Colombian version of the Mental Health eClinic.

[c]Not applicable.

[d]NMHS: National Mental Health Survey.

[e]QIDS-SR-16: Quick Inventory of Depressive Symptomatology-16.

[f]PTSD: posttraumatic stress disorder.

The cultural adaptation of the self-report assessment started in November 2016, with the literature review. We found 6 questionnaires that could be integrated to the MHeC-C to address the already mentioned needs. To assess family structure and support network, we selected the family APGAR, which has been widely used in Colombia [50,80]. To assess social risk, we selected items assessing socioeconomical status, food insecurity, sanitation, access to drinking water, electricity, housing, assets, and health care from the NMHS [50]. Items regarding attitudes toward and experiences with violence (domestic violence, organized crime, displacement, and armed conflict) from the NMHS were also included. Select items from the Adverse Childhood Experiences questionnaire were selected to enrich the trauma component [62]. In relation to resilience, we found 3 scales validated in the Colombian context—Adolescent Resilience Scale [84], Child and Youth Resilience Measure 12-item [85], and Connor-Davidson Resilience Scale (CD-RISC 10) [82]. All these scales assess the internal sources of resilience [86]; however, the last 2 assess external resources as well. We selected the CD-RISC 10 because of its length and because it has been widely used in the country. Religion and spirituality were also assessed with selected items from the NMHS. Table 2 represents the proposed self-report assessment for the MHeC-C.

User Interface

User interface refers to the visual presentation of content and functionality [44]. When shown the home page, participants agreed that the website should not only look professional but also be appealing and engaging for a young person. Horizontal menus were preferred over vertical menus in a laptop interface, but hamburger and vertical menus were the preference in tablets or mobiles. Young people (12/12) preferred to have less text

and more visual content. Health professionals (14/14) and supportive others (2/2) also recognized the importance of visual content, as they believed that young people tend to read just the minimum amount of text and that information could be lost. Participants preferred to have on the home page pictures of young people interacting with the MHeC-C, with a light background or calming landscape.

The color palette suggested in the co-design workshops was blue-green complemented with yellow-orange. However, participants from the one-on-one user-testing sessions liked the orange color. The MHeC-S logo was rejected by participants in the one-on-one user-testing sessions, as they did not find any representation of mental health on it and did not find the color appealing. Most participants (24/28) suggested a logo depicting a brain or a head (Figure 6):

> *...It reminds me of orange uniforms of the Colombian Civil Defense...* [Young person, quote E]
>
> *...I might be wrong but the logo needed to include a brain or a head or something like that...* [Health professional, quote F]

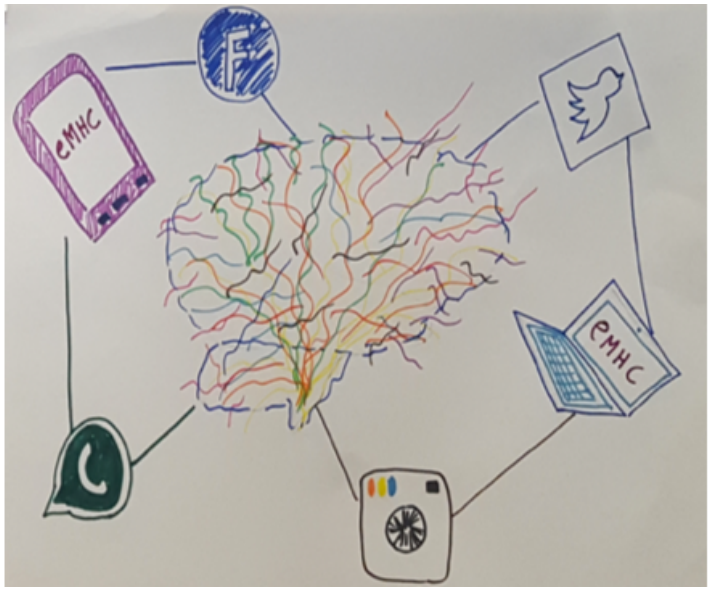
Participants felt that the *Need Help Now* button needed to draw individuals' attention, and they suggested making this button bigger or brighter and perhaps adding an icon that represented help, such as a ringing phone, a Christian cross, or an SOS acronym. Participants also felt that *Need Help Now* should provide chat functionality and information about local emergency phone lines.

In relation to the interface's language (regarding formal and informal pronoun usage), all end-user groups agreed that the preference to use a particular pronoun was not an issue; however, they highlighted the importance of using the pronouns consistently. A health professional explained the following:

> *...the country is so diverse that there are regions that use formal pronouns and others informal pronouns, the most important thing is to use it consistently...* [health professional, quote G]

As a possible solution to reconcile this discrepancy, it was proposed that the prototype should use the colloquial or familiar form of the second-person singular pronoun (in Spanish: *tu´*), as it was targeting young people.

Figure 6. Hand-drawn sketch by end users during a participatory workshop representing the Colombian version of the Mental Health eClinic's logo.



Technology Platform

Technology platform refers to the different types of hardware [44] the prototype should work on. Unanimously, participants agreed that mobile phones were the most important device to increase the reach of young people. However, health professionals also suggested that it should work on desktops, laptops, and tablets, which are their preferred devices in the workplace.

Discussion

Principal Findings

This exploratory study used a modified version of our previously established R&D cycle to co-design and culturally adapt a prototypic Spanish-language version of a Web-based MHeC-S into a Colombian version for young people in Colombia (MHeC-C). A thematic analysis resulted in adequate acceptability of the functionality of the 5 key elements of the prototype (a home page and triage system; a comprehensive Web-based physical and mental health self-report assessment; a dashboard of results and progress report; a booking and videoconferencing system to enable video visits; and the generation of a personalized well-being plan that includes links to evidence-based, young person–suggested, and health professional–recommended apps and e-tools). However, for these elements to be relevant in Colombia, participants stress the need to develop additional functionalities, such as backing up the system with a phone network, a chat system, a geolocation system, and wide integration with electronic medical records and other already available apps and e-tools. Participants stated that to make the MHeC-C appropriate to the (Colombian) context, it needed to operate in alliance with academic institutions, health providers (at all levels), and other community

organizations. Owing to the unique Colombian context, the self-report assessment needed to include items evaluating (including the creation of specific algorithms) the social determinants of health, attitudes toward and experiences with violence, and resilience, and extending the trauma module to assess childhood adverse experiences. In relation to the future build of the MHeC-C, it needed to include refinements to the interface, such as changing the color palette, designing a logo that refers to mental health, and making further modifications in language.

Although the MHeC-S was comprehensible to our Colombian participants, many changes were requested. In agreement with other authors [87], we strongly advocate for the need to adapt HITs beyond language by considering cultural variations. The same authors suggest adapting or designing HITs to acknowledge cultural differences in 4 main dimensions: content, functionality, technology platform, and user interface [44]. However, the methodology needed to achieve this has not been conceptualized. Continuing with our previous research [31], we aimed to adapt our prototype by using a modified version of our previously established R&D approach [30] within a framework comprising 2 dimensions (language and culture). During this study, a new theme emerged, which added the missing piece of the methodology, the contextual adaptation. As a result, it was possible to obtain culturally and contextually appropriate information about what is required in terms of content and functionality, as well as preferences for the prototype's interface and the technology platform. All of this was done in a participative, collaborative, and time-efficient manner. The approach enabled us to collect information, define the needs, and find solutions on how the MHeC-C would respond to these requirements.

To make these HITs available in other languages, cultures, and places, it is necessary to tailor them beyond just language. In other words, it is important to consider them within a culturally and contextually appropriate framework. This framework should also incorporate the use of PD methodologies that involve stakeholders and end users from the beginning in the co-design, development, and adaptation of these HITs (Figure 2). To our knowledge, this paper reports the first body of research that proposes a methodology that researchers can replicate and use to adapt HITs to a myriad of cultures and contexts. A systematic use of such methodologies would finally result in the development of evidence-based, culturally sensitive, and contextually adapted HITs that are relevant, appropriate, engaging, and usable in the short and long term.

Data show that people living in rural areas receive less mental health treatment than those residing in metropolitan areas [88]. As almost one quarter of the Colombian population lives in rural areas, the systematic adaptation process used in this study allowed us to thoroughly identify the potential specific requirements for rural populations, such as the chat functionality to support local general practitioners (including those health professionals completing their social compulsory service), a geolocation system that will help tailor helplines and services available around them, and necessary adaptations of the content of the MHeC-C's self-report assessment to reflect rural needs. Despite the proposed benefit, it is important to consider the barriers and challenges for implementing the MHeC-C in real-world settings. Mental health and digital literacy levels are common obstacles in the implementation of HITs; it is well known that many people around the world are unable to recognize mental disorders [89,90] and that this lack of knowledge associated with stigma could prevent people from seeking help and providing treatment to those in need. These problems are a particular concern in low- and middle-income countries where health services are already limited [91].

Health professionals in this study displayed some degree of apprehensiveness in relation to the aptitudes required for, and the pertinence of, viewing an automatic display of the dashboard of results for young people. Paternalistic attitudes are no longer desirable, as they increase the asymmetry in the relationship and finally lead individuals to agree with the health professional's decisions [92,93]. The patient-centered approach and shared decision making encouraged by the MHeC-C give individuals more control and promote mutual participation, and research has shown that this type of care translates to better health outcomes and more efficient health care [94,95]. Increasing the individuals' power, strengthening critical thinking, and empowering more informed and autonomous decisions are key concepts in HITs, as they act as digital companions by providing individuals with greater participation in the decision-making process [96]. HITs also assist health professionals in presenting their advice in a respectful manner that includes the individual's singularity and complexity [97]. The proposed elements (dashboard of results and personalized well-being plan) of the MHeC-C could enhance the young people's understanding of their health status, assist them in the decision-making process, build their sense of agency, and promote their functional empowerment.

Another challenge would be the integration of the MHeC-C with the current Colombian health care and benefit schedule, which is under the administration of several public and private institutions that use regulated government funds [98]. As there are many institutions that are involved in the provision of services, the MHeC-C would need to integrate with all of them to avoid perpetuating health inequities. The final goal of developing HITs is to actually develop a prototype that has great value for all end users even if the set of functionalities is different. For example, a young person would use the MHeC-C to improve their health and well-being, track their progress, and stay connected with their health professionals, whereas health professionals would use the system to inform their day-to-day practice, access support and training, and facilitate communication with those under their care. By building an appealing, usable prototype that responds to these specific needs based on end-user type, we aim to surpass the attrition law and sustain usage over time.

Our strategic partnerships made it possible for a native Colombian team of researchers to conduct all the phases (including data collection and analysis) in the Spanish language. This approach reduced the risk of losing information (or meaning) and increased research efficiency by decreasing time and costs [99]. In addition, through working closely with end users, the adapted R&D cycle allowed constant iterations of the MHeC-C in response to technological advances and end-user

needs. Effective engagement with local stakeholders, use of local capacities and systems, and measurement of relevant results for the community have been identified as strategies to promote translational research in low- and middle-income countries [100].

Implications

Countries such as Colombia, which have limited resources allocated to health (7% of its GPD), struggle to make decisions regarding where to invest to have the best outcomes. HITs show promise in reducing costs and being cost-effective in the long run [101,102]; however, the development (from conception to implementation and sustainability) is an expensive and arduous process [103,104]. At the same time, building capacity by training health professionals and increasing infrastructure is also a slow and expensive pathway [105-107]. As a solution, we proposed a rigorous methodology to adapt already available (and evidence based) HITs along 3 main pillars: language, culture, and context. A systematic use of this approach has the potential to reduce costs and to increase the number of HITs available (in different languages and cultures) in a time-efficient manner. HITs that show value in terms of content and appropriateness to context could integrate with already available health systems and finally help to breach not only physical but also technological and social health inequalities [108], making health care more accessible, affordable, and available.

The Colombian context is complex, as despite economic growth, it continues to be one of the most unequal countries in the world [109]. One quarter of its population lives in rural settings, with a low number of health professionals and limited infrastructure [10] and high levels of violence following five decades of internal conflict. This results in a high level of challenge for individuals, health professionals, health providers, and decision makers to change the delivery model as well as treatment standards. Web-based solutions mark a paradigm shift beyond the traditional models of health care delivery. Integrating physical resources with HITs would capitalize on Colombia's heavy investment in telecommunications and could enable the Colombian population to access new resources; make better use of expertise; and provide better access for individuals, peers, and families. This should be done through collaborative interdisciplinary work with ongoing international support to capitalize on global medical knowledge and find new solutions, leading to quicker innovations in health service delivery.

Limitations and Future Research

Although the importance of appropriately adapting HITs to the local context cannot be overstated, it must also be acknowledged that the contexts are constantly changing. For example, Colombia's population makeup has changed since 2015 (when the workshops were conducted) because of recent migration from Venezuela. In the past year, more than 350,000 people have migrated from Venezuela [1], and at the beginning of 2019, it was calculated that there were more than 1 million Venezuelans residing in the country. Migrant populations have been identified to be at a greater risk of psychological distress or common mental disorders, and host countries must effectively respond to this. A pressing future need of the MHeC-C would be to include migrant populations; therefore, a new cycle of adaptation would be required. As an initial proposal and capitalizing on our previous research [31], the new version of the MHeC-C would include the cultural adaptation and adjustment disorder (available from the MHeC-S) items as the addition of the assessment of other risk factors, such as conditions of the migration process, level of acculturation, family reunification, perceived discrimination, and the length of time of residence in the host country [110].

Another limitation was the relatively small sample size, although this number still enabled us to collect sufficient information for an analysis in the framework and reach a saturation point. It is important to consider the large percentage of young people in Colombia and their diversity; consequently, these results cannot be extrapolated to the general population; therefore, further research is needed for tailoring the MHeC-C to rural and diverse populations. Additional research is also needed to develop the MHeC-C and test its engagement, efficacy, and effectiveness in real-world settings and engage other stakeholders, such as administration and management, peers, nongovernmental organizations, other community organizations, and senior health professionals with diverse degrees of technology literacy.

Conclusions

In low- and middle-income countries, the potential to utilize already developed HITs for improved access to and better quality of mental health services is enormous. This would result not only in better mental health outcomes for young people but also more efficient, effective, and appropriate use of scarce health professional knowledge and clinical skills, as well as quality improvements in mental health service delivery. In this study, an adapted R&D cycle resulted in a technology solution acceptable for use by Colombian young people (and their supportive others) experiencing mental health problems as well as health professionals delivering care. This methodology should now be applied to other HITs as a means to bridge the digital and health care gaps not only in Colombia and the developing world but also globally to other communities or settings where resources are scarce, culture matters, and/or geography presents a challenge.

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Conflicts of Interest

IH was an inaugural Commissioner on Australia's National Mental Health Commission (2012-2018). He is the Codirector, Health and Policy, at the BMC University of Sydney. The BMC operates early-intervention youth services at Camperdown under the contract with Headspace. Professor Hickie has previously led community-based and pharmaceutical industry–supported (Wyeth, Eli Lily, Servier, Pfizer, and AstraZeneca) projects focused on the identification and better management of anxiety and depression. He was a member of the Medical Advisory Panel for Medibank Private until October 2017, a Board Member of Psychosis Australia Trust, and a member of Veterans Mental Health Clinical Reference group. He is the Chief Scientific Advisor to and an equity shareholder at Innowell. Innowell has been formed by the University of Sydney and PricewaterhouseCoopers to deliver the Aus $30 million Australian Government-funded "Project Synergy." Project Synergy is a 3-year program for the transformation of mental health services through the use of innovative technologies.

Multimedia Appendix 1
Original quotes in Spanish.
[DOCX File , 16 KB - mental_v7i2e15914_app1.docx]

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Abbreviations

BMC: Brain and Mind Centre
CD-RISC: Connor-Davidson Resilience Scale
GDP: gross domestic product
HIT: health information technology
MHeC: Mental Health eClinic
MHeC-C: Colombian version of the Mental Health eClinic

MHeC-S: Spanish version of the Mental Health eClinic
NMHS: National Mental Health Survey
PD: participatory design
R&D: research and development

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Original Paper

Assessment of Microstressors in Adults: Questionnaire Development and Ecological Validation of the Mainz Inventory of Microstressors

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Abstract

Background: Many existing scales for microstressor assessment do not differentiate between objective (ie, observable) stressor events and stressful cognitions or concerns. They often mix items assessing objective stressor events with items measuring other aspects of stress, such as perceived stressor severity, the evoked stress reaction, or further consequences on health, which may result in spurious associations in studies that include other questionnaires that measure such constructs. Most scales were developed several decades ago; therefore, modern life stressors may not be represented. Ecological momentary assessment (EMA) allows for sampling of current behaviors and experiences in real time and in the natural habitat, thereby maximizing the generalization of the findings to real-life situations (ie, ecological validity) and minimizing recall bias. However, it has not been used for the validation of microstressor questionnaires so far.

Objective: The aim is to develop a questionnaire that (1) allows for retrospective assessment of microstressors over one week, (2) focuses on objective (ie, observable) microstressors, (3) includes stressors of modern life, and (4) separates stressor occurrence from perceived stressor severity.

Methods: Cross-sectional (N=108) and longitudinal studies (N=10 and N=70) were conducted to evaluate the Mainz Inventory of Microstressors (MIMIS). In the longitudinal studies, EMA was used to compare stressor data, which was collected five times per day for 7 or 30 days with retrospective reports (end-of-day, end-of-week). Pearson correlations and multilevel modeling were used in the analyses.

Results: High correlations were found between end-of-week, end-of-day, and EMA data for microstressor occurrence (counts) ($r \geq .69$ for comparisons per week, $r \geq .83$ for cumulated data) and for mean perceived microstressor severity ($r \geq .74$ for comparisons per week, $r \geq .85$ for cumulated data). The end-of-week questionnaire predicted the EMA assessments sufficiently (counts: beta=.03, 95% CI .02-.03, $P<.001$; severity: beta=.73, 95% CI .59-.88, $P<.001$) and the association did not change significantly over four subsequent weeks.

Conclusions: Our results provide evidence for the ecological validity of the MIMIS questionnaire.

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KEYWORDS

microstressor; daily hassles; validation; ecological momentary assessment

Introduction

Background

The impact of microstressors on mental health, either alone or in addition to macrostressors, has been reported in a large body of research [1-5]. The term *macrostressor* refers to potentially traumatizing events, such as natural or human-made disasters, whereas the term *microstressor*, or daily hassle, refers to the "irritating, frustrating, distressing demands that to some degree characterize everyday transactions with the environment" ([4] page 3).

For the assessment of stress and stressors, several approaches have been suggested and discussed in the literature. The response-based approach focuses on the effect of stressors on the individual. This line of research emerged with Selye [6], who was particularly interested in the physiological response to stress and the development of illness. However, it has been criticized that the response-based approach does not take into account the characteristics of the stressor, but rather assumes a nonspecific response to adverse stimulations regardless of the situation [7]. Instead of focusing on the individual response to stress, the stimulus-based approach suggests focusing on the stressor itself. This approach has its origins in the work by Holmes and Rahe [8], who measured life stress by assigning numbers (so-called *life change units*) to a list of critical life events to assess the adaptive effort required to cope with the event. The stimulus-based approach has also been applied to assess the effect of microstressors [9]. Stone and Shiffman [10] pointed out that the frequency and type of stressors occurring in a certain time period provide information about the level of stress experienced in the same period.

Assessment of Microstressors

So far, a number of validated self-report scales for the assessment of microstressors have been developed. The first validated scales for the assessment of microstressors are the Hassles and Uplifts Scales [4,11]. Several other microstressor questionnaires have been published subsequently, such as the Inventory of Small Life Events [12], the Daily Stress Inventory [13], and the Weekly Hassle Scale [14]. Moreover, questionnaires for specific target groups have been published, such as the Adolescent Stress Questionnaire [15], an adaptation of the Everyday Stressor Index [16] for the assessment of microstressors occurring in everyday life of Turkish or German mothers with young children, or a microstressor questionnaire for students, the Inventory of College Students' Recent Life Experiences (ICSRLE) [17]. Multimedia Appendix 1 provides an overview of the questionnaires.

Methodological Considerations in the Assessment of Microstressors

A criticism is that many of the existing microstressor scales do not exclusively focus on objective (ie, observable) stressors, but also include items assessing cognitions, emotions, and consequences of stress or symptoms, which may conceptually overlap other questionnaires assessing the same constructs and may consequently result in spurious associations [5,7,14,18-21]. In clinical routine, the issue of nonobservable stressors and spurious associations may be negligible when assessing patients on an individual level to obtain information on their current stressor load; however, the methodological issue arises in studies on associations between microstressors and other topics or concepts that are also partially covered by items in the microstressor questionnaire. For example, the Daily Hassles and Uplifts Scale includes items about inner concerns (eg, trouble making decisions or concern about the meaning of life) [11], and similar items may also be found in symptom scales of stress-related mental disorders. Consequently, in studies using both scales, the overlapping items and constructs may result in an overestimation of the association between the hassles scale and the symptom scale. This may lead to wrong conclusions about the impact of microstressors on mental health because similar questions were asked in both questionnaires. In resilience research, for example, it is theorized that individual differences in the subjective reactions to stressors are a key determinant of why some people stay healthy under stressor exposure while others with similar stressor exposure develop mental health problems [22]. This theory can obviously only be tested if one can separately quantify stressor exposure and subjective reactions to the stressor exposure.

To avoid this methodological issue, it has been suggested to strictly focus on objective (ie, observable) situations instead of subjective aspects, such as interpretations, cognitions, emotions, or symptoms [5,18,21]. This allows for an unconfounded analysis of the effect of microstressors on the outcome in question (eg, perceived distress or physical health). In some studies, this issue is addressed by excluding potentially confounding items [23]. Until now, there have been only a few microstressor questionnaires in which that issue has been taken into account during the development phase of the questionnaire [12].

Many of the existing questionnaires were developed and validated between 1980 and 1990 [4,11-13]. Consequently, stressors that have occurred as a consequence of later developments, such as globalization, urbanization, and digitalization, may not be represented.

All studies validating the previously mentioned questionnaires rely on retrospective data. Real-time data, as obtained by using ecological momentary assessment (EMA), has rarely been used

for the validation of microstressor questionnaires. EMA methods allow for sampling of current behaviors and experiences of a subject in real time and in their natural habitat [24]. EMA aims to maximize ecological validity (ie, generalization of the findings to real-life situations) to minimize recall bias, and it also allows for the study of microprocesses that impact behavior in real-world contexts [24]. The method has already been applied in studies on the effects of microstressors [25-27] and for comparisons between retrospective and momentary data for alcohol consumption [28], headache [29], pain [30], or affect and sexual behavior [31], for example. A recent systematic review evaluated studies on mobile phone-based self-assessment of stress in healthy adults [32]. The authors found in only three of 35 studies included in the review was the validity of the mobile phone-based stress assessment against validated retrospective stress questionnaires examined [33-35]. In one of those studies (N=48 participants), a moderate statistically significant positive correlation was found (r=.4, P<.05) [35]. No statistically significant correlations were found in the other two studies, which may be caused by small sample sizes (N=7 and N=17) [33,34]. Pórarinsdóttir and colleagues [36] also conducted a study and found a statistically significant positive correlation between mobile phone-based stress assessment and a validated stress scale (beta=.0167, 95% CI .0070-.0026; P=.001). However, all four studies used the Cohen's Perceived Stress Scale [37] for validation of the mobile phone-based stress assessment, which focuses on subjective, rather than objective, aspects of stress.

Aims and Objectives of This Study

In this study, we aimed to develop a questionnaire that (1) allows for retrospective assessment of microstressors occurring during the course of one week, (2) focuses on objective (ie, observable) microstressors to overcome the risk of spurious associations caused by assessing subjective aspects (such as cognitions or emotions), (3) also includes stressors of modern life, and (4) combines the stimulus- and response-based approach for stressor assessment to measure the occurrence of the stressors and the perceived severity of the stressor.

In addition, we applied a validation strategy that maximizes ecological validity by using EMA for the validation of the questionnaire.

Methods

Overview

The validation of the questionnaire was conducted in three phases. The first phase involved item generation of objective stressors (see Multimedia Appendix 2), the second phase involved questionnaire construction and revision, and the third phase involved EMA evaluation of the retrospective questionnaire. The first version of the questionnaire included 67 items and was applied in the first and the second phase of questionnaire development. The final version of the questionnaire included 58 items and was used in the third phase. In both versions of the questionnaire, participants were asked to provide information about microstressors occurring during the past seven days. To obtain additional information about the individual impact of each stressor, the questionnaire includes a five-point Likert scale (0-4; 0=not at all severe, 4=extremely severe) after each item, asking for the perceived severity of the stressor (see Multimedia Appendix 2).

All participants were recruited at the Johannes Gutenberg University, Mainz, Germany. Data were collected online using the survey tool SoSci Survey [38].

The study protocols were approved by the ethics committee at the Rhineland-Palatinate state chamber of physicians (837.085.13 [8770-F] and 837.183.16 [10502]). The Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [39] was applied (see Multimedia Appendix 3).

Questionnaire Construction and Revision

A cross-sectional study (study 1) and a small-scale EMA feasibility study (study 2) were conducted to evaluate the 67-item version of the Mainz Inventory of Microstressors (MIMIS) (study 1) and to test the feasibility of a mobile phone-based EMA assessment of the questionnaire (study 2).

Study 1: Cross-Sectional Study

There were no explicit inclusion or exclusion criteria. The sample included 120 undergraduate students (data collection period: October 2014 to January 2016). All participants completed a questionnaire assessing sociodemographic variables (age and sex) and the 67-item version of the MIMIS, retrospectively assessing the number of microstressors and their severity over the past seven days. A free-text input was provided to include additional microstressors in case the experienced microstressor was not already on the list. Data from 108 participants were used for the assessment of the questionnaire; 11 participants did not complete the questionnaire and one participant was excluded due to extreme response tendency (ie, all items rated at the highest level). The final sample included 72.5% women (79/108) and 27.5% men (30/108). The mean age was 23.91 (SD 4.06, range 18-43) years.

Study 2: Ecological Momentary Assessment Feasibility

This study was conducted to test the feasibility of a mobile phone-based EMA assessment of the questionnaire. Inclusion criteria were no severe mental disorder (eg, schizophrenia) and good mental health (screening questionnaire: General Health Questionnaire total score <24 [40]). Participants who were in current psychiatric or psychotherapeutic treatment and users of illegal drugs or those with reported high levels of alcohol consumption (average consumption of standard glasses of alcohol per week >15) were excluded [41,42]. Potential participants were invited for an initial briefing session. After written consent was obtained, each participant was provided with a study mobile phone (type: Motorola Moto E) to avoid technical problems related to different operating systems. The study was conducted over seven subsequent days.

For the mobile phone-based EMA assessment, we implemented the 67 items of the MIMIS questionnaire in a mobile phone-based ambulatory assessment using the app MovisensXS [43]. Ambulatory data of microstressors were collected with an event-contingent assessment (ie, participants recorded the microstressor immediately after it occurred). After activating the MovisensXS app, participants were asked to select from the

list of 67 prespecified microstressors. In case the experienced microstressor was not already in the list, a free-text input was provided to include additional microstressors. As in the original version of the MIMIS (end-of-week assessment, see study 1), participants were asked to rate the severity of the selected microstressor. Data entry was possible at any time. In addition to the mobile phone-based assessment, we administered a modified version of the MIMIS at the end of each day, asking for microstressors occurring on that particular day ("How many times did the situation occur during the day?" "To what extent did you find the situations mentally straining?"). At the end of the seven-day assessment period, we also used the original version of the 67-item MIMIS questionnaire (see study 1). The data collection ended with a final session the following week. At this final session, participants returned the study mobile phones and were asked to provide feedback on the study in a semistructured interview.

The sample included 10 undergraduate students (six females; data collection: June 2016). The mean age of participants was 26.6 (SD 2.05, range 23-30) years.

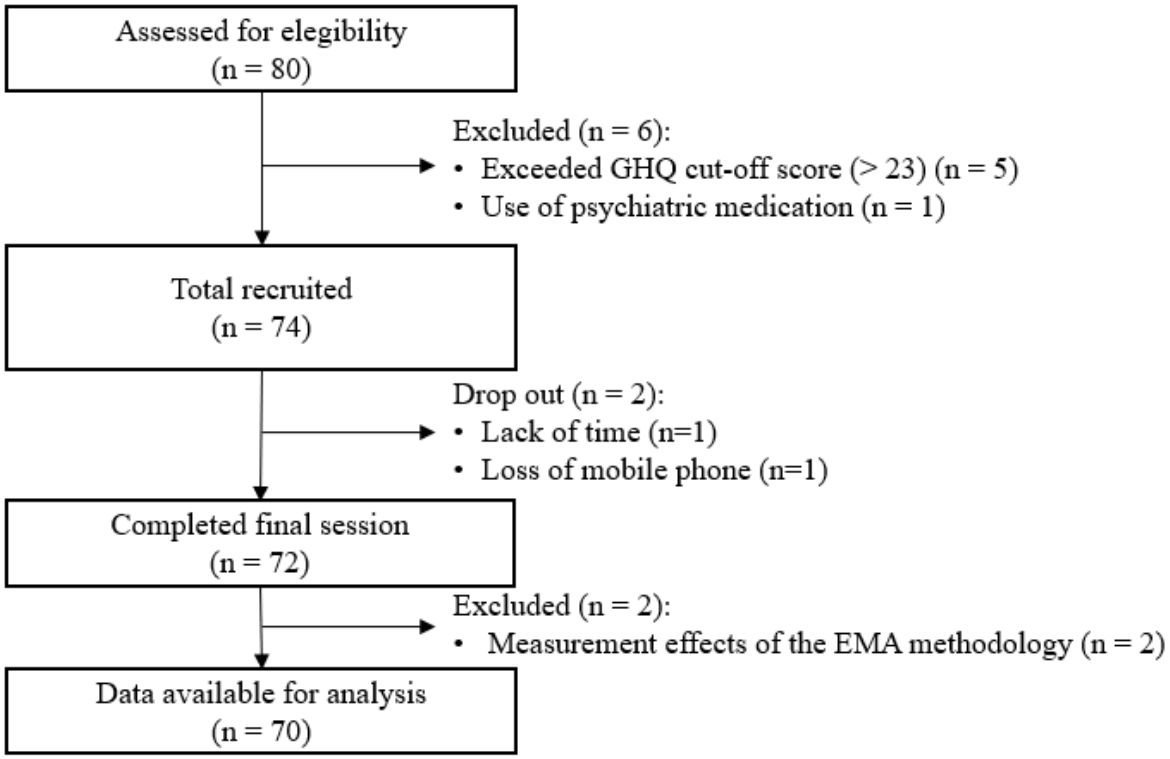
The data from study 1 and study 2 were used to revise the 67-item questionnaire. We analyzed the data of both studies (1 and 2) by considering the total occurrence per microstressor, and excluded those microstressors that were discarded (ie, frequency=0; 19 items removed). We used the information provided by the free-text input to identify additional relevant microstressors, which resulted in 10 additional items. We also revised the wording of the items to emphasize the objective character of the microstressor. The revised version of the MIMIS questionnaire consisted of 58 items covering a large range of aspects of daily living (eg, noise, traffic, interpersonal conflicts, workload or time pressure) (see Multimedia Appendix 4). The 58-item questionnaire was then included in a four-week longitudinal EMA study using the study design tested in study 2.

Study 3: Longitudinal Ecological Momentary Assessment Study

Sample

Data collection was between September 2016 and March 2017. We applied the same exclusion criteria as in study 2. Figure 1 provides an overview of the recruitment process. Two participants reported changes in their behavior (handling of microstressors) during the study period because of the EMA assessments in the postmonitoring interview. Therefore, we excluded the data after data collection. The final sample included 70 participants with a mean age of 23.93 (SD 3.15) years.

Figure 1. Flowchart of the longitudinal ecological momentary assessment study (study 3).

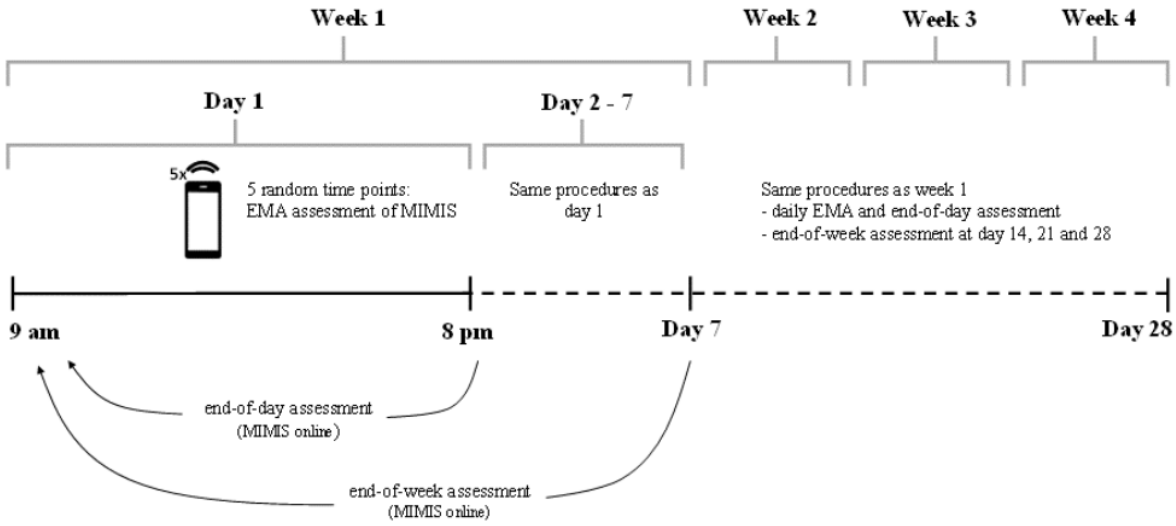


Study Design and Procedures

For each participant, the study was conducted over four subsequent weeks (28 days). We used the same procedure as in study 2. In addition, data on sociodemographic variables (sex, age, employment status, nationality, and education), mental health-related variables (mental dysfunction and well-being), and chronic stress (discussed subsequently) were collected. The revised 58-item version of the MIMIS questionnaire was implemented in a mobile phone-based ambulatory assessment. In contrast to study 2, we used a signal-contingent approach; that is, an acoustic and visual signal ("please answer the questions below" on the display) notifying participants to record data on the occurrence and perceived severity of microstressors at five random time points between 9 am and 8 pm for 28 subsequent days. If participants were not able to answer the questionnaire by the time the signal occurred, they were reminded every 30 minutes to complete the questionnaire for the subsequent 90 minutes. Participants could also ignore the initial signal and manually activate data entry during the following 90 minutes. As in study 2, at each assessment point, participants were provided with the list of microstressors and asked whether any of these occurred since the last alarm ("Please indicate which of the following situations occurred since the last alarm, independent from whether they were perceived as a hassle or not"). For each selected microstressor, participants were then asked to rate the severity of the stressor on a five-point Likert scale from 0 (not at all severe) to 4 (very severe). Similar to study 2, participants completed an end-of-day assessment on each of the 28 days and an end-of-week assessment at the end of each of the four weeks using the 58-item MIMIS questionnaire with the respective time scale (past day, past seven days). Every evening at 7:58 pm or every Sunday at 11 am, participants were reminded via email with a link to the online survey to complete the end-of-day or end-of-week assessment, respectively. As in study 2, a final session was conducted in the week after the 28-day assessment period, in which participants returned the study mobile phones and provided feedback in a semistructured interview.

The participants received monetary compensation at the end of the study. Here we applied a scoring system to increase the motivation to participate in the study and provide complete datasets. The score accounted for the number of complete datasets provided in the EMA assessments and the online questionnaires. Participants received up to €176 (see Multimedia Appendix 3). To increase compliance, participants were informed of their actual total score every evening via email during the 28-day study period. Figure 2 provides an overview of the study design.

Figure 2. Study design of the longitudinal ecological momentary assessment study.



Statistical Analysis

Sample Characteristics

To describe the sample, proportions were derived for categorical variables; means and standard deviations were used for continuous variables.

Quantification of Retrospective Bias

The primary analysis was the analysis of the retrospective bias of the MIMIS questionnaire assessing microstressors at the end of a week over the past seven days.

To examine the level of retrospective bias of the MIMIS, we compared the EMA, end-of-day, and end-of-week assessments for each of the four weeks and over the entire four-week period using Pearson correlations. Here, we considered the total counts (number of days on which the microstressor occurred) of all 58 microstressors. To reach comparability with the end-of-week assessment, microstressors measured with the EMA and end-of-day assessments were counted nominally (0=did not occur during the day, 1=did occur at least one time during the day) per day. For the correlations of severity, we considered the mean of the average severity of each microstressor over all microstressors in the end-of-week, end-of-day, and EMA assessments. In addition, we used multilevel modeling to further assess to what extent the end-of-week assessment predicted the ecologically valid EMA assessments and whether the association varied over the four subsequent weeks. Two models were applied: model 1 included the total counts and model 2 included

the mean severity ratings of all microstressors reported in the end-of-week assessment or EMA. The outcome was the end-of-week assessment; level one was the observations in EMA (model 1: total counts; model 2: mean stressor severity), level two was the weeks, and level three was the participants. We first calculated the null model to assess whether there was an intraclass correlation (ICC), which refers to the extent of variance that can be explained by differences within and between persons. We subsequently included several predictors hierarchically, including total counts of all microstressors of each week (model 1) or mean severity over all microstressors of each week (model 2), age, sex, week of assessment, and the interaction term total counts of microstressors assessed in EMA × week of assessment, and analyzed whether model fit was improved by the predictors using likelihood ratio tests. We used likelihood ratio tests to determine whether the predictors should not only be included as fixed effects but also as random effects. This would allow for the slopes of the association between the predictors and the criterion to vary between the participants [44]. Model 1 included the interaction term "total counts of microstressors assessed in EMA × week of assessment" as a fixed effect and "week of assessment and total counts of all microstressors of each week" as a random effect as indicated by likelihood ratio tests. Model 2 included the interaction term "mean severity over all microstressors of each week × week of assessment" and age as fixed effects and week of assessment as a random effect, as indicated by likelihood ratio tests.

