JMIR Mental Health

Journal Impact Factor (JIF) (2023): 4.8
Volume 5 (2018), Issue 1 ISSN 2368-7959 Editor in Chief: John Torous, MD, MBI

Contents

Original Papers

Short Paper

Review

Original Paper

A Web-Based Toolkit to Provide Evidence-Based Resources About Crystal Methamphetamine for the Australian Community: Collaborative Development of Cracks in the Ice

Katrina Elizabeth Champion[1,2], BA Psych (Hons), BHealth, PhD; Cath Chapman[1], BA (Hons), PhD; Nicola Clare Newton[1], BPsych (Hons), PhD; Mary-Ellen Brierley[1], BPsych (Hons); Lexine Stapinski[1], BPsych (Hons), MClinPsych, PhD; Frances Kay-Lambkin[1,3], BScPsych (Hons), PhD; Jack Nagle[4]; Maree Teesson[1], BPsych (Hons), PhD

[1]National Health and Medical Research Council Centre of Research Excellence in Mental Health and Substance Use, National Drug and Alcohol Research Centre, University of New South Wales, Sydney, Australia

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

[3]Priority Research Centre for Brain and Mental Health, The University of Newcastle, Callaghan, Australia

[4]The Real Drug Talk, Melbourne, Australia

Corresponding Author:
Katrina Elizabeth Champion, BA Psych (Hons), BHealth, PhD
National Health and Medical Research Council Centre of Research Excellence in Mental Health and Substance Use
National Drug and Alcohol Research Centre
University of New South Wales
22-32 King Street, Randwick
Sydney, 2052
Australia
Phone: 61 293850333
Email: k.champion@unsw.edu.au

Abstract

Background: The use of crystal methamphetamine (ice) and the associated harms for individuals, families, and communities across Australia has been the subject of growing concern in recent years. The provision of easily accessible, evidence-based, and up-to-date information and resources about crystal methamphetamine for the community is a critical component of an effective public health response.

Objective: This paper aims to describe the codevelopment process of the Web-based *Cracks in the Ice Community Toolkit*, which was developed to improve access to evidence-based information and resources about crystal methamphetamine for the Australian community.

Methods: Development of the *Cracks in the Ice Community Toolkit* was conducted in collaboration with community members across Australia and with experts working in the addiction field. The iterative process involved the following: (1) consultation with end users, including community members, crystal methamphetamine users, families and friends of someone using crystal methamphetamine, health professionals, and teachers (n=451) via a cross-sectional Web-based survey to understand information needs; (2) content and Web development; and (3) user testing of a beta version of the Web-based toolkit among end users (n=41) and experts (n=10) to evaluate the toolkit's acceptability, relevance, and appeal.

Results: Initial end user consultation indicated that the most commonly endorsed reasons for visiting a website about crystal methamphetamine were "to get information for myself" (185/451, 41.0%) and "to find out how to help a friend or a family member" (136/451, 30.2%). Community consultation also revealed the need for simple information about crystal methamphetamine, including what it is, its effects, and when and where to seek help or support. Feedback on a beta version of the toolkit was positive in terms of content, readability, layout, look, and feel. Commonly identified areas for improvement related to increasing the level of engagement and personal connection, improving the ease of navigation, and balancing a "low prevalence of use, yet high impact" message. A total of 9138 users visited the website in the 3 months immediately post launch, and over 25,000 hard-copy *Cracks in the Ice* booklets and flyers were distributed across Australia. Of these resources, 60.93% (15,525/25,480) were distributed to relevant organizations and mailing list subscribers, and 39.07% (9955/25,480) were ordered directly by individuals, services, and community groups via the *Cracks in the Ice* website.

Conclusions: The codevelopment process resulted in an engaging Web-based resource for the Australian community to access up-to-date and evidence-based resources about crystal methamphetamine. The *Cracks in the Ice Community Toolkit* provides much-needed information and support for individuals, families, and communities.

(JMIR Ment Health 2018;5(1):e21) doi:10.2196/mental.8891

KEYWORDS

methamphetamine; substance-related disorders; internet; preventive psychiatry; health education

Introduction

Background

The use of methamphetamine and related harms has been the subject of growing concern among the Australian community and media in recent years. Although methamphetamine is not a new drug in the Australian market [1,2], growth in the availability and consumption associated with the high-purity, crystalline form of methamphetamine (crystal methamphetamine or ice) has caused considerable concern among the community. Recent data suggest that there has been a shift toward using crystal (ice) rather than powder (speed) forms of methamphetamine among regular methamphetamine users [3,4] as well as an increase in methamphetamine-related harms [2] and deaths [5]. Indeed the physical, psychological, and social harms associated with methamphetamine use are significant. Major harms include increased risk of stroke and other cardiovascular problems, dependence, psychosis and other mental health problems, violence, and overdose [5-9].

In April 2015, the Australian Government established a National Ice Taskforce to provide advice to the government on the impacts of crystal methamphetamine in Australia and the actions needed to address this growing problem. Findings from the taskforce indicated that there was a clear need to support families, workers, and communities to better respond to drug and alcohol issues, including crystal methamphetamine use [10]. One critical aspect of responding to this issue is the provision of easily accessible, evidence-based, and up-to-date information and resources about crystal methamphetamine for the general population. Over the past 10 to 15 years, there has been a rapid growth in the number of individuals with access to the internet, with almost 40% of the world's population now having access to online information [11]. In 2017, 86% of Australia's population were internet users [12] and an estimated 80% of Australians use the internet to search for health information [13]. The potential of the internet to improve accessibility and to overcome geographic and physical constraints makes it a medium of growing importance for the dissemination of health information, support, and treatment [14], including in relation to substance use and mental health problems [15]. With similar rates of internet access reported among active users of illicit drugs [16], the potential for technology to reach marginalized groups in the community is large.

Objectives of This Study

Although there has been a proliferation of information about crystal methamphetamine in Australia, both in the media and on the Web, the credibility of such information is not always apparent, and it is likely difficult for members of the community to evaluate what is evidence-based and what is not. Thus, as part of a coordinated response to the National Ice Taskforce recommendation, the *Cracks in the Ice Community Toolkit* [17] was developed. The Web-based toolkit was designed to improve access to evidence-based and up-to-date information and resources about crystal methamphetamine for Australians, including concerned community members, users, their friends and family members, health professionals and emergency service workers, and schools. This paper summarizes the comprehensive codevelopment and beta-testing process of the *Cracks in the Ice Community Toolkit.*

Methods

Overview of the Codevelopment Process

Development of the *Cracks in the Ice Community Toolkit* was a broad-reaching and iterative process, involving multiple phases over an 18-month period. As an initial step, an Expert Advisory Group (EAG), consisting of researchers with expertise in drug and alcohol prevention and treatment, internet interventions, and intervention development, was established to provide guidance and advice throughout the development process. Collaborations with consumer experts (ie, individuals with a lived experience of addiction, especially related to ice use, or mental health issues) were also established to provide advice throughout the development process. For example, consumer experts contributed to initial brainstorming, provided feedback on preliminary designs and different iterations of the Web-based toolkit, reviewed the beta website, and provided ideas for future development. Consumer participation is important to ensure that consumer needs, concerns, and values are not overlooked [18,19]. Engaging and linking with consumers was a critical component of the codevelopment process and ensured a strong end user voice in the final *Cracks in the Ice* toolkit.

The development process was informed by the latest available literature and data on crystal methamphetamine