Statistical significance of effects was determined by *P* values of less than .05 or by 95% confidence intervals (CIs). All analyses were conducted in Stata version 15 [45].

Results

Sample Characteristics

Table 1 provides an overview of the sample characteristics in the longitudinal EMA study. Of the 70 participants, 41 (59%) were women; 66 of 70 (94%) were German and 47 of 70 (67%) worked 20 hours or less per week. The study adherence was excellent. On average, the participants completed 90% of the assessments (end-of-day, end-of-week, and EMA) over the four weeks.

Table 1. Descriptive statistics of the psychometric study sample (N=70).[a]

Variable	Participants
Gender, n (%)	
Female	41 (59)
Male	29 (41)
Age (years), mean (SD)	23.9 (3.2)
Nationality, n (%)	
German	66 (94)
Others	4 (6)
Employment status, n (%)	
Full-time	5 (7)
Part-time[b]	15 (21)
Others[c]	32 (46)
Not employed	18 (26)

[a]All participants had a high school diploma (≥12 years of formal education) or equivalent.

[b]18-20 hours per week.

[c]Occasional jobs, jobs with less than 18 hours per week.

In total, the participants responded to 9162 of the EMA prompts and missed 478 prompts. They filled in 1935 end-of-day and 282 end-of-week assessments. We excluded 39 end-of-day forms and 6 end-of-week assessments because the questionnaires were not filled in within the prescribed time period (end-of-day: n=29, end-of-week: n=3) or were submitted twice (end-of-day: n=10, end-of-week: n=3). Participants missed 64 end-of-day assessments and 4 end-of-week assessments. With regard to stressor frequency, the 10 most frequent (in counts) stressors reported in the end-of-week assessment were journey/commute to work, university, or school (n=65, counts: 987); housekeeping (n=66, counts: 982); waiting time or delay (n=68, counts: 741); interruption during an activity (n=62, counts: 693); high demands or high workload at work, school, or university (n=54, counts: 670); time pressure (n=59, counts: 666); lack of sleep (n=66, counts: 603); own physical discomfort (n=67, counts: 600); boring tasks (n=56, counts: 429); and bad weather (n=60, counts: 429).

With regard to stressor severity, the 10 most severe stressors reported in the end-of-week assessment were discrimination or mobbing by another person (n=1, mean 3.0); problem with a pet (n=8, mean 2.4, SD 1.01); conflict or disagreement with close persons (n=51, mean 2.19, SD 0.90); performance situation at work, school, or university (n=42, mean 2.17, SD 1); side effects of medications (n=8, mean 2.16, SD 0.93); high demands or high workload at work, school, or university (n=54, mean 2.15, SD 0.75); bad news (n=22, mean 2.02, SD 1.37); child

care problems (n=4, mean 2, SD 0); problem or inconvenience due to house hunting or moving (n=9, mean 2, SD 0.87); and time pressure (n=59, mean 1.98, SD 0.82).

Multimedia Appendix 5 provides an overview of frequency and severity over all three measurement modalities (EMA, end of day, end of week).

Quantification of Retrospective Bias

Table 2 shows the correlations across subjects between end-of-week, end-of-day, and EMA microstressor assessments in the subjectwise summed microstressor counts, both per week and cumulated for the entire assessment period (week 1 to week 4). With regard to the comparisons per week, all correlation coefficients were high ($r \geq .69$), with the highest correlations between the end-of-week and end-of-day comparisons. Regarding the comparison of cumulated data, all correlation coefficients were r≥.83, with the highest correlation again found between end-of-week and end-of-day data.

Table 2. Pearson correlations between the end-of-week, end-of-day, and ecological momentary assessments (EMAs) in subjectwise summed microstressor counts (N=70).

Assessment	Week, r[a]				
	1	2	3	4	Cumulative (weeks 1-4)
End-of-week vs EMA	.76	.81	.77	.69	.83
End-of-week vs end-of-day	.88	.90	.90	.77	.94
End-of-day vs EMA	.85	.85	.89	.86	.89

[a]P<.001 for all correlations.

Table 3 shows the correlations across subjects between end-of-week, end-of-day, and EMA microstressor assessments in the subjectwise averaged severity ratings of all microstressors, both per week and cumulated for the entire assessment period (week 1 to week 4). For the comparisons per week, all correlation coefficients were high ($r \geq .74$), with the highest correlations between end-of-week and end-of-day comparisons. Regarding the comparison of cumulated data, all correlation coefficients were $r \geq .85$, with the highest correlation again found between end-of-week and end-of-day.

Table 3. Pearson correlations between the end-of-week, end-of-day, and ecological momentary assessment microstressor assessments (EMAs) in subjectwise averaged microstressor severity ratings (N=70).

Assessment	Week, r[a]				
	1	2	3	4	Cumulative (weeks 1-4)
End-of-week vs EMA	.74	.83	.85	.81	.85
End-of-week vs end-of-day	.84	.90	.91	.90	.95
End-of-day vs EMA	.74	.86	.87	.80	.86

[a]P<.001 for all correlations.

Table 4 shows the results of the multilevel modeling analysis for model 1 (total counts of microstressors). The null model showed an ICC of 0.31 for the participants, meaning that 31% of the total variance in the EMA microstressor counts was explained by differences between subjects and 69% by differences within subjects. It also showed an ICC of 0.36, which means that 36% of the total variance in the EMA microstressor counts within persons was explained by differences between weeks and 64% by differences within weeks. The ICC indicated that a large proportion of variance was explained by differences within subjects or within weeks; therefore, we continued with mixed models to account for these within-person/within-week processes. The microstressor counts reported in the end-of-week assessments (weekly, total) predicted the EMA assessments (beta=.03, 95% CI .02-.03, P<.001) (see Table 4). That association did not change significantly over the four subsequent weeks (see Table 4: stability assessment). The reported total counts of all microstressors in EMA did not differ significantly between the four weeks (see Table 4: total count of microstressor of each week × week of assessment).

Table 4. Multilevel model assessing the association between microstressor counts reported by ecological momentary assessment and end-of-week assessments and potential time-related variations over the course of four subsequent weeks (N=70).

Variable	Beta (SE)	z	*P* value	95% CI
Weekly, total	.03 (.003)	8.67	<.001	.02, .03
Stability assessment				
Week 1	Reference			
Week 2	−.08 (.14)	−0.62	.53	−.35, .18
Week 3	−.12 (.14)	−0.86	.39	−.40, .16
Week 4	−.16 (.16)	−1.00	.32	−.46, .15
Total counts of microstressors of each week × week of assessment				
Week 1	Reference			
Week 2	−.0006 (.003)	−0.21	.84	−.006, .005
Week 3	−.00001 (.003)	−0.00	.96	−.006, .006
Week 4	−.003 (.003)	−0.84	.40	−.009, .004

Table 5 shows the results of the multilevel modeling analysis for model 2 (mean severity of the microstressors). The null model showed an ICC of 0.35 for the participants, meaning that 35% of the total variance in the mean severity of microstressors reported by EMA was explained by differences between subjects and 65% by differences within subjects. It also showed an ICC of 0.42, which means that 42% of the total variance in the EMA assessment within persons was explained by differences between weeks and 58% by differences within weeks. As in the previous section, the ICC indicated that a large proportion of variance was explained by differences within subjects or within weeks. Therefore, we continued with mixed models to account for these within-person/within-week processes. The mean severity of the microstressors reported in the end-of-week assessments (weekly, total) predicted the EMA assessments (beta=.73, 95% CI .59-.88, *P*<.001) (see Table 5). That association did not change significantly over the four subsequent weeks (see Table 5: stability assessment). The reported mean severity of all microstressors in EMA did not differ significantly between the four weeks (see Table 5: mean severity of microstressor of each week × week of assessment).

Table 5. Multilevel model assessing the association between the mean severity of microstressors reported by ecological momentary assessment and end-of-week assessments and potential time-related variations over the course of four subsequent weeks (N=70).

Variable	Beta (SE)	z	*P* value	95% CI
Mean severity of all microstressors of each week[a]	.73 (.07)	9.83	<.001	.59, .88
Stability assessment				
Week 1	Reference			
Week 2	−.19 (.12)	−1.54	.12	−.42, .05
Week 3	−.15 (.12)	−1.18	.24	−.39, .10
Week 4	−.14 (.13)	−1.01	.31	−.40, .13
Mean severity of microstressors of each week × week of assessment				
Week 1	Reference			
Week 2	.07 (.08)	0.93	.36	−.08, .23
Week 3	.07 (.08)	0.83	.41	−.09, .23
Week 4	.04 (.09)	0.42	.67	−.13, .21
Age	−.03 (.01)	−2.58	.01	−.06, −.01

[a]For each selected microstressor, the severity per microstressor was rated using a five-point Likert scale (0, 1, 2, 3, 4; with 0=not at all severe to 4=extremely severe).

Discussion

Principal Findings

In this paper, we report the development process and the validation of a retrospective microstressor questionnaire, the Mainz Inventory of Microstressors (MIMIS), which focuses on objective microstressors, includes modern life stressors, and separates stressor occurrence from perceived stressor severity.

In the longitudinal EMA study (study 3), we found high correlations in microstressor counts between the end-of-week,

end-of-day, and EMA data ($r \geq .69$ for comparisons per week, $r \geq .83$ for cumulated data) and high correlations in the mean perceived severity of microstressors between the three measurement methods ($r \geq .74$ for comparisons per week, $r \geq .85$ for cumulated data). For the reported microstressor counts, the end-of-week questionnaire predicted the EMA assessments sufficiently, and the association did not change significantly over the measurement period of four subsequent weeks. A weaker, although still statistically significant, association was found for microstressor severity. Here again, the association did not change significantly over four subsequent weeks. Our results provide evidence for the ecological validity of the questionnaire.

Comparison With Existing Scales

Compared with the existing questionnaires [4,11-13,16,17], the MIMIS also includes stressors of modern life due to its recent development. Most of the existing microstressor questionnaires also assess subjective (ie, nonobservable) stressors, except for the Inventory of Small Life Events [12] and the Inventory of College Students' Recent Life Experiences [17]. However, these questionnaires were developed more than 30 years ago and may not include stressors that result from recent technological or societal developments.

Strengths and Limitations

A major strength of our study is the use of EMA data for the validation of the questionnaire. To the best of our knowledge, this method has not yet been used in validation studies for microstressor questionnaires. In addition, many of the existing and widely used questionnaires have been developed and validated between 1980 and 1990 [4,11-13]. With developing a new microstressor questionnaire, we were able to include microstressors of modern life. Another strength of our study is the high compliance rate (on average 90%) in the longitudinal EMA study. In addition, the established ecological validity of the MIMIS allows for the quantification of microstressors in a retrospective, low-burden fashion, which does not sacrifice the advantages of EMA in a significant way.

A potential limitation is the length of the questionnaire. However, compared with other microstressor lists, which often include more than 80 items [4,11,17], the MIMIS questionnaire is still a relatively economical assessment method to assess a wide range of microstressors. Another limitation may be the objectivity of the microstressor items. Although we tried to ensure all microstressor items were observable and discretely countable events, one cannot exclude the subjective perception of survey items. The subjective perception may be influenced by individual differences in attention and mood of the participants and consequently influence if someone perceives a particular item as a hassle or not. Another limitation may be that the questionnaire includes microstressors usually occurring in the lives of younger or middle-aged adults. Although some items may apply, we did not specifically take account of microstressors that are most prevalent in older age. Moreover, the samples included in this study were relatively homogeneous for age, education, and employment status. Additional validation studies may be required to test whether the microstressors included in the MIMIS questionnaire are those typically occurring in older age groups and whether there are any differences in samples that are representative of the general population. Two participants reported changes in their behavior due to the assessment in the postmonitoring interview and were excluded from the study. Those participants did not differ from the remaining participants in terms of sociodemographic or psychometric data. There is no reason to assume that the exclusion of those participants introduced bias into the study. In addition, our data do not allow for conclusions on concurrent external validity because data on mental health or other variables related to the effects of microstressor exposure, such as well-being or symptoms of chronic stress, were not assessed at the end of the 28-day period. Future studies should focus on the evaluation of the concurrent external validity by comparing the MIMIS with respective constructs. Another potential limitation may lie in the validation procedure itself, in the way that the repeated EMA assessment could have an effect on the awareness of microstressors that are then reported in the retrospective assessment at the end of the week. Future studies should address that issue by examining potential differences between groups that monitored or did not monitor their microstressors via EMA in the preceding week before completing the MIMIS questionnaire.

Conclusions and Outlook

In contrast to other microstressor questionnaires that include cognitions, emotions, or consequences of stress, the MIMIS only includes objective stressors. The MIMIS can be applied in basic and applied studies to examine the frequency and perceived severity of a variety of stressors. As applied in this study, it can also be included in the real-life assessment of stressors using mobile technology.

For clinical applications, the MIMIS could serve as a quick and easy-to-administer tool for the assessment of the frequency and the perceived severity of microstressors in the past seven days. In that way, it would provide insight into the current stressor load of the person being investigated. As pointed out elsewhere, the actual stressor load during a period is essential to assess psychological resilience in that period in basic research and intervention studies [22,46].

The aim of this study was to develop the questionnaire and assess the ecological validity of the MIMIS by quantifying the potential retrospective bias. Future studies should focus on the external validation of the MIMIS by, for example, comparing the subjective severity of microstressors reported in MIMIS with biological markers for stress response, such as cortisol levels [14]. In that way, it could be investigated whether microstressors that are subjectively rated as more severe also lead to higher stress responses, as would be expected.

This study provides evidence for the ecological validity of the MIMIS. In future studies, the questionnaire should be tested on other age groups, such as older adults or teenagers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of self-report scales for the assessment of microstressor considered for the development of MIMIS.
[DOCX File , 17 KB - mental_v7i2e14566_app1.docx]

Multimedia Appendix 2
Item generation.
[DOCX File , 14 KB - mental_v7i2e14566_app2.docx]

Multimedia Appendix 3
Checklist for Reporting Results of Internet E-Surveys (CHERRIES).
[DOCX File , 22 KB - mental_v7i2e14566_app3.docx]

Multimedia Appendix 4
Mainz Inventory of Microstressors (MIMIS).
[DOCX File , 69 KB - mental_v7i2e14566_app4.docx]

Multimedia Appendix 5
Counts and average severity of each microstressor.
[DOCX File , 51 KB - mental_v7i2e14566_app5.docx]

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Abbreviations

EMA: ecological momentary assessment
ICC: intraclass correlation
MIMIS: Mainz Inventory of Microstressors

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Original Paper

Brief, Web-Based Interventions to Motivate Smokers With Schizophrenia: Randomized Controlled Trial

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Abstract

Background: In-person motivational interventions increase engagement with evidence-based cessation treatments among smokers with schizophrenia, but access to such interventions can be limited because of workforce shortages and competing demands in mental health clinics. The use of digital technology to deliver interventions can increase access, but cognitive impairments in schizophrenia may impede the use of standard digital interventions. We developed an interactive, multimedia, digital motivational decision support system for smokers with schizophrenia (*Let's Talk About Smoking*). We also digitalized a standard educational pamphlet from the National Cancer Institute (*NCI Education*). Both were tailored to reduce cognitive load during use.

Objective: We conducted a randomized trial of *Let's Talk About Smoking* versus *NCI Education* to test whether the interactive motivational intervention was more effective and more appealing than the static educational intervention for increasing use of smoking cessation treatment, quit attempts, and abstinence among smokers with schizophrenia, accounting for the level of cognitive functioning.

Methods: Adult smokers with schizophrenia (n=162) were enrolled in the study from 2014 to 2015, randomly assigned to an intervention condition, and assessed in person at 3- and 6-month follow-ups. Interventions were delivered on a laptop computer in a single session. All participants had access to standard, community-delivered cessation treatments during follow-up. Multivariate models were used to evaluate outcomes.

Results: Treatment initiation outcomes were not different between intervention conditions (27/84 [32%] for *Let's Talk About Smoking* vs 36/78 [46%] for *NCI Education*; odds ratio [OR] 0.71 [95% CI 0.37-1.33]); 38.9% (63/162) of participants initiated treatment. Older age (OR 1.03 [95% CI 1.00-1.07]; *P*=.05), higher education (OR 1.21 [95% CI 1.04-1.41]; *P*=.03), and fewer positive symptoms (OR 0.87 [95% CI 0.80-0.96]; *P*=.01) predicted cessation treatment initiation, whereas level of cognition did not. The mean satisfaction and usability index score was higher for *Let's Talk About Smoking* versus *NCI Education* (8.9 [SD 1.3] vs 8.3 [SD 2.1]; $t_{120.7}$=2.0; *P*=.045). Quit attempts (25/84, 30% vs 36/78, 46%; estimate [Est]=−0.093, SE 0.48; *P*=.85) and abstinence (1/84, 1% vs 6/78, 7%; χ^2_1=3.4; *P*=.07) were not significantly different between intervention conditions. Cognitive functioning at baseline (Est=1.47, SE 0.47; *P*=.002) and use of any behavioral or medication cessation treatment (Est=1.43, SE 0.47; *P*=.003) predicted quit attempts with self-reported abstinence over the 6-month follow-up.

Conclusions: The interactive, multimedia intervention was not more effective than the static, text-based intervention among smokers with schizophrenia. Both tailored digital interventions resulted in levels of treatment engagement and quit attempts that

were similar to findings from previous studies of in-person interventions, confirming the potential role of digital interventions to educate and motivate smokers with schizophrenia to use cessation treatment and to quit smoking. These findings indicate that additional cessation treatment is needed after brief education or motivational interventions, and that cessation treatment should be adjusted for people with cognitive impairment.

Trial Registration: ClinicalTrials.gov NCT02086162; https://clinicaltrials.gov/show/NCT02086162

(JMIR Ment Health 2020;7(2):e16524) doi:10.2196/16524

KEYWORDS

schizophrenia; smoking; tobacco; technology; digital; motivational interviewing; education; cognition

Introduction

Background

Clinics serving people with schizophrenia aim to provide interventions for schizophrenia and the common comorbidities associated with this disease. Cigarette smoking, for example, is thrice more likely to occur in people with schizophrenia than in the general population [1,2] and leads to disparate morbidity from smoking-related diseases and early mortality [3]. However, workforce shortages are a challenge for community clinics in the United States [4,5] and interfere with the ability to provide the array of needed interventions for smoking. In addition, treatment providers experience competing demands and may lack clinical expertise for providing tobacco-related interventions [6,7]. Deploying digital tools to deliver behavioral interventions to patients is one way to improve the capacity for behavioral interventions.

People with schizophrenia and other severe mental illnesses are increasingly using digital technology and are interested in receiving health and mental health interventions via their devices [8-10]. However, people in this group typically have cognitive impairments and distracting symptoms that impede the use of standard digital tools that have complex design features and lower levels of usability [11-14]. To address this problem, we have designed digital tools with evidence-based content that can be easily used by people with cognitive impairments and easily implemented in treatment settings where smokers with schizophrenia receive services [15,16]. Other researchers are also beginning to design and pilot test smartphone apps for smoking cessation in this population [17-19].

One potential purpose for digital tools in clinics may be to educate and motivate a user for medical treatments. A growing body of literature indicates that cessation medications with behavioral interventions are safe among people with schizophrenia [20,21] and increase the probability of cessation [22-24]. Specifically, cognitive behavioral therapy, motivational counseling, and supportive counseling combined with nicotine replacement therapy, bupropion, or varenicline have been shown to improve cessation outcomes; behavioral interventions with varenicline have resulted in the highest rates of abstinence [20-24]. However, misperceptions about cessation treatment may impede their utilization [25-27]. Single-session [28,29] and multiple-session [30,31] in-person motivational and educational interventions for patients may overcome this problem, increasing treatment initiation and quit attempts among smokers with schizophrenia and other severe mental illnesses. Whether interventions delivered with digital technology can similarly increase cessation treatment initiation and quit attempts among people with schizophrenia has not yet been tested.

Objectives

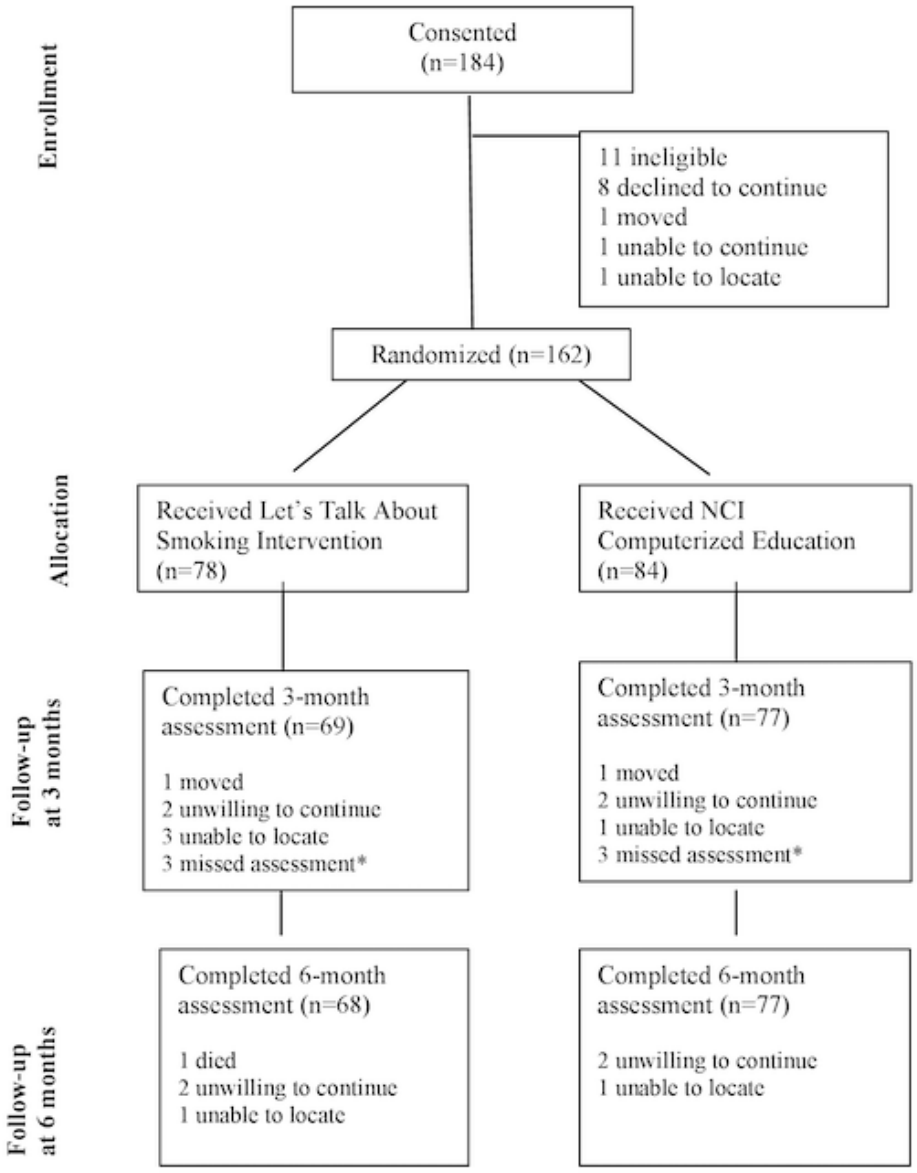
We conducted a randomized trial of a brief, interactive, multimedia intervention (*Let's Talk About Smoking*) compared with a static, computerized version of an education pamphlet from the National Cancer Institute (NCI) among smokers with schizophrenia. Both interventions were tailored to reduce cognitive load on the user. We hypothesized that the rate of treatment initiation and cessation behaviors would be higher among participants assigned to *Let's Talk about Smoking* than among those assigned to *NCI Education*. In addition, we hypothesized that the level of cognitive ability would moderate participants' use of cessation treatment and ability to achieve abstinence.

Methods

Enrollment and Study Participants

Potentially eligible smokers with schizophrenia were recruited via flyers in waiting rooms and by clinician invitation from mental health treatment programs in New Jersey, Massachusetts, and Illinois from 2014 to 2015. We enrolled English-speaking, daily smokers with schizophrenia spectrum disorders, aged 18 to 65 years, who were psychiatrically stable in outpatient treatment for mental illness (Brief Psychiatric Rating Scale (BPRS) score <70) [32] and who were willing and able to give informed consent. Smokers were excluded if they had recently (past month) used evidence-based smoking cessation treatment (indicating the participant was already motivated to use treatment), were pregnant or nursing, or had current untreated alcohol or drug dependence diagnoses. Computer experience was not required. As the intervention was designed to increase motivation for cessation, intention to quit smoking was not required. In total, 184 participants were consented and assessed for eligibility; 173 were eligible, 162 were randomized and received study interventions, and 145 (89.5% of those randomized) completed the 6-month follow-up (see Figure 1 for participant flow).

Figure 1. Study flow. *Participants missed 3-month visit but completed the 6-month visit. NCI: National Cancer Institute.



Study Procedures

After obtaining informed consent through reading the consent form aloud and answering questions, research staff conducted baseline assessments in 2 in-person meetings, with neurocognitive assessments obtained at the second meeting to reduce fatigue. Within 2 weeks of consent, eligible participants were randomized 1:1 to receive one of the interventions using computer-generated random order lists in blocks of 8, stratified by study site, with study participant allocation provided via preprepared, individual envelopes that were unsealed by research staff at the time the participant arrived for the intervention visit. Participants were not informed of the details of the study hypothesis and did not know which comparator was hypothesized to outperform the other.

Using a standard protocol, research staff oriented participants to their assigned intervention, which was provided in a clinic office on a laptop computer with a mouse. They provided brief training, coaching, and assistance if needed. After completing either intervention, participants completed a computerized satisfaction questionnaire (to reduce social desirability bias) and received referral information to locally available cessation treatment (cessation medications and cessation counseling) by clinicians who were trained in providing evidence-based cessation treatment to people with serious mental illnesses (SMIs). At 3 and 6 months, research interviewers who were blinded to intervention assignment assessed participants in person for the use of verifiable cessation treatment (main outcome), smoking characteristics, self-reported quit attempts (days of abstinence), and biologically verified abstinence (secondary outcomes; see Measures section). Research staff provided participants US $50 on completion of each assessment visit. Data quality was monitored throughout the study by the first author, the research data team, and a Data Safety and Monitoring Board. The study was reviewed and monitored by the Dartmouth Committee for the Protection of Human Subjects and the Institutional Review Boards of research sites.

Intervention Conditions

Web-Based Motivational Intervention

Let's Talk About Smoking is a Web-based intervention tailored for smokers with severe mental illnesses and designed to increase motivation to quit smoking using evidence-based treatment. The development of the intervention's content and interface involved extensive input from the intended users and has been described previously [15]. The program is linear, modularized, and interactive, taking 30 to 90 min to complete. Users choose a video host who identifies him/herself as an ex-smoker with mental illness and guides users through modules, each with assessments and exercises used in motivational interviewing and health decision aid systems [33,34]. In module 1 (assessment/feedback), users respond to questions and receive personalized feedback about the personal, financial, and health impact of smoking. In module 2 (quit intention), change decisions are facilitated by cessation treatment information and exercises, including creation of a personalized pros and cons list. Module 3 (education about cessation treatments, feedback, and referral) provides selectable quit story videos as well as text and video information about cessation treatments, including the benefits of combined behavioral counseling with pharmacotherapy. A personalized report highlights the desire to quit, treatment choices, and referral information. The developers and their institutions were listed at the end of the intervention.

By developing the intervention interface and content with iterative user feedback, we ensured that the intervention was easy to use among people with the symptoms and cognitive impairments associated with psychotic disorders [15]. We previously showed that the decision support system was similarly effective among smokers with high and low levels of education, cognitive function, and symptom distress [35]. The intervention content remained constant during the trial.

Computerized National Cancer Institute Patient Education

Participants assigned to *NCI Education* received a computerized version of the NCI patient educational handout [36], which provides information about risk factors and protective factors for cancer and other smoking-related diseases, quitting smoking as a prevention factor, and smoking cessation treatments (both counseling and drug treatments, including nicotine replacement therapy, bupropion, and varenicline). This static intervention was delivered by a laptop computer in a format similar to *Let's Talk About Smoking*: large black font on a white background with no distracting images; one concept per page in a short paragraph or bulleted sentences. Automated audio, which read the content to users, could be turned on if the user wished. The publisher of the pamphlet, the NCI, was named as sponsor of the pamphlet in standard text in the beginning and at the end of the intervention.

Measures

Demographics, History, and Diagnosis

Demographics and smoking history were assessed with a structured, in-person interview. Physician-completed Diagnostic and Statistical Manual, Fourth Edition, Text Revision, psychiatric and substance use disorder diagnoses were obtained from clinic chart review.

Mental Health Symptoms

Trained research staff assessed psychiatric symptom severity at baseline with the BPRS [32], a widely used symptom scale for symptoms of mental illness. The scale includes five subscales that measure positive psychosis symptoms, negative psychosis symptoms, depression, disorganized symptoms, and activation [37].

Smoking Characteristics

Research staff assessed all participants for the level of nicotine dependence with the Fagerström Test for nicotine dependence at baseline and at 3 and 6 months [38-40].

Motivation for Cessation and Treatment

We assessed participants for their stage of change for quitting smoking with the single question, "Are you seriously thinking about quitting?" [41]. We also assessed attitudes about using cessation treatment with an adapted Treatment Motivation Scale-Revised, a 23-item scale assessing attitudes about using treatment based on self-determination theory [42]. This scale has five additive subscales that assess perceptions of reasons for treatment, including external motivation (range 4-20), introjected motivation (range 2-10), intrinsic motivation (range 7-35), lack of confidence in using treatment (range 4-20), and relatedness in treatment (range 7-35) [43].

Primary Outcome—Confirmed Use of Smoking Cessation Treatment and Quit Attempts

Blinded assessors completed a structured interview to assess all self-reported use of cessation treatment (including nicotine replacement therapy) at any time during each past 3-month period. The use of cessation treatment was confirmed via clinic record review, clinician confirmation, and viewing medications and nicotine replacement at the assessment. The use of cessation treatment and quit attempts were expected to directly result from the use of the study interventions.

Secondary Outcome—Abstinence

At the follow-up assessment visits, the self-reported, past week of abstinence from smoking was verified with expired carbon monoxide less than 9 ppm (Smokelyzer Breath Carbon Monoxide Monitor; Bedfont Scientific) [44,45]. In addition, any self-reported quit attempts with abstinence during the treatment period were captured with the Timeline Follow-Back method [46-48]. With this method, trained research staff assessed participants for the amount of smoking and other tobacco product use each day, going back week-by-week over the past 3 months using a calendar to cue memories of smoking and abstinence. The Timeline Follow-Back method has been shown to be reliable and valid in the general population [48] and in people with severe mental illnesses [49]. Abstinence was identified as a secondary outcome that would rely on the use of additional cessation medication and behavioral cessation treatment.

Intervention Satisfaction, Usability, and Likeability

Participants completed the Perceived Usefulness and Ease of Use Scale, an adapted 15-item semiqualitative instrument [50] to obtain perceptions of usability and satisfaction with the intervention.

Cognition

We assessed cognition at baseline with a battery comprised of the following 6 standard neuropsychological tests that measure cognitive functions typically impaired in schizophrenia and thought to be important for engagement and success in smoking cessation treatment (Multimedia Appendix 1). We assessed sustained attention (Continuous Performance Test, dependent variable: d') [51], verbal learning (Hopkins Verbal Learning Test; dependent variable: total recall trials 1-3; *t* score from mean of the three trials)[52,53], processing speed (Trail Making Test Part A; dependent variable: seconds to completion) [54], and, because of the likelihood of important relationships of nicotine abstinence and the prefrontal cortex [55-57], we assessed cognitive flexibility (Trail Making Test Part B: dependent variable: seconds to completion) and inhibitory control (Delis-Kaplan Executive Functioning System Color-Word Interference Test; dependent variable: seconds to completion on word reading, color reading, and color-word interference trials) [58]. The mean of a participant's normative scores was used as a composite cognition score. Composite scores were not computed for people who had one or more missing test score.

We also measured word recognition at baseline, calculated from a demographically based index of premorbid intelligence (fourth edition of the Wide Range Achievement Test Reading subtest) [59]. Performance on this test is relatively preserved in people with schizophrenia [60], providing an index of premorbid intellectual function.

Statistical Analyses

We used chi-square tests and *t* tests to assess between-group differences at baseline. We then assessed dichotomous outcomes between intervention groups with logistic regressions (eg, treatment use) [61]. For count outcome variables with a high proportion of zeros and positive skewness (eg, days of abstinence), negative binomial models were used. Modeling began with bivariates and progressed to multivariates using variables providing $P<.10$ in bivariate models, adjusting for gender and years of education. In the multivariate model predicting any abstinence, the total mean cognitive battery score was used to avoid collinearity among the cognitive function scores. Missing observations for the primary outcome, cessation treatment utilization, were set as missing. Missing observations for the secondary outcome, abstinence, were set as smoking (nonabstinent). Analyses were conducted with SAS version 9.4 (SAS Institute, Cary, North Carolina).

Results

Overview

Participants are described in Multimedia Appendix 1. The group included 162 smokers with schizophrenia, with a mean age of 45.91 years (SD 11.32). Two-thirds were male (108/162, 66.7%), more than half identified as black (86/162, 53%). The group was moderately symptomatic (BPRS mean score 41.06, SD 11.11) and reported a mean of 11.12 (SD 13.69) hospitalizations for psychiatric treatment over their lifetimes, demonstrating long-term severe mental illness. Participants smoked an average of 14.56 cigarettes per day (SD 10.59). A low proportion (8.02%) of participants were motivated to quit smoking, and the level of motivation to use cessation treatment was generally low, and it was lowest in perceived external sources of motivation. The group demonstrated moderate cognitive impairments, as expected among people with schizophrenia. Characteristics were not significantly different between participants in the *Let's Talk About Smoking* and *NCI Education* conditions.

Primary Outcome

As shown in Table 1, more than one-third (63/162, 38.9%) of all participants used any verifiable cessation treatment during the 6-month follow-up period, and cessation treatment use was not different between intervention groups (27/84, 32.1% of *Let's Talk About Smoking* vs 36/78, 46.2% *NCI Education*; odds ratio [OR] 0.71 [0.37-1.33]; $P=.28$).

Table 1. Confirmed cessation behaviors over 6-month follow-up.

Cessation behaviors	Total sample (N=162)	Let's Talk About Smoking (N=84)	National Cancer Institute Education (N=78)
Verified use of cessation treatment, n (%)			
Met with doctor to discuss cessation	72 (44.4)	37 (44)	35 (45)
Nicotine replacement therapy	34 (20.9)	18 (21)	16 (21)
Bupropion	7 (4.3)	6 (8)	1 (1)
Varenicline	3 (1.9)	0 (0)	3 (4)
Individual cessation counseling	35 (21.6)	16 (19)	19 (24)
Group cessation counseling	15 (9.3)	7 (8)	8 (10)
Cessation counseling and medication	21 (13.0)	12 (14)	9 (11)
Started any treatment	63 (38.9)	27 (32)	36 (46)
Self-reported or verified use of cessation treatment, n (%)			
Met with doctor to discuss cessation	92 (56.8)	44 (56)	48 (57)
Nicotine replacement therapy	52 (32.1)	24 (31)	28 (33)
Bupropion	13 (8.0)	8 (10)	5 (6)
Varenicline	15 (9.3)	7 (9)	8 (10)
Individual cessation counseling	52 (32.1)	25 (32)	27 (32)
Group cessation counseling	25 (15.4)	10 (13)	15 (18)
Cessation counseling and medication	35 (21.6)	17 (22)	18 (231)
Started any treatment	82 (50.6)	34 (44)	48 (57)
Abstinence outcomes, n (%)			
Verified abstinence at 6 months[a]	7 (4.3)	1 (1)	6 (8)
Any quit attempt with ≥1 day abstinence[b]	61 (37.2)	25 (30)	36 (46)
Any quit attempt with ≥7 days abstinence[b]	24 (14.8)	13 (15)	11 (14)

[a]Calculated from randomized sample.

[b]Calculated from follow-up sample.

Table 1 shows the number of participants who used each type of cessation treatment. Of the 63 participants who used any type of cessation treatment, some individuals used several types of medications, and some used group and individual behavioral cessation counseling. Of 162 participants, 21 (13.0%) had used at least one type of any verified cessation medication, 21 (13.0%) had used at least one type of any verified behavioral intervention, and the same number had used the recommended combination of both a behavioral and a medication intervention (21/162, 13.0%; these summary numbers are not shown in Table 1). A larger number of participants self-reported the use of treatment or had verified the use of treatment (also shown in Table 1). In bivariate logistic models, any verified treatment initiation was significantly predicted by older age (OR 1.03 [95% CI 1.00-1.06]; *P*=.05), higher levels of education (OR 1.18 [95% CI 1.02-1.37]; *P*=.02), and lower positive symptom scale scores (OR 0.87 [95% CI 0.79-0.95); *P*<.001). In the full multivariate model predicting cessation treatment utilization, older age, higher education, and lower level of positive symptoms, scores remained significant predictors of treatment initiation (see Table 2).

Table 2. Predictors of treatment initiation after brief interventions.

Demographic and smoking characteristics	Univariate models[a]			Multivariate models[a]		
	OR[b]	95% CI	*P* value	OR	95% CI	*P* value
Gender	1.09	0.57-2.06	.80	N/A[c]	N/A	N/A
Age	1.03	1.00-1.06	.05	1.03	1.00-1.07	.05
Education	1.18	1.02-1.37	.02	1.21	1.04-1.41	.02
Fagerström Score	1.03	0.88-1.21	.74	N/A	N/A	N/A
Cigarettes per day	1.00	0.97-1.03	.89	N/A	N/A	N/A
Cognitive function						
TM[d] A time	1.00	0.99-1.01	.80	N/A	N/A	N/A
TM B time	1.00	1.00-1.00	.30	N/A	N/A	N/A
Color time	0.99	0.96-1.02	.53	N/A	N/A	N/A
Word time	1.00	0.96-1.03	.83	N/A	N/A	N/A
Interfere T	0.99	0.98-1.01	.24	N/A	N/A	N/A
Hopkins Verbal Learning Test	1.06	0.87-1.28	.56	N/A	N/A	N/A
Continuous performance test	0.89	0.76-1.03	.12	N/A	N/A	N/A
$Cognition_{Total}$[e]	0.97	0.61-1.55	.91	N/A	N/A	N/A
Symptoms						
BPRS[f] subscales						
Positive	0.87	0.79-0.95	<.001	0.87	0.80-0.96	.01
Negative	0.95	0.81-1.11	.52	N/A	N/A	N/A
Activation	0.97	0.84-1.12	.69	N/A	N/A	N/A
Depression	0.94	0.85-1.04	.24	N/A	N/A	N/A
Disorganized	0.95	0.83-1.08	.42	N/A	N/A	N/A
BPRS total score	0.97	0.94-1.00	.06	N/A	N/A	N/A
PANAS[g] positive	1.01	0.98-1.05	.50	N/A	N/A	N/A
PANAS negative	1.01	0.98-1.05	.47	N/A	N/A	N/A
Intervention						
Intervention group	0.71	0.37-1.33	.28	0.65	0.33-1.31	.23

[a]Logistic regression models.

[b]OR: odds ratio.

[c]N/A: not applicable.

[d]TM: trial making.

[e]Only total cognition score was included in multivariate model.

[f]BPRS: Brief Psychiatric Rating Scale.

[g]PANAS: Positive and Negative Affect Schedule.

Secondary Outcome

Although more than one-third of participants (61/162, 37.7%) reported that they had tried to quit and 24 participants (24/162, 14.8%) reported at least 7 days of self-reported abstinence over the follow-up period, only 4.3% (7/162) of participants had biologically verified 7-day point prevalence abstinence at the 6-month assessment (1/78, 1%, in *Let's Talk About Smoking* vs 6/84, 7%, in *NCI Education*; χ^2_1=3.4; *P*=.07). Quit attempts and abstinence were not significantly different between intervention groups. In bivariate models predicting any self-reported abstinence during the follow-up period, greater level of education (beta=.214; SE 0.11; *P*=.04), greater positive affect (beta=.055; SE 0.03; *P*=.05), better overall cognitive functioning (composite score; beta=1.293; SE 0.42; *P*=.0002), and use of any cessation treatment (beta=1.112; SE 0.48; *P*=.02) significantly predicted abstinence (see Table 3). Better performance on most of the individual cognition scale scores also predicted self-reported abstinence. In adjusted multivariate models predicting days of abstinence, greater cognitive ability

composite score and engagement in cessation treatment significantly predicted days of abstinence (see Table 3).

Table 3. Predictors of abstinence after brief interventions.

Demographic and clinical characteristics	Univariate models[a]			Multivariate models[a]		
	Est[b]	SE	*P* value	Est	SE	*P* value
Gender	−0.155	0.51	.80	N/A[c]	N/A	N/A
Age	0.001	0.02	.96	N/A	N/A	N/A
Education	0.214	0.11	.04	0.110	0.09	.22
Fagerström	−0.093	0.13	.50	N/A	N/A	N/A
Cigarettes per day	−0.025	0.02	.20	N/A	N/A	N/A
Cognitive function						
TM[d] A time	−0.024	0.01	.02	N/A	N/A	N/A
TM B time	−0.003	0.00	.06	N/A	N/A	N/A
Color time	−0.056	0.02	.005	N/A	N/A	N/A
Word time	−0.056	0.03	.04	N/A	N/A	N/A
Interfere T	−0.020	0.01	.05	N/A	N/A	N/A
Hopkins Verbal Learning Test	0.166	0.19	.40	N/A	N/A	N/A
Continuous performance test	0.256	0.11	.02	N/A	N/A	N/A
$Cognition_{Total}$[e]	1.293	0.42	.002	1.471	0.47	.002
Symptoms						
BPRS[f] subscales						
Positive	−0.011	0.07	.90	N/A	N/A	N/A
Negative	−0.091	0.13	.50	N/A	N/A	N/A
Activation	0.031	0.09	.70	N/A	N/A	N/A
Depression	0.057	0.08	.50	N/A	N/A	N/A
Disorganized	−0.016	0.10	.90	N/A	N/A	N/A
BPRS total score	0.015	0.02	.50	N/A	N/A	N/A
PANAS[g] positive	0.055	0.03	.05	0.004	0.03	.91
PANAS negative	0.009	0.03	.80	N/A	N/A	N/A
Intervention and cessation treatment						
Intervention group	−0.093	0.48	.85	0.155	0.46	.74
Engaged in cessation treatment	1.112	0.48	.02	1.427	0.47	.003

[a]Negative binomial models.

[b]Est: estimate.

[c]N/A: not applicable.

[d]TM: trial making.

[e]Only total cognition score was included in multivariate model.

[f]BPRS: Brief Psychiatric Rating Scale.

[g]PANAS: Positive and Negative Affect Scale.

Intervention Usability and Satisfaction

Usability and satisfaction mean summary index scores were significantly higher among participants assigned to *Let's Talk About Smoking* compared with those assigned to *NCI Education* (8.9 [SD 1.3] vs 8.3 [SD 2.1]; $t_{120.7}$=2.0; *P*=.045). Most participants (95.38% of *Let's Talk About Smoking* users vs 83.1% of *NCI Education* users) reported that they were satisfied or very satisfied with the intervention. All participants completed the intervention to which they were assigned; no adverse events were reported during the use of the interventions. Approximately 97% of both groups said they would recommend their respective intervention to a friend.

Discussion

Principal Findings

To our knowledge, this is the first randomized trial testing an interactive, multimedia digital motivational intervention to a static digital educational intervention for motivating smokers with schizophrenia to try to quit smoking using evidence-based cessation treatment. Contrary to our hypothesis, smokers with schizophrenia assigned to the interactive intervention were not more likely to initiate cessation treatment. However, these brief, digital interventions led to rates of treatment engagement consistent with studies of earlier versions of *Let's Talk About Smoking* [62-64] and consistent with in-person motivational interviewing, in which 28% to 32.7% of smokers with schizophrenia and bipolar disorder attended an initial treatment appointment [28,29]. Similar to other studies of digital tools for people with schizophrenia and other SMIs [65,66], this study suggests that carefully designed, automated, digital interventions are feasible and acceptable among people with schizophrenia. Such tools could be used to engage smokers with schizophrenia into quit attempts using evidence-based smoking cessation treatment, potentially reducing demands on clinicians and clinics serving this population.

Although both interventions were rated highly, the interactive, multimedia intervention was significantly more appealing than the static educational intervention. In a previous study, young adults with SMI rated the video content of *Let's Talk About Smoking* the highest among the various types of content [67]. In nonstudy environments, future uptake of digital interventions might be most successful with a multimedia approach, including video compared with text-only interventions such as *NCI Education*.

The computerized *NCI Education* performed numerically but not statistically significantly better than *Let's Talk About Smoking* in this study, and numerically better than in a previous study of a paper pamphlet (15% initiated treatment) [63] and in-person interactive education (20.4% initiated treatment) [28]. The outcomes with *NCI Education* were likely facilitated by design features that facilitated comprehension and cognitive processing, including high contrast text with large font; audio in addition to text; presentation of a single concept per page; and sequential, linear formatting of the information. All these design features were also used in the interactive, multimedia intervention. Although video media is very appealing to users, this study indicates that it does not provide an advantage over text-only interventions within a research context.

In this study, the use of any behavioral and pharmacologic cessation treatment following the study interventions significantly predicted abstinence, confirming that motivational and educational interventions should be followed by combined pharmacologic and behavioral interventions [22,24] in order for smokers with schizophrenia to achieve abstinence. Rates of biologically verified abstinence were consistent with what would be expected, given the types of cessation treatment used by the 61 participants who initiated treatment (7/61, 11% of abstinence). For example, 6 months after initiating treatment with a 3-month trial of bupropion, 4% of smokers with schizophrenia were abstinent [68]. Providing more Web-based motivational content for cessation and treatment utilization over repeated sessions and educating the clinicians to encourage and provide combined behavioral interventions and pharmacotherapy may improve utilization of the most effective combinations of treatments. Many community mental health centers do not include cessation treatment in their service array; thus, external services may be needed.

Achieving abstinence is a challenging task requiring multiple cognitive functions. Better performance on our battery of tests assessing aspects of prefrontal functioning, such as cognitive flexibility and inhibitory control, significantly predicted abstinence over the 6-month follow-up, although participants initiated treatment and attempted to quit smoking regardless of the level of cognitive functioning, similar to our previous study [35]. Consistent with the abstinence finding here, previous studies have shown that lower scores on attention [55,69,70], information processing [70], and inhibitory control [71] were associated with worse cessation outcomes in smokers with schizophrenia, although not all studies are consistent with these findings. Although we did not measure working memory, other studies have also shown that working memory was associated with abstinence outcomes [70,71]. Attention, concentration, memory, working memory, and inhibitory control are arguably needed to learn smoking cessation skills and to use them while inhibiting the urge to smoke. Cognitive remediation interventions have been shown to improve cognition and functional outcomes among people with SMI who are receiving psychosocial interventions [72]. One promising initial study of cognitive remediation added to addiction treatment enhanced substance abuse outcomes among people with schizophrenia [73]. Cognitive remediation delivered with smoking cessation treatment has not been tested among smokers with schizophrenia.

These results among middle-aged smokers with schizophrenia contrast with our previous work among young adults with SMIs [74]. In young adult smokers with SMI, the use of a similar digital intervention resulted in greater numbers of quit attempts and a greater proportion of people with biologically verified abstinence but less use of cessation treatment in the 3 months following the intervention [67].

Several study limitations should be mentioned. First, this study used an active, computerized control condition; thus, we were unable to determine the level of advantage these interventions provide over usual care, such as doctor's advice. Second, we were not able to obtain detailed information about the frequency and intensity of the community-delivered cessation medication and behavioral interventions, which would have facilitated a better understanding of our secondary abstinence outcome. Finally, study participants were recruited from three large community clinics in three states and included smokers with schizophrenia from several racial and ethnic groups, yet they may not be representative of all smokers with schizophrenia in the United States or other countries.

Conclusions

The interactive, multimedia, digital intervention was not more effective than a static digital intervention tailored to reduce

cognitive load among smokers with schizophrenia. Both brief digital interventions garnered results similar to those found in previous studies of in-person motivational interventions among smokers with SMIs. Technology-delivered tobacco treatments have the promise to expand access in this high need population with high rates of smoking in clinics with longstanding workforce challenges but must be developed with user input and tested for efficacy, address data safety and privacy, and eventually integrate with electronic medical records and data systems [75]. Technology-delivered tobacco treatments could provide brief or long-term cessation skills training and cessation support, which could augment or replace in-person interventions for this population, as has been shown to be effective for the treatment of addiction in the general population [76]. Further research is warranted to evaluate efficacy and implementation strategies for digital interventions for smokers with schizophrenia and other SMIs.

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Conflicts of Interest

During the study period, MB had funding from Alkermes to conduct research on medication treatment for schizophrenia and alcohol disorder. JW had grant funding from Pfizer. The remaining authors did not report potential conflicts of interest. The version of Let's Talk About Smoking tested in this study is owned by the first author's primary institution.

Multimedia Appendix 1
Baseline demographics and characteristics of 162 study participants.
[DOCX File , 43 KB - mental_v7i2e16524_app1.docx]

Multimedia Appendix 2
CONSORT-EHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 105 KB - mental_v7i2e16524_app2.pdf]

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Abbreviations

BPRS: Brief Psychiatric Rating Scale
Est: estimate
NCI: National Cancer Institute
OR: odds ratio
SMI: serious mental illness

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Original Paper

The Acceptability of Text Messaging to Help African American Women Manage Anxiety and Depression: Cross-Sectional Survey Study

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Abstract

Background: The rates of mental illness among African American women are comparable with the general population; however, they significantly underutilize mental health services compared with their white counterparts. Previous studies revealed that interventions delivered via text messaging are effective and can be used to increase access to services and resources. More insight into whether or not this modality is acceptable for use to deliver mental health care to help African American women manage anxiety and depression is needed.

Objective: This exploratory study aimed to gain insight into the acceptability of using text messaging to help African American women manage anxiety and depression.

Methods: A self-administered Web-based survey was launched in June 2018 and closed in August 2018. Eligible participants were African American women (18 years or older) who reside in the United States. Participants were recruited through convenience sampling (eg, email sent via listservs and social media posts). Respondents were provided an anonymous link to the questionnaire. The survey consisted of 53 questions on the following subjects: sociodemographic characteristics, attitudes toward seeking professional psychological help, mobile phone use, and acceptability of using a mobile phone to receive mental health care.

Results: The results of this exploratory study (N=101) showed that fewer than half of respondents endorsed the use of text messaging to communicate with a professional to receive help to manage anxiety (49/101, 48.5%) and depression (43/101, 42.6%). Approximately 51.4% (52/101) agreed that having the option to use text messaging to communicate with a professional if they are dealing with anxiety would be helpful. Similarly, 48.5% (49/101) agreed that having the option to use text messaging to communicate with a professional if they are dealing with depression would be helpful. Among participants who agreed that text messaging would be helpful, more than 80% noted being comfortable with its use to receive help for managing anxiety (approximately 86%, 45/52) and depression (approximately 82%, 40/49; highly significant positive association, all $P<.001$). More than 50% of respondents (56/101, 55.4%) indicated having concerns about using text messaging. No statistically significant associations were found between age and agreement with the use of text messaging to communicate with a professional to receive help for managing anxiety ($P=.26$) or depression ($P=.27$).

Conclusions: The use of text messaging was not highly endorsed by African American women as an acceptable mode of communication with a professional to help them manage anxiety or depression. Concerns around privacy, confidentiality, and the impersonal feel of communicating about sensitive issues via text messages must be addressed for this modality to be a viable option. The findings of this study demonstrated the need for further research into the use of mobile technology to provide this population with more accessible and convenient options for mental health care.

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KEYWORDS

African Americans; women; anxiety; depression; mHealth; text messaging

Introduction

African American women experience rates of mental illness comparable to the general population (18.6% vs 18.9%) [1]. However, they use mental health services at less than half the rate of their white counterparts (10.6% compared with 23.4%) [1]. Approximately 16% of non-Hispanic black women reported having generalized anxiety in their lifetime [2]. Furthermore, 27% of non-Hispanic black women reported experiencing depression in their lifetime [2]. Historically, mental illness has been underreported in the African American community; therefore, the true burden may actually be significantly higher than reported prevalence estimates.

More than 64% of African American women who reported experiencing mental illness in the last year did not receive any mental health treatment during that time [1]. A study by Watson and Hunter [3] explored the attitudes and perceptions of African American women toward professional help seeking for mental health services and found that they "held less favorable attitudes toward professional help-seeking than previous, non-African American samples." There are many reasons why African American women may not seek mental health services when needed. Barriers such as stigmatization of mental illness, less access to treatment, no or inadequate health insurance, mistrust of providers, and low health literacy prevent traditionally marginalized populations from seeking care [4,5].

Evidence from previous studies showed that telehealth interventions for anxiety [6-13] and depression [7,9-20] are effective. Previous interventions have used modalities such as telephone [9,16], videoconferencing [11,17], text messaging [18,20], Web-based formats (eg, websites and email) [6,15,21], and mobile-optimized websites and apps [13,19] to help participants reduce anxiety or depressive symptoms. The convenience and familiarity of using telehealth modalities (eg, text messaging), coupled with the use of proven psychotherapy treatments, such as cognitive behavioral therapy (CBT), make telemental health interventions suitable alternatives to traditional in-person treatment. Furthermore, mobile health (mHealth) interventions have been increasingly used because of the potential to reduce access issues, such as geographic proximity to a preferred mental health care professional (eg, therapist). Previous studies have shown that African American women are comfortable with participating in mHealth research and interventions [22,23], and 80% of African American women own smartphones [24]. This presents a great opportunity to use mobile technology to help reduce the disparity in mental health service utilization and improve health outcomes for this population.

Previous literature reviews have found that, overall, text messaging is effective in improving mental health–related outcomes, treatment adherence, and appointment attendance [25,26]. However, the majority of the published studies were conducted with predominantly white study samples. Therefore, the results may not be generalizable to all racial groups. To our knowledge, there have been no studies that have examined the acceptability of text messaging to help African American women manage anxiety or depression. Nonetheless, prior studies that included a representative sample of African American participants (>13% of the study sample) and used text messaging for weight management, physical activity, or prenatal care education interventions have been effective [27-30]. Therefore, the insufficient representation of African Americans in previous telemental health studies may be largely because of ineffective recruitment and retention strategies, in addition to the previously discussed barriers that prevent them from seeking mental health care [31,32].

Owing to the scarcity of studies that include a significant representation of African American women in the sample and the underutilization of mental health services by this population, the population should be surveyed to determine the acceptability of using text messaging for mental health care. The aim of this exploratory study was to gain insight into the acceptability of using text messaging to help African American women manage anxiety and depression, specifically comfortability with using text messaging to communicate with a professional to receive help to manage anxiety and depression.

Methods

Study Design and Recruitment

The Web-based questionnaire was opened in June 2018 and closed in August 2018. Women (18 years or older) who identify as African American and reside within the United States, regardless of mental health history, were eligible to participate. Participants were recruited through convenience sampling. Recruitment methods included receiving an invitation to take the survey via a direct email from the first author or email sent through listservs whose membership is primarily African American women or solicitation via social media posts (eg, posts in Facebook groups) or direct messages. A research information sheet about the study was provided via a link in the email text or social media posts. Following the snowball sampling method, respondents were encouraged to share the link to the survey with their networks (eg, family, friends, and professional organizations). No remuneration was offered for participation. The Institutional Review Board of the University of North Carolina at Chapel Hill provided the study a notification of exemption from further review.

Measures

The computer-assisted Web interviewing data collection method was used to administer the survey because of the sensitive nature of the questions and to reduce respondent burden. Respondents were provided an anonymous link to the Web-based questionnaire. No personally identifiable information (PII) was collected in the survey. The survey was self-administered using Qualtrics software. The 53 questions included in the survey covered the following domains: sociodemographic characteristics, attitudes toward seeking professional

psychological help, mobile phone use, and acceptability of using a mobile phone to receive mental health care.

Questions about sociodemographic characteristics, such as the respondent's race, ethnicity, age, gender, and highest level of education attained, were asked at the beginning of the survey. The race, age, and gender questions were used as screener questions to determine eligibility to continue the survey. If the respondent did not self-identify as African American (or biracial, African American, and another race), female, and 18 years or older, they were routed directly to the end of the survey.

Attitudes Toward Seeking Professional Psychological Help

Respondents' attitudes toward seeking professional psychological help were measured using questions from an adapted version of the validated *Inventory of Attitudes Toward Seeking Mental Health Services* (IASMHS) [33]. The IASMHS consists of 24 questions that contribute to a total IASMHS score and the following factors: psychological openness, help-seeking propensity, and indifference to stigma. Response options to the survey items were on a 5-point Likert-type scale ranging from 0 (disagree) to 4 (agree). Before data analysis, all negatively worded items were reverse coded.

In the survey, the term *professional* referred to individuals who have been trained to deal with mental health problems (eg, psychologists, psychiatrists, social workers, and family physicians). To collect data specifically about attitudes toward seeking professional help for managing anxiety and depression, 6 questions in the inventory were revised. In these 6 questions, the words *psychological problems* or *mental disorder* were substituted with *anxiety* and then repeated for substitution with *depression*. For example, item #16 in the IASMHS reads, "I would be uncomfortable seeking professional help for psychological problems because people in my social or business circles might find out about it." The 2 corresponding revised survey questions state, "I would be uncomfortable seeking professional help for *anxiety* because people in my social or business circles might find out about it" and "I would be uncomfortable seeking professional help for *depression* because people in my social or business circles might find out about it." This increased the total number of questions in the inventory to 30 and permitted calculation of a total IASMHS score related to anxiety; a total IASMHS score related to depression; and subscores for psychological openness, help-seeking propensity, indifference to stigma for anxiety, and indifference to stigma for depression. Scores on the IASMHS range from 0 to 96, with subscale scores ranging from 0 to 32. Higher scores indicate more positive attitudes toward seeking professional psychological help.

Acceptability of the Use of Text Messaging for Mental Health Care

The use of text messaging was ascertained with the following items: (1) current mobile phone ownership (yes/no) and (2) frequency of sending text messages (never, <1 time per week, 1-6 times per week, 1-3 times per day, and ≥4 times per day). Acceptability of using text messaging to receive help to manage anxiety or depression was measured by response to the statements, "I would feel comfortable communicating with a professional through text messaging to receive help for managing *anxiety*" and "I would feel comfortable communicating with a professional through text messaging to receive help for managing *depression*." Respondents were also asked about the perceived helpfulness of having the option to use text messaging to communicate with a professional if they are feeling anxious or depressed. Perceived helpfulness was gauged by response to the statements, "Having the option to use text messaging to communicate with a professional if I am dealing with *anxiety* would be helpful for me" and "Having the option to use text messaging to communicate with a professional if I am dealing with *depression* would be helpful for me." Response options to the survey items were on a 5-point Likert-type scale ranging from 0 (disagree) to 4 (agree). Before completing the survey, respondents were asked, "Do you have any concerns about using text messaging to communicate with a professional?" If they answered "Yes" to this question, they were presented with an open-ended question asking them to note their concerns in the textbox provided.

Statistical Analysis

Quantitative Data Analysis

Descriptive statistics were calculated for sample characteristics and responses to text messaging questions as mean, standard deviation, and range for continuous variables and as frequencies and percentages for categorical variables. As reported in prior work, age was dichotomized into 2 groups (<50 years and ≥50 years), education was categorized into 3 levels (less than bachelor's degree, bachelor's degree, and graduate degree), and response options were dichotomized as agree/somewhat agree and disagree/somewhat disagree [22]. Fisher exact test was used to determine whether an association exists between the response to each text messaging question and age group and to test for association between agreement with comfortability and perceived helpfulness of having the option to communicate with a professional through text messaging to receive help for managing anxiety and depression, respectively. Independent groups *t* tests were separately performed to assess group differences in mean scores for each on psychological openness, help-seeking propensity, indifference to anxiety stigma, indifference to depression stigma, and IASMHS scores for anxiety and depression, respectively, between the participants who agreed with the use of text messaging to communicate with a professional to receive help to manage anxiety and depression and those who disagreed.

Furthermore, a sensitivity analysis was performed using independent groups *t* tests to assess group differences in mean scores, in the aforementioned categories, between the participants who agreed (agree/somewhat agree) with the use of text messaging to communicate with a professional to receive help to manage anxiety and depression and those who did not indicate agreement (disagree/somewhat disagree/undecided). *Undecided* responses were included to see whether the statistical significance changed. Statistical significance was determined at the 2-sided $P<.05$ level for all tests. Statistical analyses were conducted using SPSS version 25 software.

Qualitative Data Analysis

Thematic analysis was conducted on responses to the question, "What are your concerns about using text messaging to communicate with a professional?" The responses were imported into NVivo 12 for analysis. The data were categorized by TM and SK reading through each response and coding the emerging themes. Responses could be assigned as many themes as were pertinent.

Results

Participants

The characteristics of the study participants are summarized in Table 1. Out of the 113 respondents who started the survey, 102 completed it (90.3% completion rate). Of the 102 respondents, 1 was removed because of item nonresponse, providing an analysis sample of 101 participants. Participants ranged in age from 19 to 80 years (mean age 38.9 [SD 13.2] years), and all participants identified as African American or biracial (ie, African American and another race) and female. Most respondents (99/101, 98.0%) identified as non-Hispanic. Approximately 15% (15/101) of respondents had less than a bachelor's degree, 23.8% (24/101) obtained a bachelor's degree, and 61.4% (62/101) had a graduate degree. All participants reported the use of text messaging, and 90.1% (91/101) of participants indicated texting 4 or more times per day.

Table 1. Characteristics of study participants (N=101).

Characteristics	Values
Age (years), mean (SD)	38.9 (13.2)
Age group (years), n (%)	
<50	80 (79.2)
≥50	21 (20.8)
Race, n (%)	
African American	99 (98.0)
Biracial[a]	2 (2.0)
Ethnicity, n (%)	
Hispanic	2 (2.0)
Non-Hispanic	99 (98.0)
Education[b], n (%)	
Less than bachelor's degree	15 (14.9)
Bachelor's degree	24 (23.8)
Graduate degree	62 (61.4)
Frequency of using text messaging, n (%)	
1-6 times per week	2 (2.0)
1-3 times per day	8 (7.9)
≥4 times per day	91 (90.1)

[a]Biracial defined as identifying as African American and another race.

[b]Percentages may not sum to 100% because of rounding.

Communicating With a Professional Via Text Messaging

The results of this exploratory study showed that less than half of respondents endorsed the use of text messaging to communicate with a professional to receive help to manage anxiety and depression. Only 48.5% (49/101) of respondents indicated agreement (26/101, 25.7% agree and 23/101, 22.8% somewhat agree), 10.9% (11/101) were undecided, and 40.6% (41/101) showed disagreement (26/101, 25.7% disagree and 15/101, 14.9% somewhat disagree) with the statement, "I would feel comfortable communicating with a professional through text messaging to receive help for managing *anxiety*." Similarly, 42.6% (43/101) of respondents indicated agreement (23/101, 22.8% agree and 20/101, 19.8% somewhat agree), 14.9% (15/101) were undecided, and 42.5% (43/101) showed disagreement (26/101, 25.7% disagree and 17/101, 16.8% somewhat disagree) with the statement, "I would feel comfortable communicating with a professional through text messaging to receive help for managing *depression*."

Approximately 51% (52/101) of respondents agreed that having the option to use text messaging to communicate with a professional if they are dealing with anxiety would be helpful. Similarly, 48.5% (49/101) of respondents agreed that having the option to use text messaging to communicate with a professional if they are dealing with depression would be helpful. Figures 1 and 2 illustrate the bivariate relationship

between perceived helpfulness and comfortability with having the option to communicate with a professional via text messaging to receive help dealing with anxiety and depression, respectively.

Among participants who agreed that text messaging would be helpful, approximately 86% (45/52) noted being comfortable with its use to receive help for managing anxiety (highly significant positive association; *P*<.001); in contrast, among participants who disagreed that text messaging would be helpful, approximately 7% (3/49) noted being comfortable with its use to receive help for managing anxiety (Figure 1). Of those who agreed with the statement, "Having the option to use text messaging to communicate with a professional if I am dealing with *depression* would be helpful for me," approximately 82% (40/49) indicated being comfortable with its use to receive help for managing depression (highly significant positive association; *P*<.001); however, among participants who disagreed that text messaging would be helpful, approximately 6% (3/52) indicated being comfortable with its use to receive help for managing depression (Figure 2). No statistically significant associations were found between age and agreement with the use of text messaging to communicate with a professional to receive help for managing anxiety (*P*=.26) or depression (*P*=.27). Furthermore, no statistically significant association was found between age and response to the question, "Do you have any concerns about using text messaging to communicate with a professional?" (*P*>.99).

Figure 1. Sample percentages showing the bivariate relationship between perceived helpfulness and comfortability with using text messaging to communicate with a professional to receive help to manage anxiety (*P*<.001).

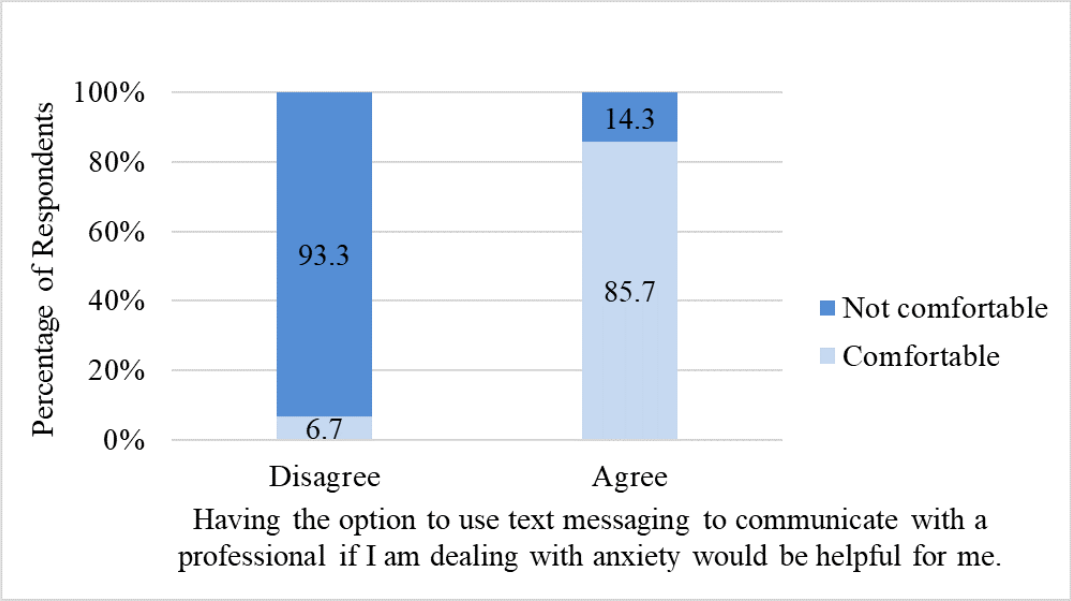
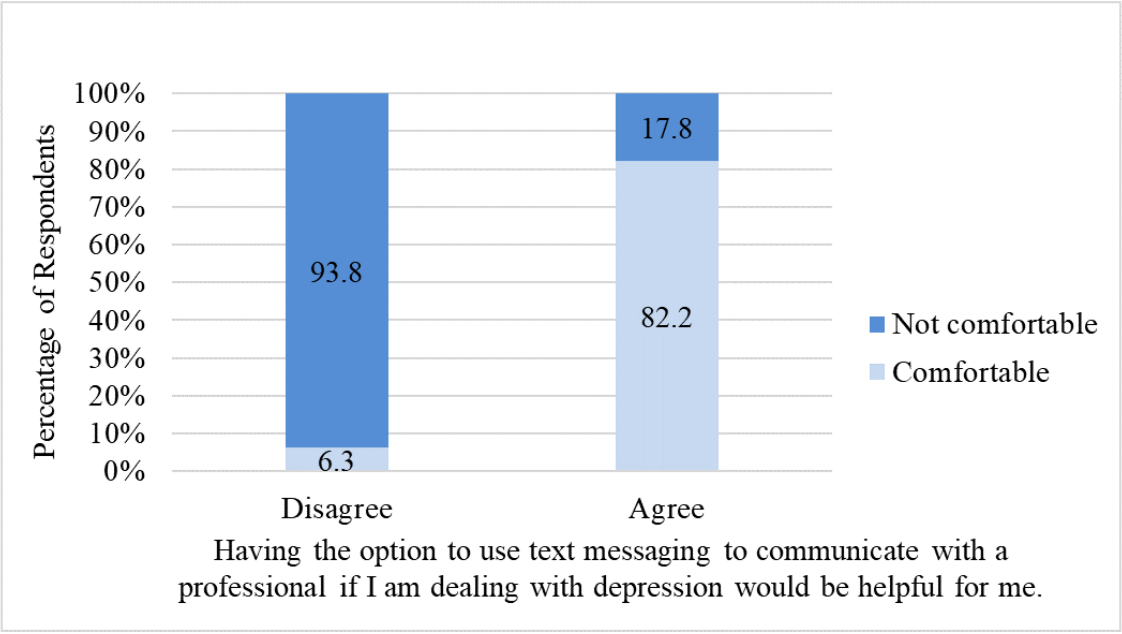


Figure 2. Sample percentages showing the bivariate relationship between perceived helpfulness and comfortability with using text messaging to communicate with a professional to receive help to manage depression (*P*<.001). Note: percentages may not sum to 100% because of rounding.



Attitudes Toward Seeking Mental Health Service and Acceptance of Text Messaging

The study participants held favorable views toward seeking mental health services. Respondents' reports of psychological openness (mean 23.95, SD 4.53) and help-seeking propensity (mean 26.11, SD 4.89) were comparable with the adult female normative scores for psychological openness (mean 23.19, SD 6.00) and help-seeking propensity (mean 24.95, SD 4.74) [33]. The indifference to stigma questions were adapted to collect data on indifference to sigma for anxiety and depression. The participants' scores on indifference to anxiety stigma (mean 24.34, SD 6.08) and depression stigma (mean 23.58, SD 6.43) were similar.

Tables 2 and 3 display group IASMHS factor scores by the level of agreement with using text messaging to communicate with a professional to receive help for managing anxiety and depression, respectively. There were no statistically significant differences between group mean scores for psychological openness (*P*=.96), help-seeking propensity (*P*=.68), indifference to anxiety stigma (*P*=.28), and IASMHS scores (*P*=.47) between the participants who agreed (agree/somewhat agree) with the use of text messaging to communicate with a professional to receive help to manage anxiety and those who disagreed (disagree/somewhat disagree). Similarly, there were no statistically significant differences between group mean scores for psychological openness (*P*=.78), help-seeking propensity (*P*=.93), indifference to depression stigma (*P*=.67), and IASMHS scores (*P*=.94) between the participants who agreed (agree/somewhat agree) with the use of text messaging to communicate with a professional to receive help to manage depression and those who disagreed (disagree/somewhat disagree). In addition, the results of the sensitivity analysis revealed no statistically significant difference between group mean scores, in the aforementioned categories, between the participants who agreed (agree/somewhat agree) and those who did not indicate agreement (disagree/somewhat disagree/undecided) with the use of text messaging to communicate with a professional to receive help to manage anxiety (psychological openness: *P*=.88; help-seeking propensity: *P*=.93; indifference to anxiety stigma: *P*=.32; and IASMHS scores: *P*=.55) and depression (psychological openness: *P*=.62; help-seeking propensity: *P*=.56; indifference to depression stigma: *P*=.81; and IASMHS scores: *P*=.59).

Table 2. Inventory of Attitudes Toward Seeking Mental Health Services factor scores by agreement with using text messaging to communicate with a professional to receive help for managing anxiety.

Factor	Agree (n=49), mean score (SD)	Disagree (n=41), mean score (SD)	Mean difference (95% CI)
Psychological openess	23.9 (5.0)	23.9 (4.0)	0.0 (−1.9 to 1.8)
Help-seeking propensity	26.1 (5.1)	26.5 (4.8)	−0.4 (−2.5 to 1.6)
Indifference to anxiety stigma	23.7 (6.2)	25.1 (5.9)	−1.4 (−3.9 to 1.1)
Inventory of Attitudes Toward Seeking Mental Health Service total	73.7 (12.9)	75.5 (11.3)	−1.9 (−7.0 to 3.2)

Table 3. Inventory of Attitudes Toward Seeking Mental Health Services factor scores by agreement with using text messaging to communicate with a professional to receive help for managing depression.

Factor	Agree (n=43), mean score (SD)	Disagree (n=43), mean score (SD)	Mean difference (95% CI)
Psychological openess	24.2 (5.1)	23.9 (4.1)	0.3 (−1.7 to 2.3)
Help-seeking propensity	26.4 (4.7)	26.3 (5.0)	0.1 (−2.0 to 2.2)
Indifference to depression stigma	23.8 (6.5)	24.3 (6.1)	−0.6 (−3.3 to 2.1)
Inventory of Attitudes Toward Seeking Mental Health Service total	74.4 (12.8)	74.6 (12.0)	−0.2 (−5.5 to 5.1)

Concerns About Text Messaging

More than half of the respondents (56/101, 55.4%) indicated having concerns about using text messaging to communicate with a professional. The most common themes identified from responses to the question, "Do you have any concerns about using text messaging to communicate with a professional?" are presented in Table 4. A total of 78 responses were coded into themes. Most of the concerns (73/78, 94%) centered around the following themes: privacy and confidentiality (33/78, 42%), the impersonal feel of communicating by text messaging (17/78, 22%), possible miscommunication (16/78, 21%), and belief that the mode is insufficient for treatment (7/78, 9%).

Table 4. The most common concerns about using text messaging to communicate with a professional (N=78).

Themes[a]	Value, n (%)	Examples
Privacy and confidentiality	33 (42)	• *"There are risks with sending sensitive information in text messages such as being mistakenly sent to the wrong person, someone other than the professional seeing/reading my messages, and someone other than the professional sending them in response to my messages."* [Participant, 34 years old] • *"Security of the content of the text messages."* [Participant, 31 years old] • *"Lack of privacy. The government has been known to search the cell phones of law abiding individuals for ridiculous reasons."* [Participant, 58 years old]
Impersonal feel	17 (22)	• *"Lack of intimacy with counselor. How can healing take place without a relationship?"* [Participant, 29 years old] • *"Too impersonal—and tone is too difficult to determine and you cannot read compassion."* [Participant, 48 years old] • *"Not personal enough."* [Participant, 62 years old]
Miscommunication	16 (21)	• *"I believe body language is really important in communication. Text messaging doesn't allow for the counselor to observe body language. Writing can also sometimes be misunderstood by the reader."* [Participant, 29 years old] • *"It's hard to convey emotions via text message."* [Participant, 34 years old] • *"Words are just 35% of communication."* [Participant, 65 years old]
Insufficient mode for treatment	7 (9)	• *"Their response time...with video conferencing you can get immediate feedback versus waiting for someone to respond [via text] which may increase my anxiety."* [Participant, 34 years old] • *"It depends on the severity of the issue I am working through. I believe there are instances were text messaging is inappropriate or insufficient."* [Participant, 32 years old] • *"I'm not sure if [text messaging] would be as effective."* [Participant, 33 years old]

[a]A total of 78 responses were coded into themes, however only the most common themes are presented in the table.

Discussion

Principal Findings

To our knowledge, this preliminary study was one of the first to measure the acceptability of using text messaging to deliver mental health care to African American women. The results of this study showed that less than half of respondents endorsed the use of text messaging to communicate with a professional to receive help to manage anxiety and depression. No statistically significant associations were found between age and agreement with the use of text messaging. Approximately half of the women agreed that having the option to use text messaging to communicate with a professional if they are dealing with anxiety or depression would be helpful. However, more than half of respondents indicated having concerns about using text messaging to communicate with a professional. No statistically significant association was found between age and having concerns about using text messaging to communicate with a professional.

The results revealed that African American women have favorable views toward seeking mental health services, comparable with non–African American women [27]. Our findings are contrary to the results of a previous study by Watson and Hunter who found that African American women have less favorable attitudes toward professional help seeking than their non–African American counterparts [3]. However, the differences in reported results between the studies may be because of significant differences in age and education level between the study samples. The mean age of the women in the study by Watson and Hunter [3] was 20.9 years, and the majority of participants (92.6%) reported attending a 4-year university. In comparison, the mean age of the women in our study was 38.9 years, and the majority of participants (85.2%) had at least a bachelor's degree. Therefore, the 18-year difference in mean age between the study samples and the difference in education level could contribute to the contrasting findings.

An exploration into the reason for low acceptance of text messaging was conducted by analyzing group IASMHS factor scores by the level of agreement with using text messaging to communicate with a professional to receive help for managing anxiety and depression. Findings showed that there were no statistically significant differences between group mean scores for any of the factors. One might expect to see a significant difference in psychological openness, help-seeking propensity, indifference to anxiety stigma, or indifference to depression stigma between the participants who agreed (agree/somewhat agree) with the use of text messaging and those who disagreed (disagree/somewhat disagree). Specifically, the authors expected that those who indicated acceptance of the use of text messaging would have higher scores for all factors than those who did not. These findings could be interpreted as indicating that the reason for low acceptance is not because of a difference in attitudes toward seeking mental health care but because of the modality used to do so.

The most common concerns respondents had were about privacy and confidentiality, the impersonal feel of communicating by text messaging, possible miscommunication, and belief that the mode is insufficient for treatment. For example, regarding privacy and confidentiality, 1 respondent stated:

> *There are risks with sending sensitive information in text messages such as being mistakenly sent to the wrong person, someone other than the professional*

> *seeing/reading my messages, and someone other than the professional sending them in response to my messages.*

Concerns around privacy and confidentiality must be addressed for the successful implementation of mHealth interventions for African American women [23]. Future studies should provide clear communication to participants about who they will receive text messages from, who will have access to the text messages, and information on how the data will be protected. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) sets national standards to protect sensitive patient health information. Researchers and clinicians should ensure that transmission and storage of text messages that contain electronic protected health information are HIPAA compliant.

Furthermore, concerns around the impersonal feel and possible miscommunication must be considered. One respondent noted:

> *[text messaging is] too impersonal—and tone is too difficult to determine and you cannot read compassion.*

Another respondent voiced concerns about possibly being misunderstood by stating:

> *I believe body language is really important in communication. Text messaging doesn't allow for the counselor to observe body language. Writing can also sometimes be misunderstood by the reader.*

It is important that participants feel connected to the person they are disclosing sensitive information to, especially within a population where mental illness is highly stigmatized. Feelings of disconnection and being misunderstood are counterproductive to treatment. Although text messaging is known to increase the feeling of connectedness between patient and mental health professionals, successful use is limited to simple messages (eg, supportive messages to prevent suicide attempt) and not real-time prolonged conversation to manage a current episode (eg, panic attack) [25].

Finally, text messaging may not be appropriate to use in all situations. One respondent stated:

> *It depends on the severity of the issue I am working through. I believe there are instances were text messaging is inappropriate or insufficient.*

Furthermore, a unique finding was that the use of text messaging may actually increase anxiety because of a lag in response time. A participant noted the following concern:

> *Their response time...with video conferencing you can get immediate feedback versus waiting for someone to respond [via text] which may increase my anxiety.*

The combination of concerns around privacy and confidentiality, in addition to the impersonal feel, fear of miscommunication, and view of text messaging as an insufficient mode for treatment, presents a significant challenge to the use of this modality for effective treatment of anxiety or depression. Although text messaging is convenient, it may not be easily adopted or sustainable to use to converse with clients regarding their anxiety or depression. A systematic review on the use of text messaging for mental health care concluded that "due to the simplicity of its content, text messaging cannot be used as a remote counseling tool;" however, previous studies have successfully used text messaging as an adjunct to in-person treatment [25]. Text messaging may be considered for symptom monitoring and appointment, medication, and *homework* reminders (eg, CBT activities), which may help to reduce no-show rates, improve medication adherence, and increase the likelihood of completing *homework* assigned by the mental health professional [34-36]. A study by Aguilera et al found that daily automatic text message–based mood ratings can be used as a proxy for the Patient Health Questionnaire-9 depression screener [37]. This may be beneficial for tracking depression severity to identify trends and adjust treatment plans as needed.

Limitations

The main limitations of this exploratory study were recruitment method and sample size. Participants were recruited through convenience sampling and encouraged to share the survey email or social media posts with their networks. Although no PII was collected in the survey and respondents accessed the survey through an anonymous link, social desirability and other selection biases could have resulted if the respondent personally knew the first author.

Furthermore, the sample size of 101 respondents is small for this cross-sectional survey and consisted of mostly younger (<50 years) and highly educated women (more than 85% had at least a bachelor's degree). This limits the generalizability of the findings. Although stigma may continue to be a barrier for highly educated African American women, access to mental health services, insurance coverage, and health literacy may be less of an issue for this group.

Conclusions and Future Directions

Owing to the high smartphone ownership by African American women (80%) [24], there is a great opportunity to use mobile technology to provide mental health care. A *one-size-fits-all* approach to designing telehealth interventions to help African American women manage anxiety or depression may lead to more options but continued disparity in receiving mental health care. This study adds to the literature by providing insight into the attitudes of African American women toward seeking mental health services to manage anxiety and depression and the acceptability of using text messaging to communicate with a professional to receive help for managing anxiety and depression. Although the use of text messaging was not highly endorsed by African American women as an acceptable mode to converse with a professional (<50% endorsed), our prior work found that mobile video calls were viewed favorably by the majority of respondents (>70% endorsed) [22]. Concerns around privacy, confidentiality, and the impersonal feel of communicating about sensitive issues via text messages must be addressed for successful participation in text message–based interventions among this population. However, it may be used as an adjunct to other methods for remote counseling (eg, video call and voice calls) [38].

The findings of this study demonstrated the need for additional research into the use of mobile technology to provide African American women with more accessible and convenient options for mental health care. More research is needed to determine whether having a preexisting relationship with a professional (eg, face-to-face sessions in the past) impacts acceptance and use of the technology to receive professional support. Future work will include relaunching the survey to a larger and more generalizable sample. Questions will be added to screen for the presence and severity of depression and anxiety and to collect data on previous mental health services utilization and history of mental illness.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
HIPAA: Health Insurance Portability and Accountability Act of 1996
IASMHS: Inventory of Attitudes Toward Seeking Mental Health Services
mHealth: mobile health
PII: personally identifiable information

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Original Paper

An Internet-Delivered Cognitive Behavioral Therapy for Depression and Anxiety Among Clients Referred and Funded by Insurance Companies Compared With Those Who Are Publicly Funded: Longitudinal Observational Study

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Abstract

Background: Anxiety and depression are leading causes of disability but are often undertreated. Internet-delivered cognitive behavioral therapy (ICBT) improves access to treatment by overcoming barriers to obtaining care. ICBT has been found to be efficacious in research trials and routine care, but there is limited research of ICBT when it is recommended and funded by insurance companies for clients on or recently in receipt of disability benefits or accommodations.

Objective: The aim of this study was to examine ICBT engagement, treatment satisfaction, and effectiveness among individuals involved with 2 insurance companies. The 2 samples were benchmarked against published outcomes from a publicly funded (PF) ICBT clinic.

Methods: Individuals who were on or recently in receipt of disability benefits and were either insurance company (IC) employees (n=21) or IC plan members (n=19) were referred to ICBT funded by the respective insurance companies. Outcomes were benchmarked against outcomes of ICBT obtained in a PF ICBT clinic, with clients in the clinic divided into those who reported no involvement with insurance companies (n=414) and those who were on short-term disability (n=44). All clients received the same 8-week, therapist-assisted, transdiagnostic ICBT course targeting anxiety and depression. Engagement was assessed using completion rates, log-ins, and emails exchanged. Treatment satisfaction was assessed posttreatment. Depression, anxiety, and disability measures were administered pretreatment, posttreatment, and at 3 months.

Results: All samples showed high levels of ICBT engagement and treatment satisfaction. IC employees experienced significant improvement at posttreatment (depression d=0.77; anxiety d=1.13; and disability d=0.91) with outcomes maintained at 3 months. IC plan members, who notably had greater pretreatment disability than the other samples, experienced significant moderate effects at posttreatment (depression d=0.58; anxiety d=0.54; and disability d=0.60), but gains were not maintained at 3 months. Effect sizes at posttreatment in both IC samples were significantly smaller than in the PF sample who reported no insurance benefits (depression d=1.14 and anxiety d=1.30) and the PF sample who reported having short-term disability benefits (depression d=0.95 and anxiety d=1.07). No difference was seen in effect sizes among IC employees and the PF samples on disability. However, IC plan members experienced significantly smaller effects on disability d=0.60) compared with the PF sample with no disability benefits d=0.90) and those on short-term disability benefits d=0.94).

Conclusions: Many clients referred and funded by insurance companies were engaged with ICBT and found it acceptable and effective. Results, however, were not maintained among those with very high levels of pretreatment disability. Small sample sizes in the IC groups are a limitation. Directions for research related to ICBT funded by insurance companies have been described.

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KEYWORDS

internet; disability; depression; anxiety; insurance; cognitive behavior therapy

Introduction

Background

Anxiety and depression are highly prevalent in adult populations and are often associated with a high degree of disability [1]. According to the World Health Organization, depression is the leading cause of ill health and disability worldwide [2], while anxiety disorders have been identified as the 9th leading cause of disability worldwide [3]. These disorders come with high personal and economic costs. The Mental Health Commission of Canada estimates that mental health concerns cost the Canadian economy approximately Can $50 billion annually [4]. Almost Can $6 billion of this is attributed to lost productivity from absenteeism, presenteeism, and turnover in working adults. Moreover, 30% of disability or insurance claims are attributed to mental health concerns. Thus, there is significant pressure to identify and implement effective interventions to assist individuals with mental health concerns in relieving their symptoms and improving work-related disability.

Although there is great need for mental health treatment, several barriers exist that prevent individuals with mental health concerns from accessing effective treatment, such as concerns about mental health stigma, time constraints, and rural or remote geographical locations [5]. Internet-delivered cognitive behavioral therapy (ICBT) has received increased attention in clinical trials and routine care because it overcomes these barriers to care [6]. ICBT typically consists of weekly Web-based modules that provide psychoeducation and skills about managing symptoms of anxiety and depression [7]. Often, therapist assistance is offered in the form of weekly secure emails or telephone calls from a therapist. ICBT has been shown to be as effective as face-to-face cognitive behavioral therapy (CBT) with comparable drop-out rates [8]. In fact, organizations such as Health Quality Ontario have reviewed the growing evidence for the efficacy of ICBT and recommended that therapist-assisted ICBT for individuals with mild-to-moderate symptoms of anxiety or depression be publicly funded (PF) [9].

Despite the growing evidence base supporting the use of ICBT for depression and anxiety, additional research is necessary to illustrate the effectiveness of ICBT when offered in different contexts and populations. Replication trials essentially serve to establish the ecological validity or generalizability of efficacious interventions delivered under different circumstances or to different populations [10]. In Canada, mental health care is funded in a variety of ways. Canada has a PF health care system that provides all Canadian residents with access to medically necessary hospital and physician services through federal taxes that are transferred to the provinces and territories [11]. Each of the 13 provinces and territories are then required to have their own health care insurance plans to ensure that residents do not pay for hospital or physician services out-of-pocket. With this federal funding, provinces and territories also typically cover some mental health care services in PF settings (eg, hospital, community mental health clinics, and Web-based clinics). Some residents of Canada also have access to additional mental health care through insurance company (IC) plans paid for by employers. Alternatively, some residents may pay for some mental health services out of pocket.

To date, in Canada, there has been reported effectiveness of PF ICBT [12], but there are no published trials in Canada on the effectiveness of ICBT among clients who are involved with an IC owing to their mental health symptoms (eg, currently or recently in receipt of disability benefits or receiving workplace accommodations), especially when ICBT is recommended and funded by the IC.

Outcomes in Insurance Company Clients

Research on face-to-face CBT indicates that outcomes of CBT may not be as promising for IC clients, suggesting it would be valuable to explore if this is also the case with ICBT. Specifically, in a recent meta-analysis conducted by Salomonsson et al [13], the efficacy of CBT for individuals on disability leave for mental health concerns was examined, and effect sizes for sick leave and reduction in symptoms were significant, but quite small (Hedges g=0.17 and 0.21, respectively). In comparison, the most recent review of CBT for anxiety and depression in the general adult population found larger effect sizes, even when effect sizes were adjusted for publication bias (g=0.59 and 0.65, respectively) [14].

Theoretically, there are multiple factors that could contribute to poorer outcomes among individuals on disability leave involved with an IC [15]. Models of mental health recognize that mental health is influenced by individuals (eg, symptoms), social (eg, work stress), and environmental (eg, access to service and injustice) factors [15]. At the individual level, those involved with ICs may have greater symptom severity, which has been associated with poorer treatment outcomes [16]. Specifically, ICs often have requirements for the severity or duration of symptoms before a disability claim can be granted, especially long-term disability, which may contribute to more severe symptoms in IC groups [17]. In terms of social factors, individuals involved with an IC may have poorer outcomes than those not involved with an IC as a result of challenges they face when returning to work after being on disability leave, such as challenges meeting workload responsibilities [18] or being faced with lack of support [19,20]. In terms of environmental factors, it has been found that the length of approval times for claims, especially for long-term disability, can create a delay in

treatment, which could negatively impact treatment outcomes [21]. It is also possible that being involved with an IC represents a negative or stressful experience for clients which then influences treatment outcomes [22]. Past research suggests, for instance, that mental health claims are regarded as more complex for ICs to manage because of diagnostic challenges as well as stigma associated with mental health issues [23]. Past research also suggests that claims management can significantly impact mental health [22,24,25] and that individuals with mental health conditions are significantly more likely to have negative experiences with disability claims and return to work [26].

Aims of the Study

The aim of this study was to examine the generalizability of outcomes of ICBT by assessing engagement, treatment satisfaction, and effectiveness of ICBT in 2 IC samples. In both samples, clients were receiving or were recently in receipt of disability benefits or workplace accommodations for mental health symptoms, and the ICs referred clients to and funded ICBT. Results from these 2 IC samples were benchmarked against a previously published trial that established the effectiveness of the same ICBT program when it was offered to clients who sought ICBT from a PF ICBT clinic [12]. Benchmarking is an established method for comparing outcomes in different groups and has been used previously in studies on the effectiveness of CBT [27,28]. Extrapolating from past face-to-face CBT research [13], we expected that IC plan members and IC employees would exhibit significant but smaller improvements on symptom measures than PF clients. Other comparisons were considered exploratory in nature given limited past research. The results of this study have implications for the use of ICBT funded by ICs; if results are promising, ICs may have greater interest in referring to and funding ICBT, which has the potential to not only improve client well-being but reduce substantial costs associated with mental health concerns.

Methods

Study Design and Ethics

This study followed an observational pre-post test design with a 3-month follow-up. Research ethics board approval was obtained from the University of Regina for the study of all samples. The PF ICBT trial was registered (ISRCTN42729166), and the results have previously been published but not divided by whether clients were or were not in receipt of short-term disability benefits [12].

One sample consisted of IC plan members, while the second sample consisted of IC employees. The 2 samples were examined separately as there was a requirement to report mid-treatment and posttreatment outcomes to a case worker for the IC plan members following disability benefit guidelines. Separate examination of the 2 samples also provided opportunity for comparison of background characteristics, which revealed some differences between the IC samples. Results from these 2 IC samples were benchmarked against a previously published trial of the same ICBT program when it was offered to clients who sought ICBT from a PF ICBT clinic [12]. The PF sample was subdivided into those who reported no insurance benefits and those who reported being on short-term disability benefits. In the latter case, although clients reported short-term disability benefits, there was no contact between the PF clinic and the clients' insurance provider. All samples received the same 8-week transdiagnostic ICBT program that addressed symptoms of both anxiety and depression. Benchmarking is a well-known strategy for examining outcomes in situations where random assignment to groups is not feasible [29].

Across all samples, to assess engagement, we examined the number of log-ins, number of emails exchanged between clients and therapists, and percentage of clients who completed 4 out of 5 ICBT lessons that covered the primary treatment strategies. To assess effectiveness, we examined improvements in depression, anxiety, and disability at posttreatment and 3-month follow-up. To assess treatment satisfaction, we examined ratings of ICBT posttreatment. Furthermore, in the 2 IC samples, we examined qualitative feedback related to strengths and challenges of ICBT.

Clients

Clients were recruited during the following time periods: IC employees (September 2017 to May 2018), IC plan members (June 2017 to June 2018), and both PF samples (November 2013 to July 2015). In all samples, ICBT was delivered by the same clinic, but the service was either funded by the government or the IC. IC employees were in receipt of, or had recently been in receipt of, short-term or long-term disability payments or had mental health workplace accommodations or benefits while at work. Recruitment for IC employees was through an email invitation sent by the insurer to eligible employees. Interested IC employees voluntarily visited the website to enroll in ICBT. IC plan members had an open short- or long-term disability claim related to anxiety or depression or were in receipt of mental health accommodations or benefits at work. Recruitment for IC plan members involved case managers providing plan members with information about ICBT, first through a phone call and then an email link to the ICBT website. With client consent, case managers of the IC plan members were sent reports on client outcomes at mid- and posttreatment. As described in a previously published study [12], all PF clients self-referred to ICBT after learning about ICBT through community mental health clinics (167/458, 36.5%), family physicians (99/458, 21.7%), word of mouth (68/458, 14.8%), media (56/458, 12.2%), Web searches and email announcements (54/458, 11.8%), or printed advertisements (14/478, 2.9%). The PF short-term disability clients self-reported being in receipt of short-term disability benefits, but their care was PF and the ICBT clinic had no contact with their IC.

To be included in the study, clients from all samples completed a Web-based screening followed by telephone screening to assess their eligibility for ICBT. All clients had to meet the following criteria: 18 years of age or older; residents of Saskatchewan (all samples) or Ontario (IC employees and IC plan members only); endorse at least mild symptoms of anxiety or depression; access to the internet and comfortable using computers; and willing to provide a health care professional as an emergency contact. Exclusion criteria included the following: reporting symptoms of mania, psychosis, posttraumatic stress

disorder, alcohol, or substance misuse that were not being effectively managed; high risk for suicide based on plan or intent in the last year; or hospitalization in the last year related to suicide risk or severe mental health concerns.

For the IC employees, 24 individuals completed the screening process, 88% (21/24) were accepted and began ICBT, 71% (15/21) completed posttreatment measures, and 57% (12/21) completed 3-month follow-up measures. For the IC plan members, 23 completed the screening process, 83% (19/23) were accepted and began ICBT, 84% (16/19) completed posttreatment measures, and 58% (11/19) completed 3-month follow-up measures. For the PF sample, 545 completed the screening process, 76.0% (414/545) were accepted and began ICBT, 81.9% (339/414) completed posttreatment measures, and 75.1% (311/414) completed 3-month follow-up measures. For the PF short-term disability sample, 65 clients completed the screening process, 68% (44/65) were accepted and began ICBT, 91% (40/44) completed posttreatment measures, and 66% (29/44) completed 3-month follow-up measures.

Intervention

All clients received the same 8-week transdiagnostic ICBT course (*Wellbeing Course*) that addresses both anxiety and depression. The course was developed by the eCentre Clinic at Macquarie University in Sydney, Australia [30], and is licensed for use by the Online Therapy Unit [12]. The course contains 5 lessons that focus on the following: (1) the cognitive behavioral model and symptom identification; (2) thought monitoring and challenging; (3) dearousal strategies and pleasant activity scheduling; (4) graduated exposure; and (5) relapse prevention. Lessons are available in a slideshow format with downloadable materials and weekly homework assignments to facilitate skill acquisition. Clients also have access to client stories and extra resources as needed (eg, communication, problem solving, and sleep).

Therapists

All IC employees and IC plan members were assigned to 1 Web-based therapist employed by the ICBT clinic who had experience in ICBT and possessed a Master's degree in Social Work. All PF clients [12] were assigned to a therapist who worked directly in the ICBT clinic (n=2 registered psychologists; n=1 registered social worker; n=13 psychology graduate students; and n=9 social work graduate students) or in 1 of 8 community mental health clinics associated with the clinic (n=10 registered psychologists; n=25 registered social workers; n=5 registered nurses; and n=1 registered counselor). All therapists participated in a 1-day workshop [12] before delivering ICBT. Graduate students received supervision from a registered provider. A more in-depth description of the training of these therapists is available elsewhere [12].

Therapist Support

Most of the contact between therapists and clients occurred over a secure Web-based messaging system. Clients were encouraged to email their therapist throughout the week as they reviewed treatment materials; the therapist, on the contrary, checked in with clients and responded to emails by secure email on 1 predesignated day each week. Telephone calls were made in the following circumstances: clients had not logged into the website in the past week, clients were not responding to emails, clients requested a phone call, or therapists were concerned about client safety because of an increase in depression symptoms or suicidal ideation as assessed by questionnaires.

Outcome Measures

Clients completed measures at pretreatment, posttreatment, and 3-month follow-up. The measures were completed by participants on the same website that was used to deliver the intervention. Participants received reminder emails to complete measures at posttreatment and 3-month follow-up. Measures of anxiety and depression were also administered at the beginning of lessons 2 to 5 to allow therapists to monitor symptoms.

Patient Health Questionnaire 9-Item

The Patient Health Questionnaire-9 (PHQ-9) [31] is a 9-item validated self-report questionnaire that is used to assess depression symptom severity. Total scores range from 0 to 27 with scores being interpreted as indicative of mild (5-9), moderate (10-14), moderately severe (15-19), and severe (20-27) depressive symptoms [32]. A cut-off score of 10 or higher is used to identify those who are likely to have a diagnosis of depression [20]. The PHQ-9 has good psychometric properties [31]. The Cronbach alpha in this study was .85.

Generalized Anxiety Disorder 7-item

The Generalized Anxiety Disorder (GAD)-7 [33] is a 7-item validated self-report questionnaire that is used to assess anxiety symptom severity, with total scores ranging from 0 to 21. Total scores are interpreted as indicative of mild (5-9), moderate (10-14), and severe (15-21) anxiety symptoms [24]. A cut-off score of 10 or higher is used to identify those who are likely to have a Diagnostic and Statistical Manual of Mental Disorders 5th edition diagnosis [33]. The generalized anxiety disorder 7-item (GAD-7) has strong psychometric properties [33]. The Cronbach alpha in this study was .88.

Sheehan Disability Scale

The Sheehan Disability Scale (SDS) [34] is a 3-item validated measure of functional impairment in work/school, social life, and family life. Scores range from 0 to 30, with higher scores indicating higher levels of impairment. The SDS has high internal consistency and sensitivity to treatment and has been used in previous ICBT research [35]. The Cronbach alpha in this study was .84.

Engagement

Engagement was measured by assessing the percentage of clients who completed the course, number of emails sent to therapist, and number of log-ins to the course.

Treatment Satisfaction

At the end of treatment, clients were asked if they felt that the treatment was worth their time (*Yes* or *No*) and if they would recommend the course to a friend (*Yes* or *No*). Moreover, clients were asked to rate treatment satisfaction (response options included *very dissatisfied*, *dissatisfied*, *neutral*, *satisfied*, and *very satisfied*), whether participating in the course affected their

confidence in managing their symptoms and whether the course increased their motivation to seek help in the future if needed (response options for the last 2 questions were *greatly reduced*, *reduced*, *no change*, *increased*, and *greatly increased*). IC plan members and IC employees also answered 2 open-ended questions to obtain feedback on the most helpful elements of ICBT and suggestions for improvement.

Statistical Analysis

Data were analyzed using SPSS 23 (IBM). To begin, descriptive statistics were used to describe and compare samples in terms of demographics and scores on pretreatment depression, anxiety, and disability. To assess engagement, we compared samples on the percentage of clients who completed 4 out of 5 core lessons over 8 weeks, the mean number of log-ins, and the mean number of emails exchanged between clients and therapists. Group differences were analyzed using one-way analyses of variance for continuous variables and chi-square tests for categorical variables. When tests were significant, post hoc analyses were conducted to examine group differences.

When examining outcome measures, missing data were imputed using multiple imputation based on chained equations [36]. The imputation model included demographic variables such as age and symptom severity at baseline as predictors. A total of 40 imputations were generated to avoid producing a large Monte Carlo error [37]. Pooled data were used for the analysis [38]. To begin, as we had not previously analyzed IC data, we examined the IC samples using generalized estimation equation (GEE) modeling to evaluate effectiveness of treatment in the 2 IC groups [39]. An unstructured working correlation matrix and maximum likelihood estimation were used. A gamma distribution with a log link response scale was specified to address positive skewness and proportionally changing scores in the dependent variables [40]. Pairwise comparisons were used to examine the statistical significance of changes in the outcomes examining group and time effects.

Additional statistics were calculated for benchmarking purposes. Cohen *d* effect sizes and 95% confidence intervals were calculated for the within-group effects based on the estimated marginal mean values derived from the GEE analysis. Consistent with the literature, d=0.20 was regarded as a small effect, d=0.50, a medium effect, and d=0.80, a large effect [41]. Effect size difference of 0.20 or greater from the benchmark groups (PF clients and PF short-term disability clients) were considered to be clinically significant [41]. In addition, consistent with the literature, we interpreted a within-group effect size of d=0.24 as the minimally important difference [42]. To assist with understanding effect sizes, we also calculated the average percentage change and 95% confidence intervals across time for each outcome measure from the GEE analyses. The percentages of clients reporting improvements in symptoms of 30% and deterioration of 30% from pre- to posttreatment and pretreatment to follow-up were calculated and compared among the groups using chi-square tests; 30% was selected as an additional method for identifying at least some meaningful improvement on measures [43]. When tests were significant, post hoc analyses were conducted to examine group differences.

To assess treatment satisfaction, we compared groups using chi-square tests in terms of the percentage of clients who found the course helpful, the percentage who would recommend the course to a friend, and the percentage who reported being *very satisfied* or *satisfied* with treatment, having *greatly increased* or *increased* confidence in managing symptoms, and *greatly increased* or *increased* motivation to seek additional health care in the future. As above, when tests were significant, post hoc analyses were conducted to examine group differences.

Among the IC plan members and IC employees, to analyze qualitative feedback on the most helpful elements of ICBT and suggestions for improving ICBT, we used conventional content analysis [44] to identify themes in clients' responses to 2 open-ended questions.

Results

Client Characteristics

The mean age of the clients ranged from 38.92 to 45.95 years. The majority of clients in all 4 groups were female (range: 32/44, 73%-17/21, 81%), had more than a high school education (range: 35/44, 80%-18/21, 86%), were married or common law (range: 11/19, 58%-33/44, 75%), and Caucasian (range: 16/19, 84%-75/414, 93.1%). A large proportion of clients lived in a small city or rural area (range: 194/414, 48.8%-11/19, 58%). Among IC employees, 29% (6/21) were at work with mental health accommodations or benefits, 48% (10/21) were on short-term disability, and 24% (5/21) were on long-term disability. Among IC plan members, 16% (3/19) were at work with mental health accommodations or benefits, 32% (6/19) were on short-term disability, and 53% (10/19) were on long-term disability. Examination of group differences revealed no differences in terms of sex, marital status, education, ethnicity, or location; however, differences among groups in terms of age and employment status were found. Post hoc analyses showed PF clients were significantly younger than PF short-term disability clients (P<.01) and IC plan members (P=.01) but comparable to IC employees (P=.11). No significant difference in age was seen among IC plan members, IC employees, and PF short-term disability clients. Table 1 includes additional demographic information for the clients, separated by sample.

Significant differences were seen among the groups on pretreatment measures of depression (PHQ-9, $F_{3,489}$=9.78; P=.01), anxiety (GAD-7, $F_{3,489}$=5.16; P<.01), and disability (SDS, $F_{3,489}$=17.55; P<.01). See Table 2 for mean scores. Post hoc analyses examining pretreatment PHQ-9 scores showed that IC plan members had significantly higher scores compared with the PF clients (mean difference=5.61; P<.01) and PF short-term disability clients (mean difference=3.73; P=.02), but not IC employees (mean difference=1.75; P=.33). IC employees had significantly higher pretreatment PHQ-9 scores compared with PF clients (mean difference=3.86; P<.01) but not PF short-term disability clients (mean difference=1.98; P=.18). PF clients had significantly lower scores compared with PF short-term disability clients (mean difference=1.88; P=.04).

Table 1. Demographic characteristics of clients separated by sample.

Sample	IC[a] employees (n=21)	IC plan members (n=19)	PF[b] short-term disability clients (n=44)	PF clients (n=414)	Statistical significance		
					F test (3,489)	χ^2 (*df*)	*P* value
Age (years)					**7.84**	—[c]	**.01**
Mean (SD)	42.76 (9.42)	45.47 (11.96)	46.36 (11.05)	38.26 (12.63)			
Range	28-65	23-63	24-64	18-74			
Sex, n (%)					—	**0.6 (3)[d]**	**.89**
Male	4 (19)	5 (27)	12 (27)	108 (26.7)			
Female	17 (81)	14 (74)	32 (73)	296 (73.3)			
Marital status, n (%)					—	**0.6 (3)[d]**	**.24**
Married/common law	15 (71)	11 (58)	33 (75)	248 (61.1)			
Unmarried	6 (29)	8 (42)	11 (25)	158 (38.9)			
Education, n (%)					—	**0.5 (3)[e]**	**.93**
High school diploma or less	3 (14)	3 (16)	9 (21)	75 (18.5)			
Greater than high school[f]	18 (86)	16 (84)	35 (80)	331 (81.5)			
Employment status, n (%)					—	**617.7 (9)[e]**	**<.01**
Working	6 (29)	3 (16)	—	282 (69.5)			
Unemployed/student/retired/not reported	—	—	—	124 (30.5)			
Short-term disability	10 (48)	6 (32)	44 (100)	—		—	
Long-term disability	5 (24)	10 (53)	—	—		—	
Ethnicity, n (%)					—	**2.4 (3)[g]**	.49
Caucasian	19 (91)	16 (84)	37 (90)	375 (93.1)			
Non-Caucasian or not reported	2 (10)	3 (16)	4 (10)	28 (6.9)			
Location, n (%)					—	**2.4 (3)[e]**	**.49**
Large city (over 200, 000)	9 (43)	8 (42)	19 (43)	212 (51.2)			
Small center	12 (57)	11 (58)	25 (57)	194 (47.8)			

[a]IC: insurance company.

[b]PF: publicly funded.

[c]Not applicable.

[d]N=488.

[e]N=490.

[f]Some college or university education.

[g]N=484.

Table 2. Estimated marginal means and 95% CI for primary outcomes separated by sample.

Estimates	Estimated marginal means		
	Pretreatment mean (95% CI)	Posttreatment mean (95% CI)	3-month follow-up mean (95% CI)
PHQ-9[a]			
IC[b] employees (N=21)	16.10 (13.51-18.68)	11.04 (8.14-13.95)	11.09 (8.70-13.49)
IC plan members (N=19)	17.84 (16.15-19.53)	14.60 (11.58-17.61)	17.94 (14.50-21.38)
PF[c] short-term disability clients (N=44)	14.11 (12.61-15.61)	8.32 (6.30-10.34)	6.88 (5.14-8.62)
PF clients (N=406)	12.23 (11.68-12.78)	5.81 (5.27-6.34)	5.72 (5.17-6.27)
GAD-7[d]			
IC employees (N=21)	13.67 (11.82-15.52)	8.07 (5.79-10.36)	9.69 (7.43-11.95)
IC plan members (N=19)	15.53 (13.47-17.59)	12.72 (10.25-15.18)	15.41 (13.13-17.69)
PF short-term disability clients (N=44)	13.11 (11.31-14.92)	6.66 (4.94-8.37)	6.07 (4.90-7.24)
PF clients (N=406)	11.57 (11.07-12.08)	5.14 (4.68-5.59)	5.18 (4.71-5.65)
SDS[e]			
IC employees (N=21)	24.10 (22.00-26.19)	16.93 (12.78-21.08)	17.83 (14.50-21.16)
IC plan members (N=19)	25.68 (24.13-27.24)	21.59 (17.70-25.48)	23.33 (19.00-27.67)
PF short-term disability clients (N=44)	22.43 (20.20-24.67)	13.96 (10.96-16.95)	12.29 (19.64-14.95)
PF clients (N=404)	17.22 (16.47-17.96)	9.83 (8.99-10.68)	8.96 (8.11-9.82)

[a]PHQ-9: Patient Health Questionnaire-9.

[b]IC: insurance company.

[c]PF: publicly funded.

[d]GAD-7: Generalized Anxiety Disorder-7.

[e]SDS: Sheehan disability scale.

On the pretreatment GAD-7 scores, IC plan members had significantly higher scores compared with the PF clients (mean difference=3.95; $P<.01$) but not the PF short-term disability clients (mean difference=2.41; $P=.09$) or IC employees (mean difference=1.86; $P=.26$). IC employees did not differ significantly on GAD-7 from the other 3 groups (P range=.07 to .69). PF clients and PF short-term disability clients did not differ significantly ($P=.06$). On pretreatment SDS scores, PF clients had significantly lower disability scores compared with the other 3 groups, who did not differ from each other.

Engagement

Overall, there was a high level of engagement in ICBT among clients in all 4 samples. There were no differences among groups in the percentage of clients who completed 4 out of 5 lessons (15/21, 71% IC employees; 17/19, 90% IC plan members; 346/414, 83.5% PF clients; and 38/44, 86% PF short-term disability clients; $\chi^2_{3,N=490}=3.0$ $P=.40$). There were also no differences in the mean number of times clients logged into the program (IC employees mean 18.76, SD 9.82; IC plan members mean 24.05, SD 12.49; PF clients mean 22.60, SD 13.81; PF short-term disability clients mean 24.59, SD 12.32; $F_{3,489}=0.955$; $P=.41$) or the mean number of emails clients sent to their therapists (IC employees mean 3.71, SD 3.44; IC plan members mean 3.84, SD 3.45; PF clients mean 4.69, SD 4.01; PF short-term disability clients mean 4.93, SD 3.22; $F_{3,489}=0.759$; $P=.51$).

Treatment Effects for Insurance Company Employees and Insurance Company Plan Members

The means and 95% confidence intervals of primary outcome measures are reported in Table 2. The GEE analyses indicated significant effects for Time on symptoms of depression (Wald's $\chi^2_{2,N=1470}=100.8$; $P<.001$), anxiety (Wald $\chi^2_{2,N=1470}=122.1$; $P<.001$), and disability (Wald $\chi^2_{2,N=1470}=131.9$; $P<.001$). Pairwise comparisons found significant improvements in scores from pretreatment to posttreatment ($P<.01$) but not pretreatment to follow-up ($P=.97$) for SDS scores. Significant improvement in PHQ-9 and GAD-7 scores were revealed from pretreatment to posttreatment and pretreatment to follow-up (range $P=.04$ to $<.01$). Main effects of Group were seen on the PHQ-9 (Wald $\chi^2_{3,N=1470}=79.0$; $P<.001$), GAD-7 (Wald $\chi^2_{3,N=1470}=74.7$; $P<.001$), and SDS (Wald $\chi^2_{3,N=1470}=88.3$; $P<.001$) showing that the IC plan members had overall higher scores than IC employees. Time by Group interactions were also observed on all the primary outcome measures (PHQ-9, Wald $\chi^2_{6,N=1470}=23.8$, $P<.001$; GAD-7, Wald $\chi^2_{6,N=1470}=27.6$, $P<.001$; and SDS, Wald $\chi^2_{6,N=1470}=14.4$, $P=.02$).

Benchmarking

Table 3 provides Cohen d and 95% confidence interval values from pretreatment to posttreatment and to 3-month follow-up for the 4 samples. From pre- to posttreatment on the PHQ-9,

effects of IC plan members were inferior to those of IC employees (IC employees *d*=0.77 and IC plan members *d*=0.58). The IC plan members were also significantly inferior to the PF short-term disability clients *d*=0.95) and PF clients *d*=1.14). IC employees were inferior to PF clients but not PF short-term disability clients. From pre- to posttreatment on the GAD-7, IC plan members had significantly inferior effect sizes *d*=0.54) compared with IC employees *d*=1.13), PF short-term disability clients *d*=1.07), and PF clients *d*=1.30); the IC employees did not differ significantly from the PF short-term disability clients or PF clients. On the SDS pre- to posttreatment, IC plan members had a significantly inferior effect size *d*=0.60) compared with the other 3 groups, which did not differ from each other (IC employees *d*=0.91; PF short-term disability clients *d*=0.94; and PF clients *d*=0.90). From pretreatment to 3-month follow-up, on measures of depression, anxiety, and disability, IC employees had large effect sizes (range *d*=0.80 to 0.94) that were significantly better than the IC plan members (range *d*=0.02 to 0.32) but inferior to the 2 benchmarking samples (range *d*=1.00 to 1.35).

Consistent with recommendations in the literature [42], within-group effect sizes of *d*=0.24 were determined as being a minimally important difference. All effect sizes from pretreatment to posttreatment on all measures in all samples were regarded as meeting this threshold. On the contrary, from pretreatment to 3-month follow-up, IC plan members were not found to have an effect size large enough to meet the minimally important difference threshold.

Table 3. Clinical reliable change from pretreatment to posttreatment and 3-month follow-up separated by group.

Estimates	Effect sizes from pretreatment, Cohen *d* (95% CI)		Improvement≥30%		Deterioration≥30%	
	To posttreatment	To 3-month follow-up	Pre- to posttreatment (%)	Pre- to 3-month follow-up (%)	Pre- to posttreatment (%)	Pre- to 3-month follow-up (%)
PHQ-9[a]						
IC[b] employees	0.77 (0.13 to 1.38)	0.84 (0.19 to 1.45)	48	50	0	14
IC plan members	0.58 (-0.08 to 1.22)	-0.02 (-0.65 to 0.62)	32	156	11	37
PF[c] short-term disability clients	0.95 (0.50 to 1.38)	1.30 (0.83 to 1.75)	67	74	7	2
PF clients	1.14 (0.99 to 1.29)	1.14 (0.99 to 1.20)	75.9	75.9	2.7	5.0
GAD-7 [d]						
IC employees	1.13 (0.45 to 1.75)	0.80 (0.16 to 1.42)	62	38	5	5
IC plan members	0.54 (-0.12 to 1.18)	0.02 (-0.61 to 0.66)	26	16	5	26
PF short-term disability clients	1.07 (0.62 to 1.51)	1.35 (0.88 to 1.81)	72.7	74	5	2
PF clients	1.30 (1.15 to 1.45)	1.30 (1.15 to 1.45)	78.3	75.9	3.2	3.2
SDS[e]						
IC employees	0.91 (0.26 to 1.53)	0.94 (0.29 to 1.56)	38	43	0	5
IC plan members	0.60 (-0.06 to 1.24)	0.32 (-0.33 to 0.95)	26.3	21	0	11
PF short-term disability clients	0.94 (0.49 to 1.37)	1.21 (0.74 to 1.65)	51.2	64	2	0
PF clients	0.90 (.76 to 1.05)	1.00 (0.85 to 1.15)	65.3	67.8	7.0	7.2

[a]PHQ-9: Patient Health Questionnaire-9.

[b]IC: insurance company.

[c]PF: publicly funded.

[d]GAD-7: Generalized Anxiety Disorder-7.

[e]SDS: Sheehan disability scale.

To further facilitate interpretation of the effects, Table 3 also includes descriptive information about the improvement in symptoms of 30% as well as deterioration of 30% for each group for each measure from pre- to posttreatment and from pretreatment to 3-month follow-up.

On the posttreatment PHQ-9, a greater proportion of clients experienced 30% reduction in scores among the PF clients (314/414, 75.9%) and PF short-term disability clients (30/44, 67%) compared with both IC employees (10/21, 48%) and IC plan members (6/19, 32%; $\chi^2_{3,N=485}$=25.1; *P*=.001). The same significant pattern was found at 3-month follow-up ($\chi^2_{3,N=485}$=38.07; *P*<.001).

On posttreatment GAD-7 scores, a significantly lower proportion of IC plan members (5/19, 26%) experienced 30% reduction in GAD-7 scores compared with IC employees (13/21, 62%), PF short-term disability clients (32/44, 73%), and PF clients (324/414, 78.3%), while no significant differences were seen among IC employees and the 2 benchmarking groups ($\chi^2_{3,N=489}$=28.4; *P*=.001). At 3-month follow-up, a significantly lower proportion of IC employees (8/21, 38%) and IC plan members (3/19, 16%) reported 30% reduction in GAD-7 scores compared with the PF short-term disability clients (33/44, 75%) and PF clients (314/414, 75.8%; $\chi^2_{3,N=485}$=44.6; *P*<.001).

On posttreatment SDS scores, IC employees (8/21, 38%) and IC plan members (5/19, 26%) did not differ significantly from PF short-term disability clients (23/44, 51%) in proportion of individuals experiencing 30% reduction on SDS scores. Furthermore, IC employees had a similar proportion of individuals experiencing 30% reduction on SDS scores compared with PF short-term disability clients. However, significantly lower proportions of individuals experiencing 30% reduction on SDS scores were seen between IC plan members and IC employees and PF clients ($\chi^2_{3,N=481}$=19.2; *P*<.001). A similar pattern was seen among the groups at 3-month follow-up on 30% reduction on SDS scores ($\chi^2_{3,N=484}$=21.81; *P*<.001).

In terms of deterioration of 30%, no significant differences were seen among the groups at posttreatment on PHQ-9 scores ($\chi^2_{3,N=487}$=6.0; *P*=.11), GAD-7 scores ($\chi^2_{3,N=489}$=0.5; *P*=.92), or SDS scores ($\chi^2_{3,N=485}$=4.3; *P*=.23) and at 3-month follow-up on SDS scores ($\chi^2_{3,N=485}$=4.0; *P*=.27). However, at 3-month follow-up on PHQ-9 scores, results showed a greater proportion of IC plan members (7/19, 37%), and IC employees (3/21, 14%) experienced deterioration compared with PF clients (21/414, 5.0%) and PF short-term disability clients (1/44, 2%; $\chi^2_{3,N=488}$=34.5; *P*<.001). Similarly, at 3-month follow-up on the GAD-7, significant differences in deterioration were seen among IC plan members (5/19 26%) compared with IC employees (1/21, 5%), PF clients (13/414, 3.2%), and PF short-term disability clients (1/44, 2%; $\chi^2_{3,N=488}$=25.0; *P*<.001).

Treatment Satisfaction

There were no differences among clients on any of the measures of treatment satisfaction. Nearly all clients stated they were confident in recommending the program to a friend (IC employees: 21/21, 100%; IC plan members: 19/19, 100%; PF short-term disability clients: 43/44, 98%; and PF clients: 392/414, 94.7%; $\chi^2_{3,N=387}$=2.1; *P*=.56) and the program was worth their time (IC employees: 21/21, 100%; IC plan members: 19/19, 100%; PF short-term disability clients: 42/44, 95%; and PF clients: 393/414, 95.0%; $\chi^2_{3,N=386}$=1.4; *P*=.70). Most clients reported that they were *satisfied* or *very satisfied* with ICBT (IC employees: 19/21, 91%; IC plan members: 13/19, 68%; PF short-term disability clients: 36/44, 82%; and PF clients: 355/414, 85.7%; $\chi^2_{3,N=490}$=5.1, *P*=.17). Clients reported that the program *increased* or *greatly increased* their confidence in managing symptoms (IC employees: 17/21, 81%; IC plan members: 16/19, 84%; PF short-term disability clients: 16/19, 86%; and PF clients: 390/414, 94.3%; $\chi^2_{3,N=490}$=10.5; *P*=.02) as well as their motivation to seek additional help in the future (IC employees: 19/21, 91%; IC plan members: 16/19, 84%; PF short-term disability clients: 31/44, 71%; and PF clients: 353/414, 85.2%; $\chi^2_{3,N=490}$=1.5; *P*=.68).

Client Feedback

A total of 14 IC employees and 13 IC plan members provided feedback on the most helpful elements of ICBT as well as suggestions for improvement. There was variability in what employees found most helpful. Half of the IC employees (7/14, 50%) found the lesson on controlled breathing and activity planning to be most helpful, while 36% (5/14) identified the lesson on thought challenging as the most helpful and 21% (3/14) identified the lesson on graduated exposure as the most helpful. The majority of IC plan members preferred the lesson on thought challenging (8/13, 61%), while 23% (3/13) preferred the lesson on controlled breathing and activity planning and 1 found the lesson on graded exposure (1/13, 8%) to be most helpful. One IC plan member (1/13, 8%) said that *nothing* was helpful in the course.

In terms of improvements, 29% (4/14) of IC employee clients reported that they would not change anything about the course, while 36% (5/14) of the IC employees made suggestions about lesson content (eg, more psychoeducation and more client stories) and course layout or aesthetics (eg, font color, bookmarking function in lessons, and audio on slides). Other suggestions made by single clients included the use of fewer surveys, allowing more time for lesson completion, and placing less pressure on clients to complete lessons; 3 23% (3/13) of the IC plan members stated that they would not change anything about ICBT; 15% (2/13) of the IC plan members found the client stories difficult to relate to and 1 client (1/13, 8%) suggested increasing the number of client stories. One IC plan member felt the pace of the course was too fast (1/13, 8%) and one found the lessons were too long (1/13, 8%). An additional recommendation was that therapist support should be increased (3/13, 23%).

Discussion

Principal Findings

Therapist-assisted ICBT is a promising alternative to face-to-face CBT that increases client access to care. There is limited research, however, on outcomes of ICBT among clients who are insurer-referred and -funded. It is important to study ICBT under these circumstances as there is growing interest among insurance companies in funding ICBT, but little evidence to draw on to inform the potential engagement, treatment satisfaction, and effectiveness of ICBT.

In this study, we examined the effectiveness of ICBT for anxiety and depression among individuals who were on short-term or long-term disability or had mental health accommodations or benefits while working and were either IC employees or IC plan members. These 2 samples were benchmarked to PF clients and PF short-term disability clients. All 4 groups reported improvements on measures of depression, anxiety, and disability at posttreatment (see Table 3). All of the groups, except IC plan members, maintained improvement on measures of depression, anxiety, and disability when examining effects from pretreatment to 3-month follow-up (see Table 3).

When examined in terms of 30% improvement in scores, there was a substantial number of clients who experienced improvements at posttreatment and 3-month follow-up in each group, although the pattern overall suggested improvements were best in PF clients and lowest in IC plan members, both at posttreatment and at 3-month follow-up. For example, 26% (5/19) to 32% (6/19) of IC plan members, 38% (8/21) to 62% (13/21) of IC employees, 51% (23/44) to 73% (32/44) of PF short-term disability clients, and 65.0% (269/414) to 78% (333/414) of PF clients experienced 30% improvement on at least one of the measures at posttreatment. At 3-month follow-up, 16% (3/19) to 21% (4/19) of IC plan members, 38% (8/21) to 50% (11/21) of IC employees, 63% (28/44) to 75% (33/44) of PF short-term disability clients, and 68% (282/414) to 76% (314/414) of PF clients experienced 30% improvement on one of the measures at 3-month follow-up. It was encouraging that deterioration of 30% was low and not significantly different among the samples at posttreatment on depression, anxiety, or disability scores, or at 3-month follow-up on disability scores. Nevertheless, at 3-month follow-up on depression, results showed a greater proportion of IC plan members (7/19, 37%) and IC employees (3/21, 14%) experienced 30% deterioration compared with PF clients (21/414, 5.0%) and PF short-term disability clients (1/44, 2%; $\chi^2_{3,N=488}=34.5$; $P<.001$). At 3-month follow-up on the anxiety, a greater number of IC plan members (5/19, 26%) had 30% deterioration compared with the other samples where deterioration ranged from 2% (1/44) to 5.0% (21/414).

Consistent with the face-to-face literature [13], overall, effect sizes were lower in IC employees and IC plan members than the benchmarking samples at posttreatment and at 3-month follow-up. This was particularly striking among IC plan members who did not maintain gains at 3-month follow-up. Of note, IC plan members had significantly higher scores on depression, anxiety, and disability than PF clients, greater depression, and disability scores than PF short-term disability clients, and greater disability scores than IC employees. The finding that IC plan members had poorer outcomes is consistent with past research on the impact of severity of conditions on ICBT outcomes [45]. Previous research has suggested that while individuals with severe symptoms of depression can benefit from ICBT, they often require longer treatment and may benefit from using ICBT in addition to other services [45]. Some studies exclude clients with severe depression [45] based on the rationale that these clients require more clinician contact and a longer duration of treatment. In this study, it is possible that IC plan members could have benefitted from receiving ICBT either for longer periods or as an adjunct to face-to-face care. Of note, this is consistent with qualitative feedback provided by some of these clients.

The other interesting finding to emerge from the analysis was that PF short-term disability clients, for the most part, had better outcomes than IC clients (eg, at both posttreatment and 3-month follow-up, effect sizes for PF short-term disability clients were better for depression, anxiety, and disability than both IC samples, with the exception that disability was comparable to IC employees at posttreatment). Nevertheless, PF short-term disability outcomes were not quite as strong as the PF sample that reported no use of insurance benefits (eg, effect sizes were lower on depression and anxiety but not disability at both posttreatment and 3-month follow-up). It is possible that PF short-term disability clients had better outcomes than IC plan members because they had lower scores on depression, anxiety, and disability, but it is not clear why the PF short-term disability clients did better than IC employees since their pretreatment scores were similar. Future research should elucidate what might account for why those receiving short-term disability appear to do better when ICBT is PF rather than insurer funded, and whether this relates to factors such as motivation or confidence in treatment or concerns that treatment outcome may be communicated with the insurer and impact benefits.

Despite lower effect sizes than the benchmarking samples and the less favorable outcomes for IC plan members, especially at 3-month follow-up, there was a comparable level of engagement and treatment satisfaction among the 4 groups. It is particularly noteworthy that IC plan members, who had smaller improvements and outcomes that were not maintained at 3-month follow-up, still regarded ICBT as worth their time (100%) and that they would recommend the course to a friend (100%). The majority also reported that their confidence in managing symptoms either *increased* or *greatly increased* (13/19, 68%), and that their motivation to seek additional help in the future if they needed either *increased* or *greatly increased* (16/19, 84%).

The findings of this research had a subsequent impact on the insurance companies involved in the research. Both companies perceived the results as positive and have secured contracts with private companies who now provide ICBT to their clients. A strength of this study was the inclusion of qualitative comments from clients. With some clients reporting greatest benefit from thought challenging, others indicating controlled breathing and activity planning and others graduated exposure, the feedback highlighted that clients differ significantly in terms of what

skills they find beneficial, thus emphasizing the importance of providing clients with multiple skills during treatment. Similarly, there is considerable diversity in suggestions for improving ICBT, ranging from desire for more stories to improvements in course layout or aesthetics (eg, font color, bookmarking function in lessons, and audio on slides) to improvements in delivery method (eg, time for lesson completion and support). The suggestions provide direction for improvement but also highlight that needs of clients vary.

Limitations

Despite these strengths, there were several limitations that impacted the conclusions that can be drawn from this study. Both IC samples had small sample sizes (*n*=21 and 19), and caution should be taken when generalizing these study results. A significant amount of follow-up data was missing from IC employees (9/21, 43%) and IC plan members (8/19, 42%) at 3-month follow-up, which makes it difficult to draw conclusions about the effects of ICBT at 3-month follow-up. It should also be noted that in this study, both of the IC samples were assigned to 1 specific therapist and that the analytical models utilized cannot account for possible therapist effects. Furthermore, we do not have information on whether our samples differed in terms of socioeconomic status or diagnostic status. Information on actual time using the website or completing specific pages on the website or suggested homework was not collected, which could provide valuable information about client engagement. Although the IC plan members seemed to benefit less from the ICBT course, this conclusion is made solely on their symptoms and their self-reported benefits. An objective measure of the benefit of the ICBT would be to assess the number of sick days or return to work following completion of the intervention.

Future Directions

The findings of this study provide directions for future research. In particular, among those referred and funded by IC, it would be valuable to compare ICBT with other forms of treatment within a randomized controlled trial. With larger samples, it would be valuable to compare the outcomes of ICBT among clients who were at work with accommodations and benefits compared with those who were on short-term disability and long-term disability. Obtaining additional outcomes beyond self-report would also be beneficial, such as health care utilization, absenteeism, and presenteeism. The qualitative comments suggest ways in which the ICBT course may be modified to better meet the needs of clients involved with an IC, such as including more personal stories relevant to clients and potentially providing more time to complete the course or more therapist support. Future trials could compare weekly to twice weekly contact with a therapist or examine the possibility of using ICBT as an adjunct to face-to-face services or providing greater attention to return to work as has been done in face-to-face CBT [13]. Some past research suggests that outcomes of CBT can be improved by including a return to work intervention among individuals on or at risk of being on short- or long-term disability. For example, at 12-month follow-up, participants who underwent work-focused CBT had significantly higher levels of work participation (44.2% vs 37.2%), with the difference remaining significant at 18-month follow-up. Furthermore, participants in the work-focused CBT group experienced a significant reduction in symptoms of anxiety and depression, as well as an increase in health-related quality of life. Of note, the recruitment with the insurance companies took a significant period of time, suggesting that more attention needs to be given to increasing the knowledge and pretreatment expectations of ICBT in this population. Past research suggests that even a brief 5-min video increases interest in ICBT [46]. Now that the insurance companies have secured contracts with private companies for delivering ICBT to their clients, it would be beneficial to examine the outcomes of ICBT offered by these companies. It is unknown how comparable programs are in terms of content, delivery methods, and ultimately outcomes. In addition, in the future, it would be beneficial to examine barriers and facilitators to implementation of ICBT when funded by insurance companies [47].

Conclusions

This study contributes to the existing literature regarding ICBT and highlights the engagement, treatment satisfaction, and effectiveness of ICBT among individuals involved with insurance companies as a result of depression and anxiety. To our knowledge, this is the first benchmarking study to compare the effectiveness of ICBT among clients who are employees of an IC and clients who have an open claim with an IC, compared with clients seeking PF ICBT in routine care. It contributes to the literature on ICBT for individuals with more severe symptoms [45], such as those who have an open disability case with an IC. The findings highlight potential directions for improving outcomes among clients insurer-referred and funded.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
GAD-7: generalized anxiety disorder 7-item
GEE: generalized estimation equation
IC: insurance company
ICBT: internet-delivered cognitive behavioral therapy
PF: publicly funded
PHQ-9: patient health questionnaire-9
SDS: Sheehan disability scale

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Original Paper

Examining the Usage, User Experience, and Perceived Impact of an Internet-Based Cognitive Behavioral Therapy Program for Adolescents With Anxiety: Randomized Controlled Trial

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Abstract

Background: Internet-based cognitive behavioral therapy (iCBT) increases treatment access for adolescents with anxiety; however, completion rates of iCBT programs are typically low. Understanding adolescents' experiences with iCBT, what program features and changes in anxiety (minimal clinically important difference [MCID]) are important to them, may help explain and improve iCBT program use and impact.

Objective: Within a randomized controlled trial comparing a six-session iCBT program for adolescent anxiety, *Being Real, Easing Anxiety: Tools Helping Electronically* (*Breathe*), with anxiety-based resource webpages, we aimed to (1) describe intervention use among adolescents allocated to *Breathe* or webpages and those who completed postintervention assessments (*Breathe* or webpage respondents); (2) describe and compare user experiences between groups; and (3) calculate an MCID for anxiety and explore relationships between iCBT use, experiences, and treatment response among *Breathe* respondents.

Methods: Enrolled adolescents with self-reported anxiety, aged 13 to 19 years, were randomly allocated to *Breathe* or webpages. Self-reported demographics and anxiety symptoms (Multidimensional Anxiety Scale for Children—2nd edition [MASC-2]) were collected preintervention. Automatically-captured *Breathe* or webpage use and self-reported symptoms and experiences (User Experience Questionnaire for Internet-based Interventions) were collected postintervention. *Breathe* respondents also reported their perceived change in anxiety (Global Rating of Change Scale [GRCS]) following program use. Descriptive statistics summarized usage and experience outcomes, and independent samples *t* tests and correlations examined relationships between them. The MCID was calculated using the mean MASC-2 change score among *Breathe* respondents reporting somewhat better anxiety on the GRCS.

Results: Adolescents were mostly female (382/536, 71.3%), aged 16.6 years (SD 1.7), with very elevated anxiety (mean 92.2, SD 18.1). Intervention use was low for adolescents allocated to *Breathe* (mean 2.2 sessions, SD 2.3; n=258) or webpages (mean 2.1 visits, SD 2.7; n=278), but was higher for *Breathe* (median 6.0, range 1-6; 81/258) and webpage respondents (median 2.0, range 1-9; 148/278). Total user experience was significantly more positive for *Breathe* than webpage respondents (P<.001). *Breathe* respondents reported program design and delivery factors that may have challenged (eg, time constraints and program support) or facilitated (eg, demonstration videos, self-management activities) program use. The MCID was a mean MASC-2 change score of 13.8 (SD 18.1). Using the MCID, a positive treatment response was generated for 43% (35/81) of *Breathe* respondents. Treatment response was not correlated with respondents' experiences or use of *Breathe* (P=.32 to P=.88).

Conclusions: Respondents reported positive experiences and changes in their anxiety with *Breathe*; however, their reports were not correlated with program use. *Breathe* respondents identified program design and delivery factors that help explain their

experiences and use of iCBT and inform program improvements. Future studies can apply our measures to compare user experiences between internet-based interventions, interpret treatment outcomes and improve treatment decision making for adolescents with anxiety.

Trial Registration: ClinicalTrials.gov NCT02970734; https://clinicaltrials.gov/ct2/show/NCT02970734

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KEYWORDS

internet; cognitive behavioral therapy; computer-assisted therapy; anxiety; adolescents; clinical effectiveness; satisfaction; minimal clinically important difference; treatment adherence

Introduction

Background

Anxiety disorders are the most prevalent mental health concern in children and adolescents, affecting about 8% to 11% of youth [1-3]. Children and adolescents with anxiety disorders are at increased risk of academic and social difficulties and have an increased likelihood of developing secondary anxiety disorders and depression [4,5]. There is strong research evidence supporting the efficacy of cognitive behavior therapy (CBT) as first-line treatment of mild-to-moderate child and adolescent anxiety disorders with number needed to treat ranging from 3 to 6, but also some evidence that CBT is not significantly more effective than active control with support and education materials [6,7]. Understanding options for treatment delivery and for whom it may be best suited is a key area in CBT research, as face-to-face CBT is not always accessible [8], and there are high dropout rates of children and adolescents in traditional outpatient therapy treatment, ranging from 20% to 70% [9].

Internet-based CBT (iCBT), with its self-help format, can increase the access and availability of CBT for adolescents with mild-to-moderate anxiety [10,11]. Recent systematic reviews and meta-analyses demonstrate that in reducing anxiety in adolescents, iCBT has comparable effectiveness with traditional, face-to-face CBT [10,12-14] and is more effective than waiting for treatment [10,13,15-18]. Unlike face-to-face CBT where treatment may involve use of a workbook and in-person meetings with a therapist, iCBT provides therapeutic content and strategies through structured modules and activities (Web-based or offline) that involve the use of multimedia (eg, video and audio) and other technological features (eg, drop-down response menus, animated demonstrations, and interactive quizzes) [19,20]. The use of iCBT can be self-led or therapist guided (synchronous or asynchronous support provided during use), and programs can include varied levels of additional communication, such as reminder emails or follow-up phone calls, to encourage use, troubleshoot issues, or deliver feedback to users during the program.

Evaluations of adolescent experiences with various iCBT program delivery and content formats have revealed *good* program usability (eg, program had few errors and it was easy to learn to use) [21-24], moderate-to-strong credibility (eg, the program contained expert and reliable information), promising treatment expectancy (eg, users' expressed confidence in the benefits of the program) [21,25-30], and moderate-to-high rates of satisfaction and acceptability (eg, users considered the content relatable and users would recommend the program to others) [26,28,31]. Yet, low usage patterns have been consistently reported in the literature, with typically more than 50% of participants not completing an iCBT program as part of a research study [14,17,32-34]. These discordant outcomes contribute to a lack of clarity about how program usability, credibility, satisfaction, and usage relate to each other as part of an adolescent's iCBT experience.

Other aspects of the user experience, such as psychosocial barriers and facilitators to program usage, adolescents' perceived program impacts (eg, perceived effects on health outcomes), and adolescents' identification of the minimum change in anxiety symptoms that they would accept to make it worth completing an iCBT program (the minimal clinically important difference [MCID] [35]), have not been explored. Yet, these aspects can deepen the understanding of how adolescent users of iCBT perceive programs and experience their use in day-to-day life. Establishing an MCID for the change in anxiety symptoms experienced following a program provides a preferred treatment effect among adolescent users [36]. An adolescent-defined MCID could inform user-centered treatment planning and advance methodological approaches in studies of iCBT effectiveness by framing the estimation of treatment effects [35-37].

Objectives

We conducted a prospective study of iCBT users' experiences in the context of a large-scale, parallel design randomized controlled trial (RCT). The large-scale trial was designed to evaluate the effectiveness of an iCBT program developed by our research team, *Being Real, Easing Anxiety: Tools Helping Electronically* (*Breathe*), in reducing anxiety symptoms among adolescents aged 13 to 19 years compared with webpages detailing anxiety resources (resource-based webpages, a usual self-help intervention). Within this trial, we had four distinct objectives for the user experience study: (1) to determine the adolescents' usage of the *Breathe* program and resource-based webpages, (2) to define the adolescents' user experiences with the *Breathe* program and the resource-based webpages and examine whether experiences differ between program and webpage use, and (3) to have adolescent users of the *Breathe* program define an MCID for anxiety symptoms after program use, and (4) to explore relationships among the user experiences, program usage, and the MCID among those adolescents who used the *Breathe* program. The overall intent of these objectives was to examine self-reported user experience data and automatically captured program usage data together for a better

understanding of the relationship between behavioral (objective usage) and experiential (subjective usage, user experience, and MCID) data [38-40] to explain and understand iCBT outcomes, not to evaluate intervention effectiveness.

Methods

Study Design

The RCT was conducted across Canada. We embedded user experience outcome measures (user experience and MCID) and automatically captured intervention data (usage) into pre- and postintervention time points of the trial. The Research Ethics Boards at the University of Alberta approved the trial (ClinicalTrials.gov identifier: NCT02970734; Evaluating an Internet-Based Program for Anxious Adolescents). The trial commenced on November 21, 2016, and the final date of data collection was November 22, 2018.

Participant Recruitment and Eligibility

Adolescents were recruited for trial participation between November 21, 2016, and July 1, 2018. Recruitment was conducted through the trial's social media platforms (Facebook, Twitter, Tumblr, and Instagram) with posts and paid advertisements across Canada and through health care professionals who provided study pamphlets to prospective participants seeking mental health care in specialty care clinics, primary care clinics, and schools in Edmonton, Alberta; Hamilton, Ontario; and Halifax, Nova Scotia. Advertisements and pamphlets directed adolescents to view the trial website [41], which provided details on the trial, including eligibility criteria, the screening and enrollment process, information on anxiety, and the research team's contact information.

Adolescents interested in participation were screened for eligibility using a secure Web-based application, Research Electronic Data Capture (REDCap). Inclusion criteria were as follows: (1) a minimum score of 25 on the Screen for Child Anxiety Related Disorders [42], indicating the presence of clinical anxiety symptoms; (2) the ability to read and write English; (3) regular access to a telephone and a computer system with high-speed internet service; and (4) the ability to use the computer to interact with Web material. Adolescents were ineligible for participation if they (1) screened as high risk for self-harm via four items from the Ask Suicide-Screening Questionnaire [43] (a *yes* answer to thoughts about killing oneself in the past week or a prior attempt), (2) indicated the possible presence of a psychosis-related disorder via the 5-item Schizophrenia Test and Early Psychosis Indicator [44] (an affirmative response to any item), (3) screened positive for harmful or hazardous alcohol consumption via the 3-item Alcohol Use Disorders Identification Test Consumption subscale [45] (a score of ≥3 for females and ≥4 for males), or (4) resided outside of Canada. Ineligible adolescents were provided with suggestions for crisis services and other helplines (ie, Canadian Association for Suicide Prevention and Kids Help Phone) and websites where evidence-based information on alcohol use, psychosis, and self-harm was available.

Procedures for Informed Consent and Assent

The consent/assent process took place in REDCap. Adolescents were provided an information sheet on the trial and asked several yes/no questions to ensure consent/assent was informed. Those aged 15 to 17 years were able to consent to the study on their own behalf; adolescents aged 13 and 14 years required online parental consent in addition to their assent to participate. Parental consent followed the same Web-based process described for adolescents. Once consent and assent were obtained, adolescents were enrolled in the trial and randomly assigned using a computer-generated sequence with a 1:1 allocation ratio to either the *Breathe* program or the resource-based webpages. This was an open-label trial, and adolescents were notified of their assigned intervention via an email that included instructions for logging into the study website.

The Breathe Program

The *Breathe* program for mild-to-moderate anxiety symptoms among adolescents is described in detail elsewhere [46]. In brief, the program was delivered via Intelligent Research and Intervention Software (IRIS), a secure, password-protected website. The program consisted of six iCBT sessions, with each session requiring approximately 30 min to complete; it was suggested that participants complete one session per week in a location convenient for them. Each *Breathe* session included four components: *Check-in*, *Discover*, *Check-out*, and *Try Out*. *Check-in* involved adolescents rating their social-emotional functioning over the past week and indicating whether they had thoughts of self-harm or harming others. Check-in served as a risk management strategy. If a safety issue was flagged (eg, decompensation in anxiety symptoms between sessions and thoughts of self-harm), there was a trigger in IRIS to notify the research assistant to contact the adolescent (and potentially the parent(s) depending on the concern) by phone within 36 hours to assess whether the adolescent required more immediate care and to provide emergent or nonemergency resources. A safety video that included recommendations for immediate safety planning was also provided to adolescents. The *Discover* component of the program introduced the session's key topics. *Check-out* involved adolescents reflecting on their responses to session content. *Try Out* outlined activities for practicing the session's key concepts and skills before the next session. An overview of session content is provided in Table 1, and Figures 1-4 provide screenshots of the *Breathe* program.

Table 1. An overview of the content presented in the six sessions of the *Breathe* program.

Session	Content covered	Description
1	Psychoeducation	Introduction to the *Breathe* program; psychoeducational information on anxiety and common symptoms (eg, *fight or flight* response and normalization of anxiety); and how cognitive behavioral therapy can be used to treat these symptoms
2	Avoiding avoidance and constructing a fear hierarchy	Identifying avoidant behavior that might be fueling anxiety; strategies for how to avoid avoiding (creating a rewards list); and planning for how to face your worries (*exposure* activities)
3	Relaxation skills	Presentation and practice of common relaxation strategies (eg, deep breathing, visualization, and progressive muscle relaxation)
4	Cognitive distortions	Identifying thinking traps; understanding the *thoughts-feelings-actions* cycle; practice strategies to break out of thinking traps
5	Realistic thinking	Recognizing unrealistic beliefs (eg, perfectionistic and control) and learning strategies for positively reframing them (eg, catch-challenge-change)
6	Fear hierarchy practice, concept integration and relapse prevention	Completing exposure activities; summarizing concepts learned in the *Breathe* program; planning for the future and maintaining gains

Figure 1. A screenshot of the Check-in activity within the *Breathe* program.

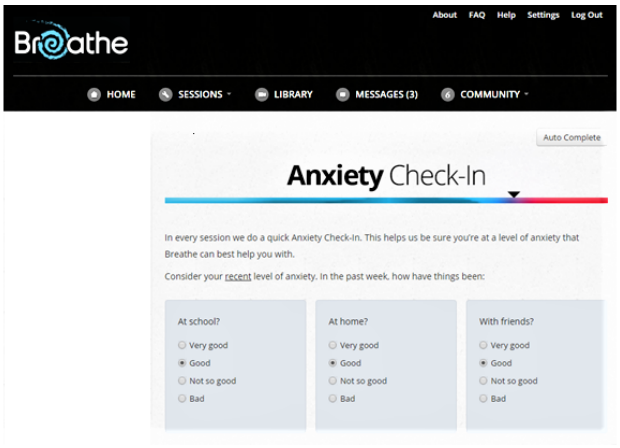


Figure 2. A screenshot of the Discover section within the *Breathe* program.

Figure 3. A screenshot of the Check-out activity within the *Breathe* program.

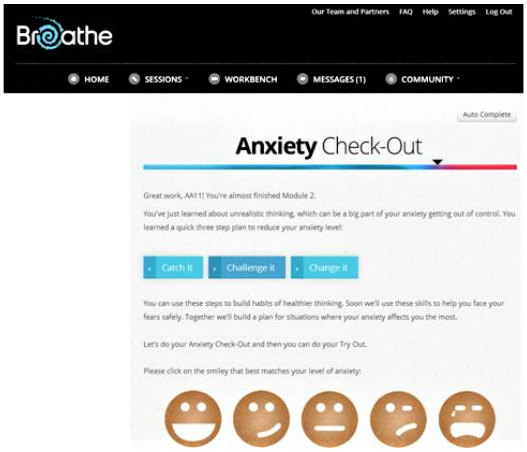
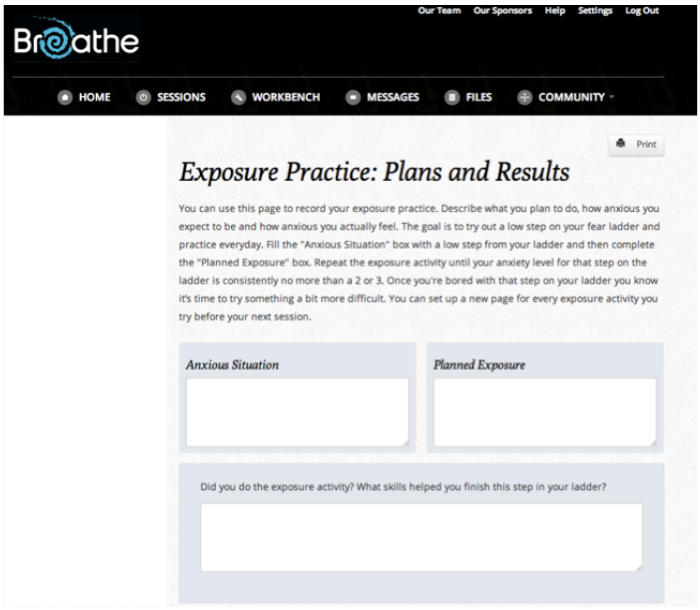


Figure 4. A screenshot of the Try Out activity within the *Breathe* program.

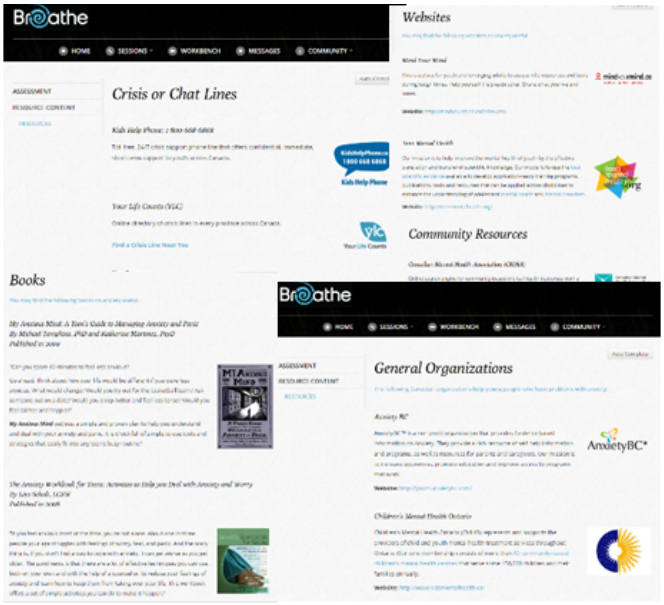


Animations, embedded video, audio playback, graphic novel style vignettes, image maps, timed prompts, and on-screen pop-ups were embedded in the program to provide an interactive and multimodal experience. Features based on persuasive systems design [47] were employed to promote program engagement and use: tailoring (provided customized content based on preferences or actions), self-monitoring (progress was tracked and presented virtually to encourage self-reflection), suggestions (key information was provided to help meet users' goals or needs), and reminders (weekly emails were provided to help users continue with the program and provide notifications of the release of new sessions). Brief Web-based and telephone support was also provided. Participants were assigned a *Breathe* coach, a trained paraprofessional, who initiated an optional telephone coaching session after session 1. The telephone call was not designed as a therapy session but was offered to answer any program-specific questions and to help participants prepare to complete program activities (ie, exposure activities). Participants were not required to complete the call to proceed with the program. Users were also provided with the option for a summary of each session to be emailed to an identified parent or guardian after each completed session.

Resource-Based Webpages

The resource-based webpages included suggestions of anxiety-based books and educational websites, contact information for local and national crisis lines, and information on the emergency department and other crisis mental health resources. Figure 5 provides a screenshot of the webpages. Webpage users were permitted unlimited access through IRIS over a 6-week period; the same time frame as the *Breathe* program was used. No coaching, safety, or anxiety monitoring was provided during the webpage use.

Figure 5. A collage of screenshots from the resource-based webpages.



Data Collection

We collected user experience data at the preintervention (baseline) and postintervention (6 weeks following enrollment) assessment time points of the trial (Table 2); assessments were independent of an adolescent's intervention progress or use. Data collection was embedded in IRIS to allow for electronically captured, securely stored, encrypted, and password-protected data. Adolescents who completed outcome measures at the postintervention time point were given a token of appreciation (Can $25 electronic gift card).

Table 2. A summary of the study's assessment time points.

Measure	Time point	
	Preintervention	Postintervention
Demography	X[a]	—[b]
Multidimensional Anxiety Scale for Children	X	X
User Experience Questionnaire for Internet-based Interventions	—	X
Intervention usage	—	X
Global Rating of Change Scale	—	X

[a]X: measure completed.

[b]Not applicable.

Measures

Demography

Adolescent demography included self-reported birth date (used to calculate participant's age), gender, and province of residence.

Multidimensional Anxiety Scale for Children

Anxiety symptoms were reported using the Multidimensional Anxiety Scale for Children—2nd Edition (MASC-2) [48]. The MASC-2 is based on the original MASC [49] that was revised to assess a broader range of anxiety symptoms in children and adolescents aged 8 to 19 years. The MASC-2 is one of the most widely used self-report measures in trials involving adolescents with anxiety because of the brevity of the measure and simplicity of its administration [50]. It consists of 50 items that assess emotional, physical, cognitive, and behavioral symptoms of anxiety using 6 scales and 4 subscales. Adolescents respond using a 4-point Likert scale, ranging from 0 (*never true about me*) to 4 (*often true about me*). The questionnaire yields several scores, including a total raw score and standardized *t* scores based on 18,000 North American children and adolescents aged 8 to 19 years. The scale has acceptable internal consistency (a coefficient alpha of .92 for the self-reported total score), test-retest reliability (all correlations >.80; $P<.001$) [50], and strong convergent validity with other published measures of anxiety symptoms [50].

Intervention Usage

We defined intervention usage as adolescent's use of the *Breathe* program or the resource-based webpages during the 6-week intervention period. Intervention usage was automatically recorded in IRIS using the number of *Breathe* sessions completed per allocated adolescent (a maximum of six sessions) and webpages visited per allocated adolescent (no maximum).

User Experience Questionnaire for Internet-Based Interventions

We developed the User Experience Questionnaire for Internet-based Interventions (UEQII) to evaluate and compare adolescents' self-reported user experience across internet-based interventions (Multimedia Appendix 1). UEQII items were informed by previously published questionnaires and key literature on user experiences [51-53]. Items were tested for face and content validity [54]. The UEQII assesses the user experience through the three constructs: (1) satisfaction and acceptability: global satisfaction, helpfulness, expectations met, convenience, engagement, privacy, and preference for mode of delivery; (2) credibility and impact: confidence in treatment, skill development, and perceived treatment effectiveness; and (3) adherence and usage: ease of use, including technical, psychosocial, and general barriers and facilitators to intervention use.

Adolescents allocated to either the *Breathe* program or resource-based webpage responded to 21 items (*Core* items) on their user experience using a 4-point Likert scale, ranging from 0 (*really worsened* or *not at all*) to 4 (*really improved* or *completely*). An additional 15 items specific to the *Breathe* program experience (items 22-36; *Treatment* items) were completed by adolescents who used the *Breathe* program. If an adolescent responded *not at all* or *slightly* to items 30, 32, or 34, an open text box appeared (subsidiary questions 30a, 32a, and 34a) for the adolescent to elaborate on their experience. Items 35 and 36 were also open text boxes where adolescents could describe what they considered to be the most challenging and enjoyable aspects of the *Breathe* program, respectively. There was not an option for adolescents to skip certain questions.

Global Rating of Change Scale

We used a Global Rating of Change Scale (GRCS) that contained a single question with an 11-point Likert scale (ranging from +5 to 0 to −5) to allow *Breathe* program users to indicate the degree to which their anxiety had changed for the better, for the worse, or whether they experienced no change at all as a result of participating in the *Breathe* program. GRCS are widely used in clinical and research settings and are reproducible, clinically relevant, and sensitive to change [55]. To validate the usefulness of the GRCS before calculating the MCID, we calculated the correlation between GRCS scores and pre- and postintervention MASC-2 mean change scores among *Breathe* users. On the GRCS, the smallest change in anxiety symptoms that adolescents identified as important after completing the program [35,56] was used to calculate the MCID.

Data Analysis

All enrolled participants were included in the analysis of demographic, MASC-2, and intervention usage data; no data imputation strategies were used. For analysis of UEQII and GRCS data, including the MCID calculation, we included adolescents who accessed their assigned intervention at least once during the trial intervention period (ie, those allocated to the *Breathe* program completed at least one session and those allocated to the resource-based webpages visited at least one webpage). This criterion ensured that adolescents commented directly on their experience with the intervention they received. For adolescents who had some missing data among the measures, we used pairwise deletion to maximize the use of all available data on an analysis-by-analysis basis. Normality testing was conducted for all variables. We used means (SDs), median (range), or number (proportion) to describe findings, as appropriate. To compare differences and explore relationships between variables, we conducted independent *t* tests and Pearson correlations (r) for parametric data, and Spearman rank-order correlation coefficients (Spearman rho) and point-biserial correlations for nonparametric data (Pearson product-moment correlation, r_{pb}). Data analysis was conducted with IBM SPSS Statistics 25. The significance level was set at *P* less than or equal to .05.

Demography

Participant demographics (age, gender, and province of residence) were summarized using means (with SDs) and numbers (proportions).

Anxiety Symptoms

The MASC-2 responses were entered in the Multi-Health Systems Online Assessment Center to generate total raw scores and validated *t* scores. We calculated pre- and postintervention symptom scores for each adolescent.

Intervention Usage

The mean number (with SD) of completed *Breathe* sessions and webpages visited was calculated at the postintervention time point. Interquartile ranges were used to establish data cutoffs (ie, high-/low-intervention users) to assist with data interpretation. We explored the relationship between intervention usage (the number of completed *Breathe* sessions or webpages visited) and user experience (UEQII total and subscale scores) using Pearson or Spearman correlation.

User Experience

User experience data were summarized using means and standard deviations. Multiple construct and total scores were calculated (Multimedia Appendix 2) with higher UEQII scores, indicating a more highly rated (positive) user experience. For both *Breathe* program and resource-based webpage users, we calculated total scores for all *core* user experience items and total subscale scores for each of the three *core* constructs. Among *Breathe* program users, we calculated total scores for all *treatment* user experience items, total subscale scores for each of the three *treatment* constructs, and a total score of all UEQII items by summing the core and treatment items. IQRs were used to establish cutoffs for the scores (ie, first quartile=*low*, second quartile=*moderate*, third quartile=*good*; and fourth quartile=*very good* user experience) to assist with data interpretation; values were rounded up to the nearest whole number for categorization. We tested differences between the user groups for the core all items total score and the three subscale construct total scores using independent samples *t* tests. Open-ended responses from *Breathe* users on the UEQII were extracted verbatim. A basic thematic analysis was conducted by a single author (AR) and reviewed by a second author (AN) [57]. Similar responses were grouped together based on an open,

inductive coding process that involved analyzing the explicit content of each response (a semantic approach) [58]. A minimum of two responses were required to generate a theme. Themes are described, and the number of responses per theme are reported.

Global Rating of Change

The total and subgroup responses to the GRCS were summarized using means with standard deviations and numbers and proportions. We created 11 subgroups based on adolescents' responses to the GRCS (a subgroup for each response value on the scale). We also applied the following interpretation to the GRCS scores:

- Adolescents who reported 0 on the GRCS were considered to have experienced no change in their anxiety.
- Adolescents who reported +1 (almost the same, hardly better at all) were considered to have experienced a very small change, but one that may not be clinically relevant.
- Adolescents who reported +2 (somewhat better) on the GRCS were considered to have experienced a small change in their anxiety.
- Adolescents who reported +3 (much better) were considered to have experienced a moderate change in their anxiety.
- Adolescents who reported +4 (a great deal better) or +5 (a very great deal better) were considered to have experienced a large change in their anxiety.

The scores of adolescents who reported a worsening of anxiety symptoms (−1 to −5) were grouped and classified in a similar manner.

Minimal Clinically Important Difference

The anchor-based method, the most commonly used method, was used to calculate the MCID. This method involved comparing the change score on the MASC-2 with the GRCS score, which served as the *anchor* [59]. MCID calculation involved three steps. First, we calculated the change in MASC-2 pre- and postintervention total raw scores for each adolescent. Second, we calculated the mean change in the MASC-2 total raw scores for each of the GRCS response subgroups that were created (*no change*, *very small change*, *small change*, *moderate change*, and *large change*). Third, we identified the mean change in MASC-2 scores for adolescents who reported experiencing a *small change* in their anxiety (ie, a +2 response rating on the GRCS, *somewhat better*) to provide the final MCID estimate [35,60,61]. The GRCS response rating used for the MCID estimate (+2) was based on the decision from research team clinicians who care for adolescents with anxiety and have experience using the MASC-2, who felt the +2 estimate (small change) would be relevant to informing their approach to treatment and be considered a positive response in the clinical setting. This GRCS change of 2 points on an 11-point scale is consistent with the MCID (change) of half a standard deviation from a large systematic review of health care outcome studies [62]. In addition to the MCID estimate, the number (proportion) of adolescents who reached (or surpassed) the MCID threshold of a small change in their anxiety improvement was calculated to identify *Breathe* program *treatment responders*. We used point-biserial correlations (a special case of Pearson product-moment correlation, r_{pb}) to determine the relationship between treatment response (dichotomous variable: treatment responder or nonresponder) and several user experience and usage variables (user experience construct and total scores and the number of *Breathe* sessions completed).

Results

Participant Demographics

The total number of adolescents enrolled in the trial was 536 (258 allocated to the *Breathe* program and 278 allocated to the resource-based webpages). Table 3 presents the characteristics of the adolescents before intervention use. The average age of participants was 16.6 years (SD 1.7), and most participants identified themselves as female (382/536, 71.3%). More than two-thirds of adolescents lived in the following 3 Canadian provinces: Ontario (145/536, 27.1%), British Columbia (134/536, 25.0%), and Alberta (81/536, 15.1%). The average baseline MASC-2 total raw score was 92.2 (SD 18.1), with an associated *t* score of 74.9 (SD 9.7; n=408), indicating a *very elevated* level of anxiety.

Table 3. Preintervention demographics of enrolled adolescents organized by total adolescents enrolled and total adolescents assigned to each intervention.

Demographic variable	All enrolled adolescents (n=536)	*Breathe* program adolescents (n=258)	Resource-based webpage adolescents (n=278)
Age (years), mean (SD)[a]	16.6 (1.7)	16.5 (1.5)	16.7 (1.9)
No response, n (%)	6 (1.1)	5 (1.9)	1 (0.4)
Gender, n (%)			
Female	382 (71.3)	190 (73.6)	192 (69.1)
Male	24 (4.5)	13 (5.0)	11 (4.0)
Other	14 (2.6)	5 (1.9)	9 (3.2)
No response	116 (21.6)	50 (19.4)	66 (23.7)
Canadian province of residence, n (%)			
Alberta	81 (15.1)	40 (15.5)	41 (14.8)
British Columbia	134 (25.0)	69 (26.7)	65 (23.4)
Manitoba	17 (3.2)	9 (3.5)	8 (2.9)
New Brunswick	8 (1.1)	5 (1.9)	3 (1.1)
Newfoundland and Labrador	7 (1.3)	4 (1.6)	3 (1.1)
Northwest Territories	1 (0.2)	1 (0.4)	0 (0.0)
Nova Scotia	24 (4.5)	10 (3.9)	14 (5.0)
Ontario	145 (27.1)	68 (26.4)	77 (27.7)
Prince Edward Island	3 (0.6)	2 (0.8)	1 (0.4)
No response	116 (21.6)	50 (19.4)	66 (23.7)
Multidimensional Anxiety Scale for Children—2nd Edition (total raw score), mean (SD)	92.20 (18.1)	92.65 (16.9)	91.77 (19.3)
No response, n (%)	125 (23.3)	54 (20.9)	71 (25.5)

[a]Adolescents indicated whether they belonged to the 13 to 14 years or 15 to 17 years age category, or neither, as part of eligibility screening. Adolescents were not required to provide their exact age to participate in the study.

Intervention Usage

Table 4 displays the total number of iCBT sessions completed by adolescents allocated to the *Breathe* program. The average number of iCBT sessions completed by all 258 allocated adolescents to *Breathe* was 2.2 (SD 2.3). Of 258 adolescents, 50 (19.4%) completed the entire six-session program. Using IQRs and the 75th percentile as a cut point, 27.9% (72/258) adolescents completed four or more sessions of the *Breathe* program and were considered to be active *Breathe* participants. Table 5 presents the total number of webpages visited by 278 adolescents allocated to access the anxiety-based resource webpages. The average number of webpages visited by adolescents was 2.1 (SD 2.7). At least one webpage was visited by 196 of 278 (70.5%) adolescents.

Table 4. The total number of *Breathe* sessions completed by allocated adolescents.

Total number of *Breathe* sessions completed	Number (proportion) of allocated adolescents (n=258), n (%)
0	91 (35.3)
1	47 (18.2)
2	27 (10.5)
3	21 (8.1)
4	15 (5.8)
5	7 (2.7)
6	50 (19.4)

Table 5. The total number of anxiety-based resource webpages visited by allocated adolescents.

Total number of webpages visited	Number (proportion) of allocated adolescents (n=278), n (%)
0	82 (29.5)
1	90 (32.4)
2	31 (11.2)
3	13 (4.7)
4	18 (6.5)
5	9 (3.2)
6	5 (1.8)
7	5 (1.8)
8	2 (0.7)
9	23 (8.3)

User Experiences

The median number of sessions completed by *Breathe* respondents was 6.0 (range 1-6). Moreover, of 81 *Breathe* respondents 61 (75%) were active participants in the program, with 43 (53.1%) completing the entire program. Among 278 adolescents allocated to the resource webpages, 148 (53.6%) provided postintervention user experience data and visited at least one webpage (herein referred to as webpage respondents). The median number of webpages visited by webpage respondents was 2.0 (range 1-9).

Table 6 presents the responses to user experience questions and differences in experiences between *Breathe* and webpage respondents (score range 0 [not at all] to 4 [completely], with higher scores indicating a more positive rating). Across both interventions, adolescents reported that the information was easy to understand (*Breathe* respondents: mean 3.5, SD 0.7; webpage respondents: mean 2.8, SD 1.2), adolescents trusted the information from the intervention (*Breathe* respondents: mean 3.6, SD 0.7; webpage respondents: mean 3.1, SD 1.0), the internet was a good method for delivering the information (*Breathe* respondents: mean 3.7, SD 0.6; webpage respondents: mean 2.9, SD 1.3), and the intervention was easy to use (*Breathe* respondents: mean 3.3, SD 0.6; webpage respondents: mean 2.4, SD 1.2). *Breathe* and webpage respondents did not consider computer access or availability and internet or technical problems as major barriers to using the interventions. *Breathe* respondents reported that personal (*Breathe* respondents: mean 1.8, SD 1.2; webpage respondents: mean 2.5, SD 1.4) and school (*Breathe* respondents: mean 1.9, SD 1.4; webpage respondents: mean 2.4, SD 1.5) commitments limited their intervention use more so than adolescents who used the webpage (*P* values <.001).

Table 7 presents and compares the total UEQII scores for the core user experience constructs and for all core user experience items (items 1-21) for *Breathe* and webpage respondents. *Breathe* users had significantly higher total satisfaction and acceptability (construct 1), credibility and impact (construct 2), and core items total scores than webpage users. We found that the adherence and usage (construct 3) total score was higher among webpage users compared with *Breathe* respondents, but this difference was not statistically significant.

Table 8 and 9 present *Breathe* respondents' user experiences with the program (treatment items). The most positive user experiences (higher scores) involved how the *Breathe* program looked, the relevance of the information to the user's situation, and the likelihood of the program being recommended to others. The lowest rated user experience items were the time required to complete the program, exposure activities (facing your fears), and whether the program helped users meet their treatment goals.

Breathe respondents provided open-ended responses for UEQII items 30a, 32a, 34a, 35, and 36. Themes associated with these responses are identified in Table 10 with example responses. Adolescents described nervousness or discomfort around completing (or thinking about completing) the telephone coaching call after session 1, limited time or forgetting to complete the sessions and homework activities (Try Outs), and difficulty in understanding the instructions for planned exposure activities (the worry ladder), including breaking down the anxious situation they wanted to overcome. A major theme surrounding program enjoyment related to respondents learning about anxiety and the new coping strategies or techniques to help them manage their worries.

Table 6. The differences in core items of the User Experience Questionnaire for Internet-based Interventions between *Breathe* respondents (n=81) and webpage respondents (n=148).

User experience item	*Breathe* respondents, mean (SD)	Webpage respondents, mean (SD)	Test statistic, *t* test (*df*)	*P* value
1. Was it easy to use?[a]	3.3 (0.6)	2.4 (1.2)	8.1 (222.2)	<.001
2. Was it convenient to use?[a]	3.0 (0.9)	1.8 (1.3)	8.2 (215.5)	<.001
3. Was the information easy to understand?[a]	3.5 (0.7)	2.8 (1.2)	5.8 (222.8)	<.001
4. Was the internet a good method for delivering this information?[a]	3.7 (0.6)	2.9 (1.3)	6.2 (217.5)	<.001
5. Were you eager to use it?[a]	2.9 (0.9)	1.9 (1.3)	6.9 (217.5)	<.001
6. Were you satisfied?[a]	3.0 (0.8)	1.8 (1.3)	8.8 (222.7)	<.001
7. Did it meet your expectations?[a]	3.0 (0.8)	1.7 (1.5)	9.4 (227.0)	<.001
8. Did it keep your interest?[a]	2.7 (1.0)	1.4 (1.3)	8.7 (203.7)	<.001
9. Did you trust the information from it?[a]	3.6 (0.7)	3.1 (1.0)	4.7 (217.8)	<.001
10. Did concerns about your privacy (eg, friends or family knowing about your online activities) affect your use of it?[b]	3.0 (1.1)	3.3 (1.0)	−2.4 (227.0)	<.001
11. Did access or availability of a computer affect your use of it?[b]	3.4 (1.1)	3.4 (1.1)	0.3 (227.0)	.74
12. Did technical computer problems (eg, trouble logging in, clicking to the next page) affect your use of it?[b]	3.6 (0.8)	3.6 (0.9)	−0.4 (227.0)	.74
13. Did internet problems (eg, slow or poor connection) affect your use of it?[a,b]	3.6 (0.7)	3.5 (0.9)	1.0 (208.3)	.34
14. Did personal commitments (eg, family time, extracurricular activities) affect your use of it?[a,b,c]	1.8 (1.2)	2.5 (1.4)	−4.0 (187.8)	<.001
15. Did school commitments (eg, class time, homework) affect your use of it?[b,c]	1.9 (1.4)	2.4 (1.5)	−2.4 (226.0)	.02
16. How likely would you be to come back to it if difficulties with your anxiety continue or return?[a,c]	2.6 (1.1)	1.9 (1.4)	4.0 (202.2)	<.001
17. How did your ability to manage your anxiety change by using it?[a,c]	2.9 (0.5)	2.3 (0.6)	8.1 (195.4)	<.001
18. How did you anxiety with activities at school (eg, speaking up in class and taking a test) change by using it?[a,c]	2.7 (0.6)	2.1 (0.6)	7.8 (163.5)	<.001
19. How did your relationship with friends and peers change by using it?[a,c]	2.5 (0.6)	2.2 (0.6)	3.9 (166.1)	<.001
20. How did your relationships with family members change by using it?[a,c]	2.4 (0.6)	2.1 (0.6)	2.6 (156.0)	.01
21. How did your overall anxiety change by using it?[a,c]	2.8 (0.6)	2.2 (0.8)	6.7 (204.6)	<.001

[a]Equal variances not assumed based on Levene test for equality of variances.

[b]Item is reverse scored so that a higher rating now indicates a more positive experience.

[c]N=147 for this analysis.

Table 7. The differences between *Breathe* (n=81) and webpage (n=148) respondents in the construct and core item total scores of the User Experience Questionnaire for Internet-based Interventions.

User experience score	Score range	*Breathe* respondents, mean (SD)	User experience indicator[a]	Webpage respondents, mean (SD)	User experience indicator[a]	Test statistic, *t* test (*df*)	*P* value
Construct 1: satisfaction and acceptability	0-32	25.2 (4.2)	Good	16.6 (7.9)	Moderate	9.2 (227.0)	<.001
Construct 2: credibility and impact	0-24	16.9 (2.2)	Very good	14.0 (3.0)[b]	Moderate	7.7 (226.0)	<.001
Construct 3: adherence and usage	0-28	19.9 (4.2)	Moderate	20.7 (4.4)[b]	Good	−1.4 (226.0)	0.18
All core items	0-84	62.0 (8.2)	Good	51.2 (11.1)[b]	Moderate	7.6 (226.0)	<.001

[a]On the basis of quartiles using all adolescent users (*Breathe* program+webpage users): first quartile=low; second quartile=moderate; third quartile=good; and fourth quartile=very good.

[b]N=147 for this analysis.

Table 8. *Breathe* respondents' ratings (n=81) from the User Experience Questionnaire for Internet-based Interventions.

Breathe user experience item	Value, mean (SD)
22. Was it a good fit for you?	2.6 (0.8)
23. Did you like the way it looked?	3.2 (0.9)
24. Did the information relate to you and your situation?	2.8 (1.1)
25. Did it help you meet your treatment goals?	2.3 (1.0)
26. Did the reminder emails affect your use of it?	3.0 (1.2)
27. Did the time required to complete the program affect your use of it?[a]	1.9 (1.2)
28. Did concerns about "facing your fears" affect your use of it?[a]	2.2 (1.3)
29. How likely would you be to recommend it to others?	3.0 (0.8)
30. Were the follow-up emails and telephone calls helpful?[b]	2.7 (1.1)
31. Were the homework ("Try Out") exercises helpful?[b]	2.4 (1.0)
32. Were the homework ("Try Out") exercises easy to complete?[b]	2.7 (0.9)
33. Was the worry ladder helpful?[b]	2.4 (1.1)
34. Was the worry ladder easy to complete?[b]	2.4 (1.0)

[a]Item is reverse scored so that a higher rating now indicates a more positive experience.

[b]N=80 for this analysis.

Table 9. *Breathe* respondents' user experiences (n=81) presented by user experience construct, treatment items, and all items total scores from the User Experience Questionnaire for Internet-based Interventions.

User experience score	Total score, mean (SD)	Score range	User experience indicator[a]
Construct 1: satisfaction and acceptability	11.6 (2.6)	0-16	Good
Construct 2: credibility and impact	9.8 (2.8)[b]	0-16	Good
Construct 3: adherence and usage	12.2 (2.9)[b]	0-20	Good
Treatment items	33.5 (6.4)[b]	0-52	Good
All items (core + treatment items)	95.3 (13.5)[b]	0-136	Good

[a]Indicator is based on quartiles of *Breathe* users only: first quartile=low; second quartile=moderate; third quartile=good; fourth quartile=very good.

[b]N=80 for this analysis.

Table 10. Themes and responses from open-ended items from the User Experience Questionnaire for Internet-based Interventions.

Open-ended question (number of respondents) and theme (number of responses contributing to each theme)[a]	Example verbatim response
30a. Why were the follow-up emails and telephone calls not very helpful? (n=10)	
Anticipating the telephone coaching call was stressful (n=8)	"I was self motivated so the emails just filled my inbox and the call was uncomfortable." [user 4992]
Emails did not motivate program use (n=4)	"Emails didn't motivate me, made me want to ignore it even more." [user 1191]
Lack of comfort during the telephone coaching call (n=3)	"I like to do things independently and I find it difficult to interact with strangers." [user 1447]
32a. Why was it a challenge to complete the homework? (n=7)	
Lack of time for program workload (n=4)	"Hard to make time and to remember to go back to things every-day." [user 2930]
Forgetting (n=2)	"I'd forget to do them." [user 107]
Feasibility (n=2)	"The boxes were small and it was hard to read all of the text." [user 1483]
34a. Why was it a challenge to complete the worry ladder? (n=12)	
Instructions/activities were hard to understand (n=4)	"For me there wasn't enough instructions for it and I was confused." [user 2449]
Uncertainty in completing (n=3)	"It was difficult coming up with all the steps, i didn't have a creative mind with creative ideas." [user 1253]
Difficulty focusing/articulating worries (n=2)	"I felt my worries were too complex to fit into it." [user 1825]
35. What was the most challenging part of the program? (n=80)	
Time management (n=24)	"Trying to complete the tasks on time with my schedule." [user 894]
Preparing for or implementing skills outside of the program (n=23)	"Finding the courage to do exposure activities. Also remembering and putting effort into coping strategies while in an anxious situation." [user 606]
Difficulty working with anxiety concerns (thoughts, feelings, and behaviors) on their own (n=20)	"Facing my fears and organizing my thoughts was a challenge because sometimes I would have to dig deep to find answers." [user 215]
Regular program use (n=18)	"Remembering to participate in the program." [user 1102]
Program format (n=2)	"Reading the format was hard to follow." [user 1006]
36. What was the most enjoyable part of the program? (n=80)	
Learning new information and skills (n=31)	"Learning more about what I can do to help myself." [user 1103]
Not feeling alone (n=10)	"I think just knowing that I'm not alone with anxiety. Knowing that other people go through it and some people want to help makes me not feel so alone and helpless." [user 215]
Program activities (n=10)	"I really liked the worry ladder and the surveys." [user 215]
Noticing improvement or impact (n=9)	"Seeing what improvements I may have as well as how this program works." [user 371]
Progress monitoring and feedback activities (n=7)	"I think answering the journals, and keeping track of my anxiety every week from school, family and friends." [user 1253]
Developing insights (n=5)	"Introspection and the ability to actually think about the things I'm doing." [user 1282]
Program format or features (n=5)	"Being able to do it online and not have to talk with anyone face to face." [user 2209]
Positive emotions while working on the program (n=4)	"Finishing the session successfully." [user 752]
Telephone coaching call (n=2)	"My phone call with my coach." [user 1102]

[a]Adolescents' responses may have been coded under more than one theme if there were multiple components (themes) to their response.

Relationships Between Intervention Usage and User Experience

Table 11 presents the relationships between intervention usage and user experience scores for *Breathe* and webpage respondents. The number of *Breathe* sessions completed was significantly correlated with the adherence and usage construct scores for both the core and treatment items, the total score for all treatment items, and the total score for all user experience items.

Table 11. The relationship between intervention usage and the user experience of *Breathe* and webpage respondents.

Items	Total number of *Breathe* sessions (n=81)		Number of webpage visits (n=148)	
	Rho	*P* value	Rho	*P* value
UEQII[a] core items (1-21)				
Construct 1: satisfaction and acceptability	0.10	.37	0.07	.42
Construct 2: credibility and impact	0.12	.28	−0.02	.84[b]
Construct 3: adherence and usage	0.22	.05	0.08	.36[b]
All core items	0.18	.10	0.07	.42[b]
UEQII treatment items (22-34)				
Construct 1: satisfaction and acceptability	0.15	.17	—[c]	—
Construct 2: credibility and impact	0.22	.06[d]	—	—
Construct 3: adherence and usage	0.37	<.00[d]	—	—
All treatment items	0.33	<.00[d]	—	—
All UEQII items (1-34)				
All core and treatment items	0.30	<.00[d]	—	—

[a]UEQII: User Experience Questionnaire for Internet-based Interventions.

[b]N=147 for this analysis.

[c]Not applicable.

[d]N=80 for this analysis.

Breathe User Ratings of Changes in Anxiety

Among the 258 *Breathe* respondents, 80 (30.6% of allocated adolescents) reported their change in anxiety using the GRCS (score range −5 to +5, with 0=no change). Among these adolescents, 75% (60/80) reported that their anxiety level improved after they had used the program with an average improvement of 2.3 (somewhat better; SD 0.8). For the 5% (4/80) of adolescents who reported that their anxiety was worse after the program, the average worsening rating was 1.3 (mostly same/hardly worse; SD 0.5). In addition, 20% (16/80) of adolescents reported no change in their anxiety after the program. The mean GRCS response among respondents was 1.7 (SD 1.3). Table 12 presents an overview of the GRCS responses from *Breathe* respondents.

Table 12. The change in anxiety levels as reported by *Breathe* respondents using the Global Rating of Change Scale.

Change in anxiety (rating)	Number (proportion) of *Breathe* respondents (n=80), n (%)
A very great deal better (+5)	1 (1)
A great deal better (+4)	3 (4)
Much better (+3)	14 (18)
Somewhat better (+2)	36 (45)
Almost the same, hardly better at all (+1)	6 (8)
No change (0)	16 (20)
Almost the same, hardly worse at all (−1)	3 (4)
Somewhat worse (−2)	1 (1)
Much worse (−3)	0 (0)
A great deal worse (−4)	0 (0)
A very great deal worse (−5)	0 (0)

Relationships Between the Global Ratings of Anxiety Change, Breathe Program Use, and the Breathe User Experience

We did not find a statistically significant relationship between the number of sessions completed (program use) and *Breathe* respondents' reported changes in anxiety on the GRCS (rho=0.02; *P*=.83). We found that the GRCS was related to the average user experience, including core total score (r=0.41; *P*<.000), treatment total score (r=0.50; *P*<.000), and the all items total score (r=0.49; *P*<.000).

Minimal Clinically Important Difference

We found a significant positive correlation between the GRCS scores and the MASC-2 change scores among *Breathe* respondents (r=0.27; *P*=.02), providing face validity for the GRCS to indicate changes in adolescents' anxiety symptoms [55]. To calculate the MCID, we used the mean change in MASC-2 raw scores among *Breathe* respondents (36/80, 45%) who reported a *somewhat better* change in their anxiety (+2; "small change") on the GRCS. This mean MASC-2 change score was 13.8 (SD 18.1). Therefore, the MCID for the improvement of adolescents' anxiety following the *Breathe* program was 13.8 points on the MASC-2. Using this estimate, the number of *Breathe* respondents who reached (or surpassed) the MCID threshold and were considered *treatment responders* was 35 of 81 (43%).

Relationships Between Treatment Response, Breathe Program Use, and the Breathe User Experience

We found no significant point-biserial correlations (r_{pb}) between the treatment response (treatment responder or nonresponder) of *Breathe* respondents and (1) the number of sessions completed (r_{pb}=0.05; *P*=.66), (2) UEQII core total score (r_{pb}=−0.04; *P*=.76), (3) UEQII treatment total score (r_{pb}=0.02; *P*=.82), (4) UEQII satisfaction and adherence total score (construct 1; r_{pb}=−0.03; *P*=.32), (5) UEQII credibility and impact total score (construct 2; r_{pb}=0.02; *P*=.88), (6) UEQII adherence and usage total score (construct 3; r_{pb}=0.02; *P*=.88), and (7) UEQII all items total score (r_{pb}=−0.03; *P*=.82).

Discussion

Principal Findings

Interest in the *Breathe* program was high, particularly given that recruitment was primarily through social media and required adolescents to self-identify as wanting help for anxiety. Approximately one-third of the participants in the iCBT intervention completed the postintervention evaluation, and three-fourths of them completed more than half the program. For iCBT programs designed and delivered to adolescents with anxiety, program evaluations should aim to understand how iCBT is experienced by adolescents to further ensure its relevance, use, and impact as a self-help treatment [63-66]. As part of a large-scale evaluation of *Breathe*, an iCBT program for mild-to-moderate anxiety symptoms among adolescents, we used user-reported measures to improve our understanding of adolescents' use of and experiences with iCBT compared with standard resource-based webpages, and what perceived impact adolescent respondents' experience following the use of an iCBT program. In the study, we recognized that multiple interacting components influence the user experience [67-69]. By using complementary measures—automatically captured administrative data (eg, session completion data) and self-report of program experience and impact data (quantitative and qualitative)—we described and compared distinct but essential parts of the user experience. As a result, we discovered (1) how iCBT program delivery may influence iCBT use and the user experience, (2) technological features and activities of the program associated with user satisfaction and acceptability, and (3) what adolescents report to be an important change in their anxiety after program use.

Program Delivery, Internet-Based Cognitive Behavioral Therapy Use, and the User Experience

Similar to previously published studies [70], program use was low among all adolescents allocated to the *Breathe* program. On average, adolescents completed a little more than one-third of the program, and approximately 20% of adolescents completed the entire 6-session program, a completion rate that falls within the range of 5% to 50% reported by other studies of iCBT programs [70]. Program use was higher among *Breathe* respondents (ie, approximately one-third of allocated adolescents who provided user experience data), 75% of whom were considered active program participants. This more engaged user group of *Breathe* respondents can be used to explore ways that we might increase program use among other adolescent iCBT users. Although other studies have looked to user demographics to provide explanations in low program use, explanations have been mixed [13,15,18], which suggests new approaches to understanding program use are needed.

Consistent with the literature, *Breathe* respondents described difficulty remembering to work on the program [29,52], concerns with privacy and stigma (eg, others knowing about or judging their help seeking) [30,71,72], time constraints, and conflicting commitments [31,73-75], and delaying or avoiding tasks they found challenging [76,77] as the biggest obstacles to program adherence and use. The time of day when adolescents opted to access the program (ie, immediately after school and before bed) or the portability of the medium used to access it (ie, desktop computer and mobile phone app) could be related to these perceived barriers and require exploration in future studies. A recent review of iCBT programs for children and adolescents with anxiety found that all programs that have undergone empirical testing included some form of program support (eg, teacher administration, weekly therapist emails, and parent-directed modules) [70] so that programs were not solely self-administered and unsupported. Most previously studied iCBT programs with completion rates greater than 50% involved regular therapist or parent involvement to support program use [26,29,78-82]. It may be that this type of support as well as the degree of support provided may help adolescents manage their time and complete challenging program activities [27,81,83-85]. There is a trend in the literature that some type of program support can increase program use or effectiveness of iCBT for children and adolescents [10]; however, inconsistent evidence is published [16,28,86,87], and what type of support, such as when it should be provided and by whom, that improves

outcomes is unclear [13,15,17,88]. As part of the *Breathe* program, adolescents received one telephone-based coaching call after completing their first session to prepare adolescents for the skills-based program activities to follow, including exposure activities, that would begin in session 2. Almost half of the adolescents allocated to the *Breathe* program did not go on to complete the next program session and the personalized exposure activities they had set up in session 1 (ie, a hierarchy of activities specific to their worries and fears). Although some adolescents described the call as a positive experience, others considered it *stressful* because they did not know the coach, and some adolescents described avoiding and delaying the call. This mixed response to coach involvement suggests that *how* support is provided is a key aspect of program delivery and the user experience. Some studies of Web-based interventions have described including rapport building activities (eg, introductory telephone call) between adolescents and the adjunct support person before treatment material is discussed (eg, preparing for exposure exercises) [29,84]. Including an activity similar to this may have helped some adolescents begin the *Breathe* program or ameliorate some of the discomfort or nervousness they experienced leading up to or during the coaching call, thereby retaining active participants in the program.

It is important to note that the stage of the program at which user experiences are measured may provide more or less information on the relationship between adolescents' use of, experiences with, or perceived impact of a program. In this study, we administered our user experience measures after program use. However, moving forward in the field, there is value in formative evaluation during program use. Such evaluations may reveal how the user experience changes over time, how it can be optimized [89], and how to improve the accuracy of collected data on the user experience (eg, reduce recall bias and link user experience domains to specific program sessions). For example, repeated measurement, using log data or routine monitoring of points of program stoppage among adolescents, may help to identify the relationship between program continuation or discontinuation, adolescents' anxiety states, or program content or features. Use of factor analysis [90] or multiple regression [91] could help to illuminate how different constructs of user experience relate to one another and to intervention use and how the constructs change over the course of treatment.

Program Features and Activities and the User Experience

Overall, in this study, user experiences were significantly more positive for *Breathe* respondents than for resource-based webpage respondents. The only user experience questionnaire construct for which we found no difference between the two intervention groups was the adherence and usage construct—both the *Breathe* program and webpage respondents reported few concerns with technology or internet accessibility or functionality during the study. Similar to other iCBT studies, *Breathe* respondents reported that the program was easy to understand [92], met their needs [79], and that they were satisfied overall [29,93,94]. Nearly half of the respondents stated that the most enjoyable parts of the program were learning about anxiety, developing new coping strategies, and feeling like others could relate to their situation or worries and vice versa. However, *Breathe* respondents' satisfaction and acceptability with the program were not correlated with their use of it, suggesting that other program factors need to be explored for their association with iCBT use. A distinguishing feature of *Breathe* compared with the resource webpages was that *Breathe* incorporated instruction and interaction (providing opportunities for *doing*) in addition to information (providing opportunities for *knowing*) as part of the intervention, helping adolescents develop their capacity and competency for self-management rather than redirecting them to alternative resources. *Breathe* respondents liked activities that improved their ability to self-manage their anxiety by informing them, empowering them, or normalizing their experiences. Respondents reported the greatest interest in developing skills that were relatively easier to learn and had a timelier impact (eg, *deep breathing exercises* and *watching videos of other teens with anxiety and relating to them*). When designing an iCBT program, it may be helpful to consider *balancing* the variety and sequence of program content and activities included according to their expected level of effort from the user and the immediacy of benefit. *Breathe* respondents reported positive experiences with more immediate (eg, relaxation or mindfulness techniques) and short-term relief tasks (eg, psychoeducation, normalization, and affirmation of support), suggesting that when long-term relief tasks (eg, exposure activities and homework) are presented in sessions, some immediate and short-term relief tasks should also be included (eg, revisited or presented) to maintain adolescents' interest and sense of self-mastery or achievement with the program. Combining immediate and short-term relief tasks with long-term ones could potentially offset the discomfort and effort required to persist through more demanding tasks (ie, exposure), making it easier for adolescents to continue with the program.

In addition to program content and activities, technological features are also inherent aspects of iCBT. The *Breathe* program was developed using persuasive systems design components (technology-based interventions designed to reinforce, change, or shape attitudes or behaviors [74]) to increase program engagement, use, and effectiveness. Yet, on average, program use was still low for all allocated adolescents. Persuasive design features are embedded within the program itself, making use of the program a prerequisite for adolescents to experience these features and their *persuasive effects*. The majority of *Breathe* adolescents did not access the first session and were not exposed to such features. Among the adolescents who did use the *Breathe* program, they described specific persuasive design features to be among the most enjoyable features of the program. These features included interactive surveys and graphs (designed to provide feedback, increase adolescents' awareness of their changes over time, and help with goal setting [95-97]), and video clips showing in-vivo exposure and diaphragmatic breathing (designed to provide step-by-step peer simulations of therapeutic activities [70]). On the basis of adolescent feedback in this study, it may be that the design features did have a positive influence on program use as intended. However, what remains an important question is how to promote adolescents' initial engagement with a persuasive systems design–based program so that they can experience the program's features. One strategy may involve the use of preintervention activities,

such as readying adolescents for the iCBT program, or assessing the fit between adolescents and the program to improve program initiation and use. For example, a *preview* of an iCBT program could be provided to adolescents before eligibility screening to pique their interest in the program. Incorporating an iCBT program preview could promote a user-centered, decision-making treatment process (adolescents can self-select programs that meet their needs and preferences), streamline the recruitment and eligibility screening process (identifying adolescents who may be unlikely to use the program early on and saving time and resources by redirecting them to treatment alternatives), uphold research or clinical practice ethics (adolescents can avoid a treatment that may be unusable, ineffective, or potentially harmful to them), and stimulate or *kick start* adolescents use of the program (adolescents become intrigued and interested in commencing the program). Another strategy to promote initial program engagement is to incorporate an assessment of beliefs and attitudes before program use. Persuasive technology aims to reinforce, change, or shape users' attitudes or behaviors toward their health goal [47,98], suggesting that a clear understanding of adolescents' psychology precedes the selection and use of an intervention. Assessing adolescents' existing health beliefs and attitudes (eg, treatment expectations, health and technology literacy, and self-efficacy) and treatment goals (eg, desired change in knowledge, skills, or symptoms) preintervention may help determine (1) the potential for successful *persuasion* to occur (an attitude or behavior change) with the use of the iCBT program; and (2) if a positive potential exists, what persuasive system design components may be most appropriate to match the beliefs and goals of the adolescent. Being able to assess and appropriately tailor a program's persuasive features based on adolescents' beliefs, attitudes, and goals could improve adolescents' experience and use of iCBT.

Considering that multiple iCBT components work together to form a complex intervention [99], we recommend connecting the persuasive system design features known to relate to a positive user experience (program reminders, progress and feedback tools, multimedia demonstrations, and flexible program support) with proposed mechanisms of change (CBT content [psychoeducation, skills training], attitude or behavior change processes [techniques that target adolescents' motivation and sense of mastery]) [70]. Future studies that systematically test the relationship between iCBT features, behavior change processes, user experience, and health outcomes would help to develop working models of iCBT effectiveness. Standardized interviews and patient-reported measures (eg, Ratings of Perceived Helpfulness in Behavior Change [74,100]) may also help researchers determine how iCBT program features have or have not engaged adolescents in behavior change, the reliability of adolescents' self-awareness/reports on their fit with a program and adolescent to determine the self-reports, and what features were most effective for improving program use.

Changes in Adolescents' Anxiety Following Internet-Based Cognitive Behavioral Therapy Use

Previous iCBT studies have measured whether program participation was perceived as *effective or useful* by adolescents [81,92] but have not formally measured the degree of meaningful change in anxiety as experienced by users of a program. This study is the first to quantify a user-reported improvement to an MCID for anxiety symptoms, a common primary outcome of trials to date. Establishing this MCID is an important step in informing future sample sizes for trials of iCBT effectiveness (eg, can provide a clinically meaningful effect size) and interpreting adolescent outcomes (eg, presenting results with a clear meaning behind anxiety changes and implications, such as whether an adolescent is a positive responder to iCBT). Reporting whether changes in anxiety across different programs met an MCID can also assist adolescents, parents, and clinicians in deciding which program best matches their expected treatment response [37,101].

In this study, most adolescents reported that their anxiety was *better* after using the *Breathe* program. On the basis of the MCID estimate generated from adolescents' ratings, 43% (35/81) of *Breathe* respondents were positive treatment responders. Previous iCBT studies have used clinical severity ratings (ratings have ranged from 0=none to 8=extremely severe) as a proximal indicator of treatment response [27,29,79,81]. However, a clinician has assigned these ratings. For programs used outside a research or clinical setting, the use of an MCID to determine treatment response can reduce costs and time associated with clinician involvement and better reflects the experience of the youth.

For *Breathe* respondents, we did not find a statistically significant relationship between treatment response and the number of program sessions completed. There is mixed evidence as to whether a causal relationship between iCBT use and change in anxiety (a *dose-response* relationship) exists—some studies have found evidence for this relationship [102,103], whereas others have not [104,105]; however, there is consensus that some degree of program use is required to reduce users' symptoms [106-108]. In our study, adolescents may have discontinued their use of a program (temporarily or definitively) once they felt their symptoms had improved, regardless of their progress in the program. Perceived impact may also be based on unique individual factors, such as treatment expectancy, preintervention anxiety severity, self-regulation abilities, or motivational factors [69,102,109], factors that we did not assess. The lack of association between treatment response and program use further emphasizes the importance of incorporating adolescents' perspectives in the evaluation of iCBT because commonly used methods (eg, standardized symptom questionnaires) may not fully capture the health and social benefits adolescents want or need from an iCBT program. More research is required to determine what treatment outcomes are important to adolescents who seek to use iCBT apart from those that researchers and clinicians typically administer.

Strengths and Limitations

This study has several strengths related to the assessment of user experiences of an iCBT program for adolescents with anxiety. Currently, there is considerable heterogeneity in how the user experience is defined and evaluated, with most research being conducted with adult populations [65,69,110,111]. To target our anticipated participants, we used current, key literature

[30,52,53,70,112-114] to develop the UEQII. This self-report measure includes three major user experience constructs (construct 1: satisfaction and acceptability, construct 2: credibility and impact, and construct 3: adherence and usage). Each construct provided diverse information to understand the adolescent experiences with an iCBT program as well as our comparison intervention. With the growing number of RCTs evaluating iCBT programs using a technology-based intervention as a control, a method to compare the user experience between two internet-based interventions for adolescents is becoming increasingly important. Although this measure is subject to response bias (recall or social desirability) and relies on adolescents' insights of their own behaviors or attitudes (experiential data), it provides information that is not directly observable and cannot be captured by traditional diagnostic assessments, a proxy respondent (ie, parent), or digital log data (objective data). In the future, other researchers can use the UEQII by administering the *core* items to other internet-based interventions and adapting the *treatment* items for their intervention under study to narrow in on what specific intervention components meet the needs and preferences of their target users. As a first step before broader use, we recommend that the UEQII undergo further psychometric testing to assess its feasibility and transferability in other contexts, ages, and patient groups and iCBT programs.

This study also has several limitations. First, we used adolescent ratings on a global rating scale (in our case, a GRCS) to calculate the MCID. There is no standard for how to calculate the MCID; therefore, a variety of methods exist and can be used depending on the study sample and data collected (for a review of the different methods, refer to the studies by Copay et al [59], Wells et al [115], Beaton et al [116], and Ebrahim et al [117]). In this study, the anchor-based approach was considered optimal because it maintains the user's perspective [117-119], an essential perspective with a primarily self-led intervention for an internalizing disorder. However, it is unclear how factors such as treatment preferences, engagement, or expectations may influence individual ratings, and therefore the MCID score (based on an average of individual scores). The GRCS significantly correlated with the MASC-2 change scores, considered a *gold standard* screen of adolescent-reported anxiety symptoms, providing support for the validity of the MCID estimate. Disadvantages of the anchor-based method, however, include the selection of the anchor itself (ie, GRCS) and the potentially arbitrary nature of the MCID cut point for a small change in anxiety (ie, *somewhat better*), although the GRCS change is consistent from other studies [62]. Thus, the MCID estimate calculated can vary between samples with different participant characteristics (eg, baseline severity and previous treatment experiences) [55,59,118]. Moving forward, we recommend that MCIDs be calculated using the same measures (GRCS and MASC-2) for adolescent users of other iCBT programs. A composite MCID estimate can then be generated by amalgamating MCID data across multiple studies to increase the generalizability and validity of the estimate [120] or provide a range of critical MCID values can be provided. The composite and ranges can be corroborated using Delphi (eg, clinical or expert opinion) or distribution-based methods (eg, effect size and standard error of measurement) [59,116], triangulating multiple approaches to calculating the MCID to improve the robustness of the estimate [101].

Finally, in this study, there was a large rate of attrition, which resulted in only about one-third of enrolled adolescents included in the user experience analysis. Attrition is said to be a fundamental characteristic and methodological limitation of longitudinal iCBT studies [121-123]; however, our attrition rates are consistent with dropouts in outpatient therapy settings [9]. Participants in this study reported high levels of anxiety on a standard screening tool (MASC-2, *very elevated*) at preintervention, which reflects a greater severity of anxiety symptoms in those seeking help than those in most minimally supported iCBT studies. This study was inclusive of youth at any stage in their treatment journey, and it is possible that some youth were exploring multiple options to access help and that an iCBT program was not the option of best fit at that time. It is also possible that the limits in timing of the evaluation at baseline and 6 weeks from enrollment may also have impacted the number of respondents as some adolescents may have been excluded who would have engaged further with a longer time course. Thus, our user experience findings may be based on adolescents who are different from those who dropped out of the study. *Breathe* respondents who used the program and completed the postintervention assessments may have had a preference for self-help programs, greater motivation, or commitment to treatment or viewed the program to be highly relevant or beneficial to them [74,121,124]. As the perceptions of adolescents who dropped out were not captured by our evaluation, we are limited in understanding of why an iCBT program is unlikely to be used once accessed. Additional adolescent demographic (eg, urban or rural residence) or clinical information (eg, psychological comorbidities) could help explain the differences in attrition between respondents and nonrespondents or be used to explore mediators or moderators of study participation, but these data were not collected as part of this study. Sample characteristics, such as most adolescents identifying as female, may limit the generalizability of our findings to other adolescents who seek self-help, technology-based interventions to manage their anxiety.

Conclusions

Given the high prevalence of anxiety disorders, the challenges in accessing CBT, and the interest of young people in internet interventions, iCBT is an important area of clinical research. In this study, we used user-reported measures, including a new measure, the UEQII, to examine the multiple components that influence anxious adolescents' experiences with an iCBT program compared with that of resource-based webpages. How iCBT is delivered may influence and help explain the relatively low number of session use, perception of time constraints, and other commonly reported challenges to completing a program. The more positive experience that *Breathe* respondents reported compared with webpage respondents may be attributed to the interactive technological features and program activities (eg, graphs, video demonstrations, and learning about anxiety) with specific focus on anxiety-coping skills that were incorporated into the iCBT program. Although most adolescent respondents experienced benefit from an iCBT program, the relationship between adolescents' use, their experiences, and perceived

impact on anxiety is still unclear, indicating that further understanding of what adolescents find challenging and enjoyable about iCBT as well as the characteristics of those who would most benefit from this delivery mode is necessary to optimize its delivery. Future studies can validate the UEQII, test and integrate our program suggestions, and apply our user experience measures toward creating robust treatment planning guidelines, including mechanisms to engage more youth in treatment completion.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The User Experience Questionnaire for Internet-based Interventions.
[PDF File (Adobe PDF File), 143 KB - mental_v7i2e15795_app1.pdf]

Multimedia Appendix 2
Scoring of the User Experience Questionnaire for Internet-based Interventions.
[PDF File (Adobe PDF File), 82 KB - mental_v7i2e15795_app2.pdf]

Multimedia Appendix 3
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1730 KB - mental_v7i2e15795_app3.pdf]

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Abbreviations

Breathe: Being Real, Easing Anxiety: Tools Helping Electronically
CBT: cognitive behavioral therapy
GRCS: Global Rating of Change Scale
iCBT: internet-based cognitive behavioral therapy
IRIS: Intelligent Research and Intervention Software
MASC-2: Multidimensional Anxiety Scale for Children—2nd Edition
MCID: minimal clinically important difference
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
UEQII: User Experience Questionnaire for Internet-based Interventions

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Original Paper

An Eight-Week, Web-Based Mindfulness Virtual Community Intervention for Students' Mental Health: Randomized Controlled Trial

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Abstract

Background: Innovative interventions are needed to address the increasing mental health needs of university students. Given the demonstrated anxiolytic and antidepressant benefits of mindfulness training, we developed an 8-week, Web-based Mindfulness Virtual Community (MVC) intervention informed by cognitive behavioral therapy (CBT) constructs.

Objective: This study investigated the efficacy of the MVC intervention in reducing symptoms of depression, anxiety, and stress among undergraduate students in Toronto, Canada. The secondary outcomes included quality of life, life satisfaction, and mindfulness.

Methods: The first 4 weeks of the full MVC intervention (F-MVC) comprised: (1) 12 video-based modules with psycho-education on students' preidentified stressful topics and topically applied mindfulness practice; (2) anonymous peer-to-peer discussion forums; and (3) anonymous, group-based, professionally guided, 20-min live videoconferences. The second 4 weeks of F-MVC involved access only to video-based modules. The 8-week partial MVC (P-MVC) comprised 12 video-based modules. A randomized controlled trial was conducted with 4 parallel arms: F-MVC, P-MVC, waitlist control (WLC), and group-based face-to-face CBT; results for the latter group are presented elsewhere. Students recruited through multiple strategies consented and were randomized: WLC=40; F-MVC=40, P-MVC=39; all learned about allocation after consenting. The online surveys at baseline (T1), 4 weeks (T2), and 8 weeks (T3) included the Patient Health Questionnaire-9 item, Beck Anxiety Inventory, Perceived Stress Scale, Quality of Life Scale, Brief Multi-Dimensional Students Life Satisfaction Scale, and Five-Facet Mindfulness Questionnaire. Analyses employed generalized estimation equation methods with AR(1) covariance structures and were adjusted for possible confounders (gender, age, birth country, paid work, unpaid work, physical activities, self-rated health, and mental health counseling access).

Results: Of the 113 students who provided T1 data, 28 were males and 85 were females with a mean age of 24.8 years. Participants in F-MVC (n=39), P-MVC (n=35), and WLC (n=39) groups were similar in sociodemographic characteristics at T1. At T3 follow-up, per adjusted comparisons, there were statistically significant reductions in depression scores for F-MVC (score change −4.03; $P<.001$) and P-MVC (score change −4.82; $P<.001$) when compared with WLC. At T3, there was a statistically significant reduction in anxiety scores only for P-MVC (score change −7.35; $P=.01$) when compared with WLC. There was a statistically significant reduction in scores for perceived stress for both F-MVC (score change −5.32; $P<.001$) and P-MVC (score change −5.61; $P=.005$) compared with WLC. There were statistically significant changes at T3 for quality of life and mindfulness for F-MVC and P-MVC vs WLC but not for life satisfaction.

Conclusions: Internet-based mindfulness CBT–based interventions, such as F-MVC and P-MVC, can result in significant reductions in symptoms of depression, anxiety, and stress in a student population. Future research with a larger sample from multiple universities would more precisely test generalizability.

Trial Registration: International Standard Randomized Controlled Trial Number ISRCTN92827275; https://www.isrctn.com/ISRCTN92827275

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KEYWORDS

mindfulness; CBT; depression; anxiety; students; universities; randomized controlled trial; Canada

Introduction

Background

Mental health disorders, especially those involving depression, anxiety, and stress, are a rising problem among college students internationally. In the United States, analyses of college data show that mental health disorders are among the top five diagnostic categories seen at college health services and responsible for the highest number of visits per student (4.93) with depression and anxiety at the top [1]. Furthermore, multiple studies indicate an increasing prevalence of mental health disorders, especially depression and anxiety, in undergraduate students [1-8]. In Canada, a large study of nursing students indicated the prevalence of mild-to-severe depression, anxiety, and stress at 33%, 39%, and 38%, respectively [9]. Similar rates of mental health difficulties are reported among students from other countries [10-14]. The counseling centers in colleges and universities provide care to students in distress through various models such as clinical services, advising, awareness workshops, and training programs [15]. However, students often experience difficulties in accessing these services (eg, stigma and time concerns for in-person sessions along with financial cost for some services) [16,17], while counseling centers are overwhelmed due to limited resources. An analysis of Canadian colleges and universities revealed that enrollment in the province of Ontario increased by 27% between 2004 and 2012, but the budget for counseling centers increased by 5%, leading to just 1 campus-based counselor for 1300 to 4835 students [18]. Similarly, in the United States, a 2014 study indicated that the average ratio of counselors to students was 1 to 2081 [19]. New and accessible strategies are needed to address the students' mental health and at an early stage. One such approach is mindfulness-based techniques.

Mindfulness is defined as "the awareness that emerges through paying attention on purpose, in the present, and nonjudgmentally to the unfolding of experience moment by moment" [20]. The techniques learned in mindfulness practices involve nonjudgmental attention directed to each present moment. Although mindfulness meditation has been practiced for centuries in Buddhist and other spiritual traditions, its application to psychological health in the West emerged in 1980s when Jon Kabat-Zinn examined its clinical use in treating chronic pain [21]. This technique known as mindfulness-based stress reduction has a core focus on "intensive [and repeated] training of mindfulness meditation to help individuals relate to their physical and psychological conditions in a more accepting and nonjudgmental ways" [22]. Further scholarly work, such as by Segal et al [23], combined the principles of mindfulness with cognitive behavioral therapy (CBT). This program called mindfulness-based cognitive therapy (MBCT) has been researched for treating mental health conditions, especially depression. In addition to the principles of mindfulness practice, MBCT "aims to change one's *awareness of* and *relationship to* thoughts and emotions" to reduce the associations between negative automatic thinking and dysphoria [22]. Other psychotherapeutic techniques with mindfulness-orientation include dialectical behavior therapy and acceptance and commitment therapy, but the meditation practice is only one aspect of the full approach. Evidence shows that mindfulness-based interventions positively impact psychological [22,24] and physical health [25], with multiple meta-analyses demonstrating positive impacts in clinical and nonclinical populations [26-30]. Recent randomized controlled trials (RCTs) on mindfulness using face-to-face sessions, prescribed exploratory mental exercises, and video programs have reflected effectiveness in reducing symptoms for one or more of the three conditions of anxiety, stress, and depression [31-38]. In relation to student population, several recent reviews have indicated that in-person mindfulness-based interventions have a positive effect on students' mood and their levels of stress, anxiety, and depression [39-42].

However, a handful of student studies exist on *Web-based* mindfulness-based programs despite its potential to complement overstretched traditional counseling services on campuses [43]. This emerging scholarly work with students has examined the impact of Web-based mindfulness on a variety of mental health–related issues and demonstrated improvements in outcomes such as mental health, well-being, mindfulness, stress and depression symptoms, life satisfaction, and social connectedness [43-50]. However, the effectiveness of a Web-based mindfulness intervention when combined with the constructs of CBT remains an area requiring more rigorous examination. This is a missed opportunity given that systematic reviews show that internet-based CBT is significantly effective compared with control groups in reducing anxiety, especially when supported by therapist's email or phone contact [51], and in reducing depression symptoms [52]. There is the potential for substantial gains by combining these two techniques—mindfulness and CBT—through Web-based interventions for students who are also technologically fluent and capable; studies also indicate that students prefer to self-initiate help-seeking for Web-based services compared with in-person services [53]. There is also a need to better understand the optimal duration and delivery style of Web-based

mindfulness-CBT interventions. Although durations of 6 to 8 weeks are more common, 2-week interventions [48] and a single Web session [47] have also been used. In terms of delivery, some of these studies supported the interventions with reminders, written feedback, and coaching, whereas others were passive. High attrition rate was a common problem in several student studies [44,45,48,50], although it was a significantly less prevalent problem in studies that used coaching, reminders, and feedback strategies [43,49]. Indeed, further scholarly work is needed to inform development of student-friendly and effective Web-based mindfulness-CBT programs. Thus, our team developed a Mindfulness Virtual Community (MVC) Web-based program (described below) after conducting eight focus groups with students and incorporating comprehensive review of pertinent literature [54-58].

Study Objective

To examine the efficacy of an MVC program for mental health among undergraduate students in a Canadian university, we conducted a pilot RCT with 4 parallel arms: full MVC (F-MVC), partial MVC (P-MVC), waitlist control (WLC), and group-based face-to-face CBT mindfulness. As the main focus of the trial was to examine the MVC program, we report here the impact of F-MVC and P-MVC vs WLC; the results for face-to-face CBT mindfulness are presented elsewhere. The primary outcomes were symptoms of depression, anxiety, and stress, and secondary outcomes were quality of life, life satisfaction, and mindfulness. It was hypothesized that (1) symptom scores for depression, anxiety, and stress at 8 weeks (T3) will be significantly improved in the F-MVC group when compared with the WLC group and (2) scores for quality of life, life satisfaction, and mindfulness at T3 will be significantly better for the F-MVC intervention group than the WLC group. The P-MVC intervention was included to explore a significantly less expensive alternative to delivering beneficial effects and was hypothesized to have similar but lesser impact than the F-MVC intervention.

Methods

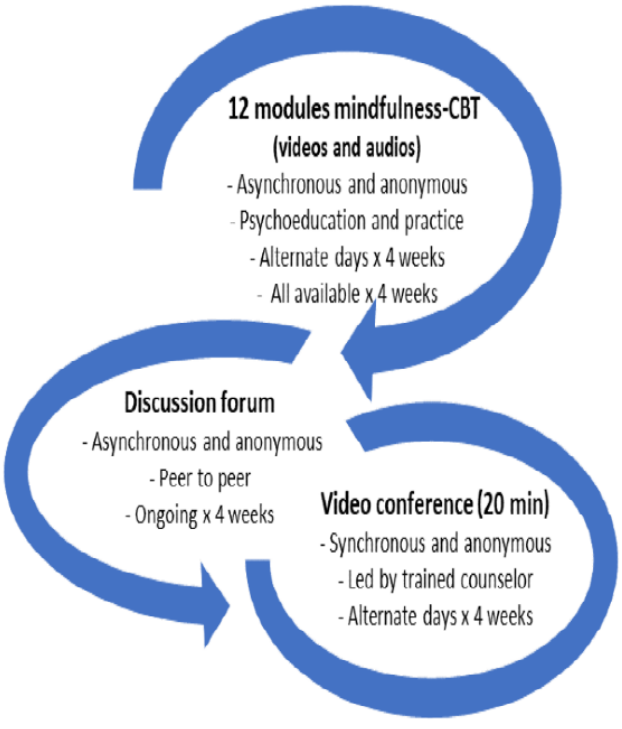
Ethics and Timeline

The Human Participant Research Committee at York University, Toronto, provided research ethics approval. We followed Consolidated Standards of Reporting Trials guidelines for nonpharmacological interventions and electronic health interventions [59,60]. The recruitment of eligible undergraduate students occurred during December 7, 2016 and January 10, 2017. These students started the parallel-arm RCT on January 16, 2017, with a baseline survey (T1) followed by exposure to 2 interventions, a 4-week online survey (T2), and an 8-week online survey (T3). The 8-week-long interventions of F-MVC and P-MVC started on January 22, 2017 and ended on March 16, 2017.

The Mindfulness Virtual Community Program

A total of three components of the Web-based MVC program (Figure 1) were (1) youth-specific mental health education and mindfulness-practice modules, delivered via video recordings for participants to watch and listen to on personal computers, phones, and tablets at convenient times; (2) anonymous, asynchronous peer-to-peer discussion boards pertaining to mental health and mindfulness practice; and (3) anonymous, 20-min live videoconferences (group-based) on module topics guided by a mental health professional.

Figure 1. Mindfulness Virtual Community program informed by cognitive behavioral therapy constructs. CBT: cognitive behavioral therapy.



Each of the 12 modules consists of one educational content and one mindfulness-practice content video, recorded in male and female voices with low volume background music, and offered in high- and low-resolution videos (a total of 8 videos per

module). The modules' topics were informed by our findings from the focus groups with students [54,55]. The module scripts and audio recordings were created by one of the investigators with extensive clinical experience (PR) and drew from combined mindfulness and CBT principles. The choice of moving and still images used in the creation of the videos involved collaborative work (PR, CE, and FA). Table 1 lists the topics of 12 modules and video duration (average of male and female voice), and Textbox 1 provides examples of the module content.

Table 1. Topics and duration of modules.

Topics	Video duration (minutes:seconds)	
	Education	Mindfulness practice
Overcoming stress, anxiety, and depression	7:09	9:00
Mindfulness and being a student	5:18	9:14
Mindfulness for better sleep	4:40	8:13
Thriving in a fast-changing world	7:23	8:23
Healthy intimacy	7:32	9:33
Destigmatization	6:13	9:12
No more procrastination	3:42	10:48
Pain reduction and mindfulness	3:48	9:48
Healthy body image	5:44	9:54
Healthier eating	10:10	9:26
Overcoming trauma	6:01	9:43
Relationships with family and friends	7:49	8:09

Textbox 1. Examples of module content.

Module 1: Overcoming stress, anxiety, and depression

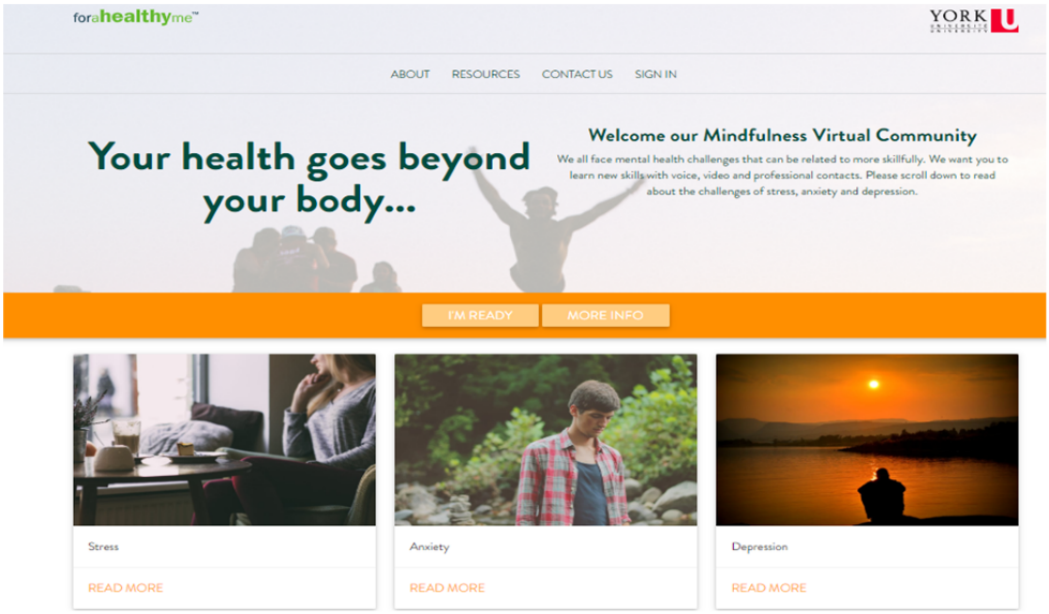
- *Education video*: The initial narration focuses on sources of stress (eg, continuous online access, information overload, and worries about the past and future distracting from focusing on the present). Video clips of human faces and activities depict mixtures of stress, relaxation, and joy. The middle section introduces mindfulness training with breath awareness as one approach to developing a present moment orientation that replaces less desirable coping attempts that involve purposeful self-distraction (eg, screen time). The video clips reflect people stressed (eg, at work, unable to sleep) and other people in a more relaxed states (eg, by a pool or on a beach or walking). The last narrative section encourages releases of accumulated stress and tension via mindfulness practice. Self-selected practice times are emphasized that may include a session at the end of day, reflected visually by clips of sunsets and people commuting home or just reading in a relaxed way within home environments.
- *Mindfulness practice*: Video clips of the flow of a natural river accompanies narration focused on instructions to find a comfortable position and focus on breathing sensations, with attention particularly directed to exhaling breaths; further instructions focus on acknowledging wandering thoughts and, after noticing them, returning attention to breathing; final suggestions (on this 9-min segment) are to accept stressful thoughts and then let them go, releasing the associated tensions. Altogether the session is characterized as a simplicity break where the focus on natural breathing rhythms assists one in attending to present moment experiences; narration concludes with the suggestion that the listener can continue to practice for periods of time that seems personally appropriate.

Module 2: Mindfulness and being a student

- *Education video*: The initial section focuses on student challenges (eg, memorization and exam taking) with video clips of students studying for and completing exams; the second section explains how mindfulness stimulates parasympathetic dominance and a psychological and physical calm, referring to experimental evidence on related benefits for learning, memory, and motivation. Video clips show people playing basketball and music (in confident ways), whereas the narrative section encourages mindfulness as a way of increasing confidence in personal skill development.
- *Mindfulness practice*: Images of very tall trees with light filtering through them accompany narration instruction on mindfulness practice with several points referring to the typical student experiences highlighted in the previous education video.

The Web platform for the intervention had separate logins for the student participant and the videoconference moderator (Figure 2). This was developed in partnership with the industry partner, ForaHealthyme Inc. The F-MVC student version provided access to the video-based modules, text-based peer-to-peer discussion forum, a calendar to book an upcoming live videoconference, a video room (camera being off as default) with ability to privately text the moderator, and a resource page with contact information on various social and health services.

Figure 2. Screenshot of the Mindfulness Virtual Community platform.



The moderator version offered access to the student version along with additional features such as populating the calendar with dates and times for the live videoconferences, starting the videoconference with camera turned on for the moderator by default, and responding privately to incoming text messages. The moderator (independent counselor with a master's degree in psychology and training in mindfulness) had weekly discussions with the team clinician (PR) to optimize engagement during videoconferences. Once the intervention was deployed, the content of modules and platform structure remained unchanged.

Study Arms

The Web-based F-MVC intervention was 8 weeks long. In the first 4 weeks, it offered 12 video-based modules, peer-to-peer discussion forums, and brief guided videoconferences; and in the second 4 weeks, it offered continued access to the video-based modules. The release of new modules in the first 4 weeks was scheduled for Sundays, Tuesdays, and Thursdays, and the video chat sessions were offered on Mondays, Wednesdays, and Fridays, with 20-min evening sessions at 9:00 PM, 9:30 PM, and 10:00 PM. Once a module was released, it remained accessible to students for the remainder of the intervention period. The Web-based P-MVC intervention was 8 weeks long and included all the video material of the F-MVC intervention following a similar release schedule, but it did not offer any videoconferences or discussion forums. The students in both groups received email reminders from the project staff before the release of each new module, whereas the reminders for conference chat were sent only to the F-MVC group. The partial and full intervention participants were instructed to use the platform ad libitum. The WLC group continued as *usual care* during the 8-week period without access to additional resources, and after completing the T3 survey, they received access to the Web-based 12 video-based modules and information on ongoing face-to-face mindfulness groups at the university to join if interested.

Recruitment and Randomization

Student eligibility criteria were a minimal age of 18 years, English language fluency, self-reported high level of confidence to complete the study, and current undergraduate student status. Their ability to use a computer and smartphone and internet literacy were assumed to be de facto skills. The study was advertised as "Mindfulness Approaches to Wellbeing on Campus" and used multiple recruitment strategies including study posters, class visits 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 further screened for substance abuse and indications of psychoses (ie, hallucinations). If either of these two conditions "interfered in routine life within last month," they were excluded and provided a list of mental health resources for access. Eligible and willing students received detailed information in-person about the study and provided informed written consent. Participants were able to select an honorarium of Can $50 or 2% in course grade (for professors who gave this permission) or three 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, 24×7 "Good To Talk" helpline for postsecondary students in Ontario). Although our study participants largely comprised healthy volunteers, our protocol included a safety mechanism whereby participants were asked verbally and in the consent form to contact the research staff if they felt distress during the trial period so that "limited counselling with a clinical psychologist could be arranged, if needed"; the collaborating psychologist

was at arms' length from the trial. No instance of such request arose during the reported study.

Participating students were randomized to either the F-MVC intervention, P-MVC intervention, WLC, or a face-to-face CBT mindfulness group using 1:1:1:1 block randomization. We report here the impact of F-MVC and P-MVC vs WLC, whereas the results for face-to-face CBT mindfulness are being presented elsewhere (manuscript under review). The randomization allocation sequence was computer-generated by an off-site team member who concealed it in sequentially numbered, opaque envelopes [61]. These envelopes were opened only after a written consent, keeping participants and research assistants blind to allocation. Each participant received a unique ID number. Those in the F-MVC and P-MVC groups also received a temporary password to access the Web-based intervention; they changed the password after first login while IDs remained the same to eliminate the possibility of creating multiple accounts or identities.

Main Outcomes and Measurement

Participants in all groups completed online surveys at T1, T2, and T3. The primary outcomes were depression, anxiety, and stress symptoms. For the measurement of depression symptoms, we used the 9-item Patient Health Questionnaire (PHQ-9) [62]; each item is rated on a scale of 0 to 3, and the total score range is 0 to 27 (score 0-9 indicates no/subclinical level of depression, 10-14 moderate, 15-19 moderately severe, and ≥20 severe). The symptoms of anxiety were measured by using the 21-item Beck Anxiety Inventory (BAI) [63]; each item is rated on a scale of 0 to 3, and the total score range is 0 to 63 (score 0-21 indicates no/low level of anxiety, 22-35 moderate, and ≥36 severe). For the measurement of stress, we used the 10-item Perceived Stress Scale (PSS) [64]; each item is rated on a scale of 0 to 4, and the total score range is 0 to 40 (score 0-13 indicates mild level of stress, 14-26 moderate, and 27-40 high). The secondary outcomes were quality of life, life satisfaction, and mindfulness. We used the 16-item Quality of Life Scale (QOLS) [65], which has a total score range of 16 to 112, and each item is rated on a scale of 1 to 7. The student life satisfaction was measured by using the 6-item Brief Multidimensional Students' Life Satisfaction Scale-Peabody Treatment Progress Battery (BMSLSS-PTPB) [66]; each item is rated on a scale of 1 to 5, and item scores are averaged together to give a total score that ranges from 1 to 5. The level of mindfulness was measured by the 24-item Five-Facet Mindfulness Questionnaire-Short Form (FFMQ-SF) [67]; each item is rated on a scale of 1 to 5, and the total score range is 24 to 120. The subscales in the FFMQ-SF are nonreactivity to inner experience (5 items), observing (4 items), acting with awareness (5 items), describing (5 items), and nonjudging of inner experience (5 items). We assessed each of the scale for internal consistency at the T1, T2, and T3 datasets, and Cronbach alpha ranged from .82 to .94: PHQ-9 .87, .89, and .86; BAI .93, .93, and .94; PSS .90, .89, and .90; QOLS .87, .91, and .92; BMSLSS-PTPB .82, .85, and .85; and FFMQ-SF .86, .87, and .89.

Participants also completed a sociodemographic questionnaire at the T1 survey that inquired about age, gender, birth country, years lived in Canada, first language, ethnic heritage, intimate relationship status, self-rated health (from poor to excellent), access to private mental health counseling, paid and unpaid work, and average minutes spent per week on rigorous physical activities. The T3 survey also asked all participants to report their self-perceived change in the academic performance (worse, same, or better) and in class attendance/absenteeism (more frequent, about same, or less frequent) since the start of this study. The T3 survey for the F-MVC and/or P-MVC groups also included questions on module use (number of videos watched in full, average frequency of watching each video), exchanges during discussion forums (for appropriateness, supportiveness, and informativeness), and videoconferences (for ease in access, convenience, help in understanding personal mindfulness practice and mental well-being, and help via the direct messaging feature). Participants answered using a scale of 1 to 5 (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree) for questions on the discussion forum and videoconferences.

Sample Size and Analysis

The outcomes of the study are continuous and measured at T1, T2, and T3. We calculated the sample size assuming the intraclass correlation coefficient to be 0.6 and standardized effect size to be 0.5 or larger. Following Hedeker et al's [68] results for sample size calculation for longitudinal study, a sample size of 47 students in each arm provides 80% power to detect significance of standardized changes of size 0.5 or larger with 5% type I error.

The trial data were first analyzed using descriptive statistics (means, frequencies, and proportions) to describe the sample characteristics for the control, partial intervention, and the full intervention groups at T1. The mean scores for each of the 6 scales (ie, primary and secondary outcomes) were calculated for the T1, T2, and T3 for the three groups. Effect size was calculated using Cohen *d*, by subtracting the mean of the treatment group from the mean of the control group and by dividing the mean difference with the pooled SD.

The approach to the outcome analysis was Intention-to-Treat. First, we analyzed the data without any imputation for missing values and then repeated the analysis with an imputation of missing values using a last observation carried forward (LOCF) method. The results were similar for the complete-case analysis and analysis with LOCF; both are reported (see Multimedia Appendices 1 and 2). The attrition rates across the three groups were low and similar between T1 and T3 (2 for F-MVC, 1 for P-MVC, and 1 for WLC). To compare score changes over time for the outcomes, linear regression analysis was done. The generalized estimation equation (GEE) with AR(1) covariance structure was used to adjust for repeated measures. The result of GEE analysis has the interpretation of population average. The mean score differences were calculated between groups and adjusted for potential confounding variables (ie, gender, age, country of birth, paid work, unpaid work, vigorous physical activities, self-rated health, and access to mental health private counseling via insurance). This choice of confounding variables was based on existing knowledge and theory. Scales were calculated as follows: if the number of missing items was more than half of the number of items of a scale, the scale was

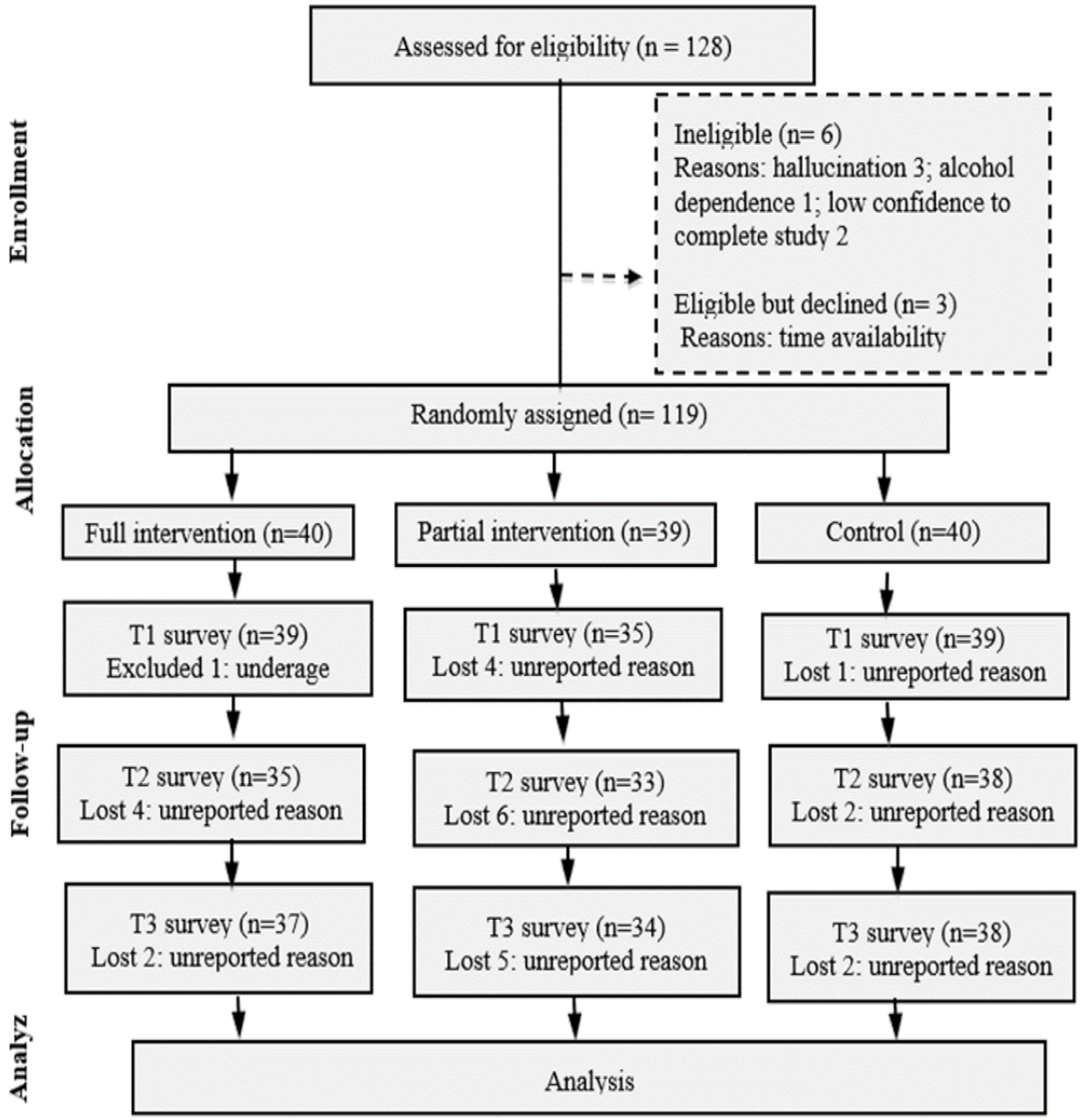
considered missing; otherwise the missing items were imputed in accord with the average of the nonmissing items of the scale. To account for multiple comparisons, due to the multiple outcomes analyzed, we considered $P<.02$ as statistically significant. The data analysis was conducted by biostatistician on our team (RM) who was not involved in the content development of the intervention and its deployment. The statistical software SAS 9.4 was used for statistical analyses.

Results

Participants

A total of 119 undergraduate students were randomized to the WLC, F-MVC, and P-MVC groups; 1 participant, following consent, was found to be underage and was therefore excluded, and 5 additional participants were nonrespondents to the T1 survey. Out of the 113 students who completed the T1 survey, a few were lost as nonrespondents at the follow-up; altogether the attrition was relatively low across all three groups (F-MVC: 2/39, P-MVC: 1/35, and WLC: 1/39; Figure 3).

Figure 3. Study flow diagram. T1: baseline; T2: 4 weeks; T3: 8 weeks.



Overall, there were 24.8% (28/113) males and 75.3% (85/113) females. The majority of participants, 59.3% (67/113), were born in Canada, and 64.6% (73/113) reported English as their first language, whereas 37.2% (42/113) self-identified as white. These and other characteristics seemed to be similarly distributed between the control and intervention groups (Table 2).

Table 2. Participant characteristics.

Characteristics	All (N=113)	Control (n=39)	Full intervention (n=39)	Partial intervention (n=35)
Age (years), mean (SD)	24.8 (6.5)	25.4 (7.3)	24.9 (6.4)	24.1 (5.7)
Gender, n (%)				
Male	28 (24.8)	8 (21)	10 (26)	10 (29)
Female	85 (75.2)	31 (80)	29 (74)	25 (71)
Country of birth, n (%)				
Canada	67 (59.3)	22 (56)	26 (67)	19 (54)
Other	46 (40.7)	17 (44)	13 (33)	16 (46)
Years in Canada, mean (SD)	4.5 (7.4)	5.6 (8.4)	2.2 (4.7)	5.7 (8.1)
First language, n (%)				
English	73 (64.6)	23 (59)	26 (67)	11 (31)
Other	40 (35.4)	16 (41)	13 (33)	24 (69)
Relationship status, n (%)				
Single, no relationship	68 (60.2)	17 (44)	32 (82)	32 (54)
Single in relationship	37 (32.7)	17 (44)	6 (15)	14 (40)
Married/common law	8 (7.1)	5 (13)	1 (3)	2 (6)
Ethnicity, n (%)				
White	42 (37.2)	17 (44)	13 (33)	12 (34)
Black	11 (9.7)	4 (10)	4 (10)	3 (9)
South Asian	22 (19.5)	7 (18)	5 (13)	10 (29)
Chinese	12 (10.6)	1 (2)	7 (18)	4 (11)
Other	26 (23.0)	10 (26)	10 (26)	6 (17)
Self-rated health, n (%)				
Poor/fair	29 (25.9)	11 (29)	6 (15)	12 (34)
Good	45 (40.2)	11 (29)	19 (49)	15 (43)
Very good/excellent	38 (33.9)	16 (42)	14 (36)	8 (23)
Access to private mental health, n (%)				
Yes	49 (43.8)	13 (34)	19 (49)	17 (49)
No	63 (56.2)	25 (66)	20 (51)	18 (51)
Weekly hours, mean (SD)				
Paid work	7.6 (9.9)	10.1 (11.1)	7.9 (10.5)	4.6 (7.0)
Unpaid work	3.7 (4.9)	3.4 (4.4)	4.4 (6.0)	3.2 (4.3)
Weekly vigorous physical activities in minutes, mean (SD)	30.2 (57.8)	25.3 (52.4)	16.4 (26.3)	50.7 (80.4)

Depression, Anxiety, and Stress Symptoms

Table 3 provides the proportion of participants at T1 and T3 for various levels of symptoms for depression, anxiety, and stress; 1 participant did not complete the mental health scales. In the total sample, 36.6% (41/112) had PHQ-9 scores ≥10, and 20.5% (23/112) had a BAI score ≥22, indicating probable clinical depression and anxiety. In the F-MVC group, 28% (11/39) and 19% (7/37) had PHQ-9 scores ≥10 at T1 and T3, respectively, and 23% (9/39) and 14% (5/37) had BAI scores ≥22 at T1 and T3, respectively. In the P-MVC group, the proportions for T1 and T3 were 40% (14/35) and 24% (8/33) for PHQ-9 ≥10, and 20% (7/35) and 18% (6/33) for BAI ≥22, respectively.

The T1, T2, and T3 means and SDs are presented in Tables 4 and 5 for the 6 scales used in the study. These tables also provide the Cohen *d* effect size for mean difference in the F-MVC group compared with the control group and the mean difference in the P-MVC group compared with the control group at both T2 and T3. Figure 4 presents the mean scores for primary outcomes as box plots.

Table 3. Symptom levels for depression, anxiety, and stress scales.

Characteristics	Control (n=38)		Full intervention (n=39)		Partial intervention (n=35)	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Patient Health Questionnaire 9-item						
T1[a] score 0-9	22 (58)	40.1-73.7	28 (72)	55.1-85.0	21 (60)	42.1-76.1
T1 score ≥10	16 (42)	26.3-59.2	11 (28)	15.0-44.9	14 (40)	23.9-57.9
T3[b] score 0-9	21 (55)	38.3-71.4	30 (81)	64.8-92.0	25 (76)	57.7-88.9
T3 score ≥10	17 (45)	28.6-61.7	7 (19)	8.0-35.2	8 (24)	11.1-42.3
Beck Anxiety Inventory 21-item						
T1 score 0-21	31 (82)	69.3-93.9	30 (77)	63.7-90.1	28 (80)	66.7-93.3
T1 score ≥22	7 (18)	7.7-34.3	9 (23)	11.1-39.3	7 (20)	8.4-36.9
T3 score 0-21	26 (68)	53.6-83.2	32 (87)	75.5-97.5	27 (82)	68.7-95
T3 score ≥22	12 (32)	17.5-48.7	5 (14)	4.5-28.8	6 (18)	5.0-31.3
Perceived Stress Scale 10-item						
T1 score 0-13	4 (11)	0.8-20.3	9 (23)	9.9-36.3	8 (23)	8.9-36.8
T1 score ≥14	34 (90)	75.2-97.1	30 (77)	60.7-88.9	27 (77)	59.9-89.6
T3 score 0-13	6 (16)	4.2-27.4	13 (35)	19.8-50.5	11 (33)	17.2-49.4
T3 score ≥14	32 (84)	68.7-94.0	24 (65)	49.5-80.2	22 (67)	48.2-82.0

[a]T1: baseline.

[b]T3: 8 weeks.

Table 4. Mean (SD) and effect size for depression, anxiety, and stress scales.

Time of measurement	Control (n=38)	Full intervention		Partial intervention	
	Mean (SD)	Mean (SD)	Effect size	Mean (SD)	Effect size
Patient Health Questionnaire 9-item					
T1[a]	9.1 (6.2)	8.1 (6)[b]	N/A[c]	8.7 (6.3)[d]	N/A
T2[e]	8.9 (6.9)	6.3 (4.8)[f]	−0.43	7.1 (4.8)[g]	−0.30
T3[h]	9.7 (6.9)	6 (3.9)[i]	−0.66	6.7 (3.9)[j]	−0.53
Beck Anxiety Inventory 21-item					
T1	13.9 (12.9)	14.7 (11.5)[b]	N/A	14.4 (12.8)[d]	N/A
T2	14 (13.2)	12.2 (10.6)[f]	−0.15	11.5 (9.6)[g]	−0.21
T3	14.2 (12.6)	10.2 (11.1)[i]	−0.34	10.2 (9.6)[j]	−0.35
Perceived Stress Scale 10-item					
T1	20.6 (7.8)	19.2 (7.5)[b]	N/A	19.7 (7.8)[d]	N/A
T2	20.8 (7.9)	17.4 (6.3)[f]	−0.47	18.2 (7.3)[g]	−0.34
T3	21.9 (8.2)	16.1 (6.6)[i]	−0.78	17.3 (7.1)[j]	−0.60

[a]T1: baseline.
[b]N=39.
[c]Not applicable.
[d]N=35.
[e]T2: 4 weeks.
[f]N=34.
[g]N=32.
[h]T3: 8 weeks.
[i]N=37.
[j]N=33.

Table 5. Mean (SD) and effect size for quality of life, life satisfaction, and mindfulness scales.

Time of measurement	Control (n=38)	Full Intervention		Partial Intervention	
	Mean (SD)	Mean (SD)	Effect size	Mean (SD)	Effect size
Quality of Life Scale 16-item					
T1[a]	73.5 (16.4)	74.4 (12.4)[b]	N/A[c]	74.7 (12.9)[d]	N/A
T2[e]	71.5 (15.8)	74.4 (14.2)[f]	0.19	75.4 (14.4)[g]	0.26
T3[h]	69.7 (16.3)	78.2 (14)[i]	0.56	77.9 (14.1)[j]	0.54
Brief Multidimensional Students' Life Satisfaction Scale- Peabody Treatment Progress Battery 6-item					
T1	3.5 (0.9)	3.6 (0.8)[b]	N/A	3.6 (0.8)[d]	N/A
T2	3.5 (0.9)	3.7 (0.8)[f]	0.23	3.6 (0.9)[g]	0.11
T3	3.3 (1)	3.8 (0.8)[i]	0.55	3.7 (0.9)[j]	0.42
Five-Facet Mindfulness Questionnaire-Short Form 24-item					
T1	76.8 (14.2)	71.4 (14.7)[b]	N/A	73.9 (9.9)[d]	N/A
T2	76.6 (12.6)	76.6 (13)[f]	0.00	74.9 (10.8)[g]	−0.14
T3	75.9 (15.6)	78.1 (15.4)[i]	0.14	78.5 (10.7)[j]	0.19
Nonreact construct					
T1	15.4 (3.3)	13.3 (3.2)[b]	N/A	13.8 (4.3)[d]	N/A
T2	14.9 (3.6)	14.5 (3)[f]	−0.12	14.5 (3.9)[g]	−0.11
T3	14.6 (4.1)	15.5 (3.3)[i]	0.24	15.5 (4.3)[j]	0.21
Observe construct					
T1	14.6 (3.7)	12.3 (3.8)[b]	N/A	13.2 (3.8)[d]	N/A
T2	14.2 (3.4)	13.6 (2.9)[f]	−0.19	12.7 (3.4)[g]	−0.44
T3	14.8 (3.8)	13.3 (3.4)[i]	−0.42	13.4 (3.1)[j]	−0.40
Act aware construct					
T1	15.4 (4.6)	16.2 (5.2)[b]	N/A	15.5 (4.5)[d]	N/A
T2	15.6 (4.9)	16.5 (3.9)[f]	0.20	16 (4.2)[g]	0.09
T3	14.4 (5.5)	16.3 (4)[i]	0.39	16.6 (4.6)[j]	0.43
Describe construct					
T1	16.5 (4.6)	15.4 (4.7)[b]	N/A	16.7 (3.7)[d]	N/A
T2	16.4 (4.1)	16.6 (3.8)[f]	0.05	17.2 (3.7)[g]	0.20
T3	16.7 (4.7)	17 (4.4)[i]	0.07	18 (4.1)[j]	0.29
Judge construct					
T1	14.8 (4.3)	14.3 (4.5)[b]	N/A	14.7 (3.9)[d]	N/A
T2	15.4 (4)	15.4 (4.6)[f]	0.00	14.4 (4.1)[g]	−0.25
T3	15.6 (5.2)	16 (4.7)[i]	0.08	15.1 (4.3)[j]	−0.10

[a]T1: baseline.

[b]N=39.

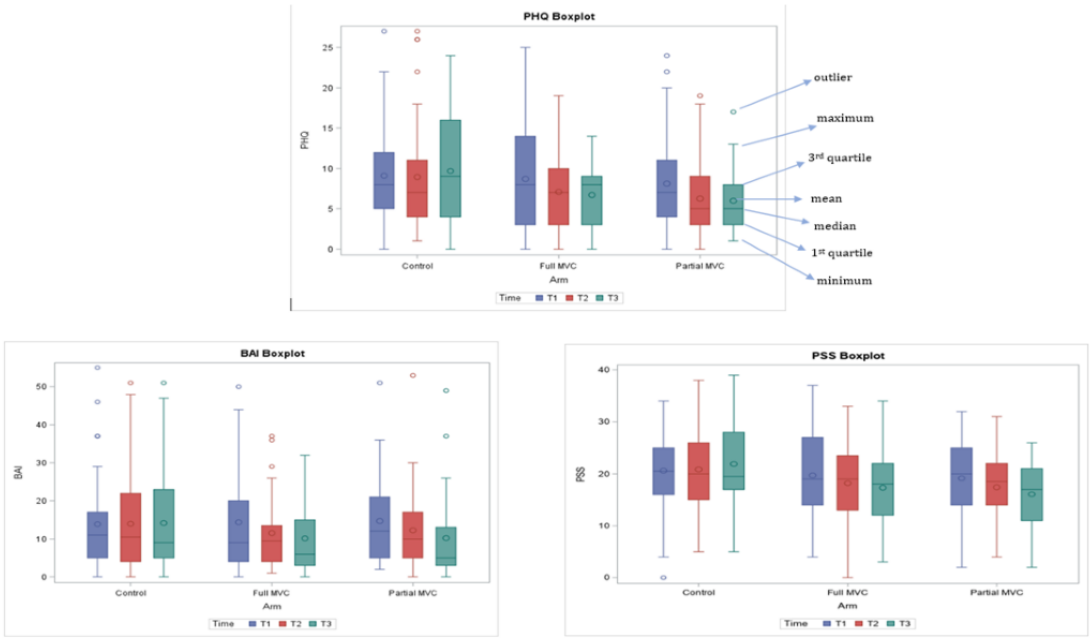
[c]Not applicable.

[d]N=35.

[e]T2: 4 weeks.

[f]N=34.
[g]N=32.
[h]T3: 8 weeks.
[i]N=37.
[j]N=33.

Figure 4. Box plots for the mean scores of depression, anxiety, and stress scales. BAI: Beck Anxiety Inventory; MVC: Mindfulness Virtual Community; PHQ: Patient Health Questionnaire; PSS: Perceived Stress Scale; T1: baseline; T2: 4 weeks; T3: 8 weeks.



Results for Primary Outcomes

Table 6 shows the difference in the mean scores of the primary outcomes between T1 and T2 and T1 and T3 in the P-MVC and F-MVC groups compared with the WLC group. GEE method with AR(1) covariance structure was used, adjusting for potential confounding variables of age, gender, country of birth, paid work, unpaid work, self-rated health, weekly vigorous physical activities, and access to mental health private counseling via insurance.

In relation to *depression* in the F-MVC group compared with the WLC group, score reductions for PHQ-9 at T2 and T3 were statistically significant in both unadjusted (T2 unadjusted score change −2.47; *P*=.01; T3 unadjusted score change −3.39; *P*<.001) and adjusted (T2 adjusted score change −3.00; *P*=.015; T3 adjusted score-change −4.03; *P*<.001) analysis. The P-MVC group compared with the control group at T2 showed significant PHQ-9 score reduction on adjusted analysis (T2 adjusted score change −3.49; *P*=.01), whereas the difference was statistically significant at T3 in both unadjusted (T3 unadjusted score change −2.70; *P*=.01) and adjusted (T3 adjusted score change −4.82; *P*<.001) analysis. In relation to *anxiety* in the F-MVC group compared with the WLC group, there was no statistically significant score reduction for BAI at T2 or T3 in adjusted analysis (see details in Table 6). However, the effect of the P-MVC intervention on BAI score reduction reached statistical significance at T3 in adjusted analysis (T3 adjusted score change −7.35; *P*=.008). Compared with the WLC group, the F-MVC intervention also had a significant effect in reducing PSS stress score at both T2 in unadjusted analysis (T2 unadjusted score change −3.08; *P*=.015) and at T3 in unadjusted and adjusted analysis (T3 unadjusted score change −5.28; *P*<.001; T3 adjusted score change −5.32; *P*<.001). For the P-MVC, the PSS score reduction reached statistical significance only at T3 in unadjusted and adjusted analysis (T3 unadjusted score change −3.90; *P*=.009; T3 adjusted score change −5.61; *P*=.005).

Table 6. Generalized estimation equation with complete cases for score difference in depression, anxiety, and stress scales.

Score change at	Full intervention compared with control, mean score difference				Partial intervention compared with control, mean score difference			
	Unadjusted (SE)[a]	*P* value[b]	Adjusted[c] (SE)	*P* value	Unadjusted (SE)	*P* value	Adjusted (SE)	*P* value
Patient Health Questionnaire 9-item								
T2[d]	−2.47 (0.98)	*.01*	−3.00 (1.21)	*.015*	−1.50 (1.06)	.16	−3.49 (1.38)	*.01*
T3[e]	−3.39 (0.97)	*<.001*	−4.03 (1.20)	*<.001*	−2.70 (1.06)	*.01*	−4.82 (1.38)	*<.001*
Beck Anxiety Inventory 21-item								
T2	−2.18 (2.04)	.29	−0.54 (2.63)	.84	−2.62 (2.06)	.21	−5.45 (2.71)	.047
T3	−4.82 (2.02)	*.019*	−3.21 (2.61)	.22	−4.22 (2.05)	.04	−7.35 (2.71)	*.008*
Perceived Stress Scale 10-item								
T2	−3.08 (1.24)	*.015*	−3.06 (1.62)	.06	−1.91 (1.47)	.19	−3.52 (1.97)	.08
T3	−5.28 (1.23)	*<.001*	−5.32 (1.60)	*<.001*	−3.90 (1.46)	*.009*	−5.61 (1.97)	*.005*

[a]SE of the mean score difference.

[b]*P* values <.02 are considered significant (shown in italic) to account for multiple comparisons.

[c]Adjusted for sex, age, country of birth, paid work, unpaid work, self-rated health, vigorous physical activities, and access to mental health private counseling via insurance.

[d]T2: 4 weeks.

[e]T3: 8 weeks.

Results for Secondary Outcomes

Table 7 shows the score differences in the secondary outcomes between T1 and T2 and T1 and T3 in the P-MVC and F-MVC groups compared with the WLC group. Compared with the control group, changes in the QOLS score for quality of life at T3 showed statistically significant increase in unadjusted and adjusted analysis for both F-MVC (T3 unadjusted score change 8.67; *P*<.001; T3 adjusted score change 9.86; *P*<.001) and P-MVC groups (T3 unadjusted score change 7.21, *P*=.01; T3 adjusted score change 12.85, *P*<.001). The student life satisfaction measured by BMSLSS-PTPB showed statistically significant increase in the score only for the F-MVC group compared with the WLC group at T3 in unadjusted analysis (T3 unadjusted score change 2.69; *P*<.001). In terms of the level of mindfulness, FFMQ-SF scores improved when compared with controls in a statistically significant manner at T3 for F-MVC in unadjusted analysis (T3 score-change 7.8; *P*=.002) and for P-MVC in adjusted analysis (score change 6.83; *P*=.01).

Table 7. Generalized estimation equation with complete cases for score difference in quality of life, life satisfaction, and mindfulness scales

Score change at	Full intervention compared with control, mean score difference				Partial intervention compared with control, mean score difference			
	Unadjusted (SE)[a]	*P* value[b]	Adjusted[c] (SE)	*P* value	Unadjusted (SE)	*P* value	Adjusted (SE)	*P* value
Quality of Life Scale 16-item								
T2[d]	3.04 (2.40)	.21	4.16 (2.86)	.15	3.16 (2.80)	.26	8.57 (3.81)	.03
T3[e]	8.67 (2.37)	*<.001*	9.86 (2.83)	*<.001*	7.21 (2.76)	*.01*	12.85 (3.78)	*<.001*
Brief Multidimensional Students' Life Satisfaction Scale- Peabody Treatment Progress Battery 6-item								
T2	1.34 (0.73)	.07	0.49 (1.03)	.64	0.28 (0.91)	.76	−0.08 (1.36)	.95
T3	2.69 (0.73)	*<.001*	1.85 (1.02)	.07	1.66 (0.90)	.07	1.32 (1.35)	.33
Five-Facet Mindfulness Questionnaire-Short Form 24-item								
T2	4.96 (2.50)	.05	3.02 (3.26)	.36	−0.62 (1.98)	.75	1.50 (2.74)	.59
T3	7.80 (2.48)	*.002*	6.02 (3.25)	.07	4.44 (1.95)	.03	6.83 (2.72)	*.01*

[a]SE of the mean score difference.

[b]*P* values <.02 are considered significant (shown in italic) to account for multiple comparisons.

[c]Adjusted for sex, age, country of birth, paid work, unpaid work, self-rated health, vigorous physical activities, and access to mental health private counseling via insurance.

[d]T2: 4 weeks.

[e]T3: 8 weeks.

Academic Performance/Absenteeism and Use of Intervention

There was a statistically significant difference in the three groups at 8-week assessment in their self-perceived academic performance, X^2_4=13.6 (n=109); *P*=.008, and in the class absenteeism, X^2_4=17.2 (n=109); *P*=.002. For the academic performance, 32% (14/37) and 38% (11/34) of the students in the F-MVC and P-MVC groups, respectively, chose "seems better" in comparing current performance with what their performance was at the start of the study; the proportion was 8% (3/38) for "seems better" in the WLC group. For the class absenteeism, 19% (7/37) and 29% (10/34) of the students in the F-MVC and P-MVC groups, respectively, chose "less frequent," whereas the proportion was 5% (2/38) in the WLC group.

In terms of the number of videos watched from "start to finish," 65% (24/37) in the F-MVC group reported 7 to 12 videos for both the educational and mindfulness content. In the P-MVC group, 38% (13/34) reported watching 7 to 12 videos from "start to finish" for the educational content and 50% (17/34) for the mindfulness content. In response to this question, a handful chose "not applicable" in the F-MVC group (education 3/37, 8%; mindfulness 1/37, 3%) and in the P-MVC group (education 3/34, 9%; mindfulness 3/34, 9%), indicating nonuse by only a few participants. On comparing the two groups for watching less than 7 or greater than or equal to 7 videos from "start to finish," the greater use of educational videos in the F-MVC group reached statistical significance, X^2_1=5.4 (n=65); *P*=.019. When asked about the "average frequency" of watching each video, the majority reported "one time" in both the F-MVC (education 24/37, 65%; mindfulness 17/37, 46%) and P-MVC (education 26/34, 77%; mindfulness 23/34, 68%) groups. Some used each video greater than or equal to 2 times in both the F-MVC (education 11/37, 30%; mindfulness 18/37, 49%) and P-MVC (education 5/34, 15%; mindfulness 8/34, 24%) groups. On group comparison for "average frequency" of using each video less than 2 or greater than or equal to 2 times, the more frequent use of mindfulness-practice videos in the F-MVC group reached statistical significance, X^2_1=4.5 (n=68); *P*=.033.

Participants in the F-MVC group also evaluated the discussion forums and videoconferencing. For the exchanges on discussion forums, participants "agreed" as to the appropriateness (mean 3.7, SD 0.77), supportiveness (mean 3.4, SD 0.82), and informativeness (mean 3.3, SD 0.77). There were 7 participants (7/27, 18.9%) who chose "not applicable" for questions on the discussion forum, indicating their nonuse. For the videoconferencing, participants "agreed" regarding its help in better understanding mindfulness practice and mental well-being (mean 3.8, SD 0.85), about help via direct message opportunity (mean 3.7, SD 1.0), as well as about ease in accessing the session (mean 3.7, SD 1.0), and session convenience (mean 3.5, SD 1.0). A total of 4 participants (4/37, 10.8%) chose "not applicable" for questions on the videoconferencing, indicating the absence of use.

Discussion

Principal Findings

The study investigated the efficacy of MVC, an 8-week internet-based mindfulness-CBT intervention aimed at reducing symptoms of anxiety, depression, and stress in undergraduate students. The Web-based full intervention, F-MVC, comprised 12 video-based modules with psychoeducational content and topically applied mindfulness practices that were released on alternate days over a 4-week period. This was followed by module access for additional 4 weeks. There were also peer-to-peer anonymous and asynchronous discussion forums for 4 weeks, and 20-min live videoconferences on mindfulness practice with a mental health professional on alternate days over the first 4 weeks. The partial intervention, P-MVC, comprised only the video-based modules, with the access schedule similar to the F-MVC intervention. Both forms of interventions were supported through email reminders over the initial 4 weeks, sent before the release of each module.

On testing, the F-MVC and the P-MVC interventions both significantly reduced scores for depression symptoms (PHQ-9), compared with the control group, at T3. The mean depression scores of participants generally reduced from the high end of subclinical depressive symptoms to the lower end. Within groups, the proportion of participants with scores of PHQ-9 ≥10 (a cutoff used to represent moderate-to-severe depression) at T3 reduced by 9% in the F-MVC and 16% in the P-MVC intervention groups. It is possible that the 8-week gains might be followed by additional positive change over the long term through continued practice of mindfulness and skill building; future research with longer follow-up periods would serve to examine such potential changes. The effects of both interventions on reducing the mean scores of perceived stress (PSS) were similar and statistically significant at T3, when compared with the controls. Another key finding of this study is that, on adjusted analysis, only the P-MVC intervention was effective in significantly reducing anxiety scores (BAI), compared with the controls, at T3, whereas the F-MVC intervention solely had a significant impact on BAI in the unadjusted analysis at T3. Although this finding could be due to inadequate sample power, the finding that the video intervention when combined with professional interactions (ie, discussion forum and videoconference) did *not* reduce anxieties, whereas the partial intervention (without professional contacts) did have a significant anxiety reduction effect may be instructive. Anxious subjects, avoidant of health professional contacts, might have responded more positively when assured that the entire program was Web-based and did not involve any "live" interactions. As the video and audio contacts apparently solely effectively reduced participant anxiety and depression levels, this finding has cost implications given that personnel costs often constitute the largest proportion of Web-based intervention costs. If the developed videos (with associated audios) are effective without the assistance of paid personnel, per participant costs may be reduced.

In terms of the secondary outcomes, both F-MVC and P-MVC interventions significantly increased quality of life scores at T3,

compared with the controls, per adjusted analysis. The scores for the self-reported levels of mindfulness increased within both intervention groups at T3, but the group differences (in comparison with controls) were statistically significant only for the P-MVC group per adjusted analysis; the F-MVC group-associated results were statistically significant only in the unadjusted analysis. Among the five constructs of the FFMQ-SF scale, the *act aware* and *observe* subscales approached a moderate effect size of 0.4 at T3. The *describing* subscale had an effect size of 0.3 only in the P-MVC at T3. Another important finding was better self-reported academic performance and less absenteeism reported by the F-MVC and P-MVC respondents at T3, which was significantly different than the self-reports of the controls. Overall, the positive results for several of the examined secondary outcomes support the use of the MVC intervention in reducing depression, anxiety, and stress symptoms in an undergraduate student population.

Strengths and Limitations

To the best of our knowledge, this is the first RCT of a Web-based interactive mindfulness-CBT program for college students in Canada. The study was implemented in a university setting with validated self-report standard instruments to measure the outcomes, completed by participants through online surveys to ensure accuracy and consistency in data collection. However, our recruitment was limited to a single institution, and the sample size was modest; both of these study elements warrant caution in interpreting and generalizing the results. Furthermore, the probability of reporting bias cannot be discounted due to the use of self-administered assessments, although such bias would be theoretically similar across study arms. We were unable to keep the participants blind to the intervention and control conditions once they opened the allocation envelopes after consenting. Another limitation is that two-third of the sample comprised female students, although female majority participation is a frequent finding in online study samples [38,41]. Nonetheless, our randomization worked, as gender was similarly distributed between the control and intervention groups (Table 2). In future research, stratification for gender would ensure more equal male-female samples. Future research with larger samples recruited from multiple universities and colleges would better test the generalizability of results. Another area for advancement is the collection of background use analytics, which was not built-in to our tested platform; although we gathered self-reported intervention use data that were encouraging.

Comparison With Prior Work

Although mindfulness and CBT-based interventions have been reported as effective in reducing self-reported symptoms of anxiety and depression, few studies have investigated internet-based versions of such interventions. The results of our study are aligned with a handful of studies on Web-based mindfulness with student populations. For example, Nguyen et al [69] reported that their Web-based mindfulness intervention for students led to significant reductions in scores for depression, anxiety, and stress over time, although this was not significantly different from a group who received a Web-based general stress management intervention. Another Web-based mindfulness training program, which involved 8 weekly sessions with telephone support, also resulted in improved mental well-being, life satisfaction, energy, and reduced pain among students, although a pure control group was lacking [46]. Similarly, a brief Web-based mindfulness intervention by Cavanagh et al [48] was associated with significant reductions of scores for depression, anxiety, and perceived stress compared with a waitlist group, but the observed attrition rate was relatively high. Some studies have effectively used Web-based acceptance and commitment therapy [43,49] and found it effective in improving depression symptoms and psychological and physiological symptoms as well as associated with high levels of satisfaction. Likewise, in our study the life satisfaction scores statistically improved though only for the F-MVC group at T3. The findings of other studies and this study with students lend support to the effectiveness of Web-based mindfulness-CBT interventions for addressing common mental health disorders and promoting mental well-being among students.

The positive impacts of the studied intervention arms, F-MVC and P-MVC, on improving the academic performance and reducing the class absenteeism are noteworthy not only for the students themselves but for the academic institutions as well. These findings are consistent with emerging research on education and mindfulness that show increases in students' focus on the task at hand and improved study habits and organization through a calmer view of their present situation [70,71]. Others have shown that mindfulness increases memory and concentration and reduces exam anxiety [72]. Given the difficulties experienced by youth entering postsecondary institutions, including students who drop out with long-term consequences, there is a need to advance further research and application of mindfulness-CBT tools, such as Web-based MVC.

The results of our study generate evidential support for CBT-informed mindfulness-based intervention in comparison with the control group, unlike other existing studies with students. The insights obtained about gains in mindfulness assessed with the FFMQ can contribute to the possible refinement of the MVC and other similar interventions. In our study, there was a noteworthy reduction in the FFMQ scores (when compared with controls) in the observation subscale in both the F-MVC and P-MVC arms at T2 and T3 (see Table 5). The observation subscale is largely associated with awareness of sensory-emotional experiences. Interestingly, the acting with awareness subscale, representing more generic instances of focal attention vs distractibility, increased in relation to controls. The increase in mean scores for the *acting with awareness* subscale is aligned with previous studies. For example, a longitudinal study with adolescents revealed that the *acting with awareness* subscale predicted a reduction in depression over time [73].

A unique feature of our study is testing both the full and partial MVC interventions. Findings supporting the reduction in anxiety symptoms among participant students who only used Web-based video modules offer a cost-effective way to address prevalent anxiety symptoms in postsecondary institutions. The student engagement process in our intervention is also noteworthy. Other Web-based mindfulness studies have revealed high attrition rates as a common problem, especially for those where

the interactive methods used were limited [44-46,48,50]. Compared with these studies, we used more interactive methods to engage students, and this may have been effective in keeping attrition very low. Furthermore, only 8%, 19%, and 11% in the intervention groups chose "not applicable" when asked about their use of video-based modules, discussion forums, and videoconferencing, respectively. This suggests that a low number of participants did not access these intervention components. For wider use of Web-based programs among students, engagement strategies seem to be vital in ensuring optimal participation, retention, and completion for positive outcomes. With the widespread accessibility of internet and the evidence from literature including this study, Web-based mindfulness-CBT interventions such as MVC could effectively reduce symptoms of depression, anxiety, and stress among students and in a cost-efficient manner. Personal visits to a professional for mental health concerns are not the only economic burden on both users and the system; difficulties to access also exist for students because of mental health stigma and the challenges of commuting to and scheduling service delivery visits [16,17]. Our work informs the designing of appropriate programs accessed by students at their convenience, with some limited moderation by a mental health professional.

Conclusions

The study demonstrated the effectiveness of an internet-based mindfulness-CBT intervention in reducing depression, anxiety, and stress symptoms among students. The student-centered design of the platform, which included design features identified through focus groups, might have contributed to the positive impact and reduced attrition. Further studies with larger samples are needed to enhance the generalizability of study results. In addition, larger samples are likely to enhance understanding from the perspective of clinical recovery by examining the number of individuals who experience a shift from the moderate or severe levels of depression or anxiety to lower levels and enhanced functioning. Nonetheless, current findings suggest that Web-based mindfulness-CBT interventions, such as the one studied here, offer a good opportunity to address common mental health conditions in a postsecondary population while simultaneously reducing the burden on traditional counseling and services.

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Authors' Contributions

FA, CE, and PR designed the study and questionnaire and received the funds and contributed equally. PR led module development, providing written content and voice. RM analyzed the data, and NO assisted in preparing tables. FA prepared the first draft, and all authors provided critical feedback and revised it. The MVC Team members are (alphabetical) Iqra Ashfaq, MSc; Yvonne Bohr, PhD; Manuela Ferrari, PhD; Wai Lun Alan Fung MD, ScD, FRCPC; Louise Hartley, PhD; Catherine Maule, MSc; Amin Mawani, PhD; Kwame McKenzie, MD, FRCPC; and Spencer Williams, BSc; they made contributions to several aspects of the project and results development. All authors approved the final version; FA, CE, PR, NO, and RM agreed to be accountable for all aspects of the submitted paper. The trial protocol can be accessed upon request from the corresponding author.

Conflicts of Interest

It is the understanding of the university and researchers that the Project Intellectual Property belongs to the CE, FA, and PR. The industry partner ForaHealthyme has title to the copyrights of any computer source code software that was developed out of this research project.

Multimedia Appendix 1
Generalized estimation equation with last observation carried forward for score difference in depression, anxiety, and stress scales.
[DOCX File , 15 KB - mental_v7i2e15520_app1.docx]

Multimedia Appendix 2
Generalized estimation equation with last observation carried forward for score difference in quality of life, life satisfaction, and mindfulness scales.
[DOCX File , 22 KB - mental_v7i2e15520_app2.docx]

Multimedia Appendix 3

CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 539 KB - mental_v7i2e15520_app3.pdf]

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Abbreviations

BAI: Beck Anxiety Inventory
BMSLSS-PTPB: Brief Multidimensional Students' Life Satisfaction Scale-Peabody Treatment Progress Battery
CBT: cognitive behavioral therapy
CIHR: Canadian Institutes for Health Research
FFMQ-SF: Five-Facet Mindfulness Questionnaire-Short Form
F-MVC: full Mindfulness Virtual Community
GEE: generalized estimation equation
LOCF: last observation carried forward
MBCT: mindfulness-based cognitive therapy
MVC: Mindfulness Virtual Community
PHQ-9: Patient Health Questionnaire
P-MVC: partial Mindfulness Virtual Community
PSS: Perceived Stress Scale
QOLS: Quality of Life Scale
RCT: randomized controlled trial
WLC: waitlist control

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Corrigenda and Addenda

Correction: Functionality of Top-Rated Mobile Apps for Depression: Systematic Search and Evaluation

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The authors of "Functionality of Top-Rated Mobile Apps for Depression: Systematic Search and Evaluation" (JMIR Mental Health 2020;7(1):e15321) noticed two errors in their published manuscript.

The Acknowledgments section was omitted from the end of the paper. It should read:

> *This work has been supported by AffecTech: Personal Technologies for Affective Health, Innovative Training Network funded by the H2020 People Programme under Marie Sklodowska-Curie grant agreement number 722022. The research of GD is funded in part by SFI grant number 13/RC/2106 to the Adapt Centre.*

Additionally, in the Discussion section, under the subheading "Conclusions and Future Work", there was an extra word ("employing") in the following sentence:

> *In addition, the analysis of app functionality provided new insights into opportunities for mitigating harm regarding the consumption of the negative content, unrestricted access by children (with related privacy concerns), and the provision of screening employing tools with less scientific validation.*

The corrected sentence is:

> *In addition, the analysis of app functionality provided new insights into opportunities for mitigating harm regarding the consumption of the negative content, unrestricted access by children (with related privacy concerns), and the provision of screening tools with less scientific validation.*

The corrections will appear in the online version of the paper on the JMIR website on February 21, 2020, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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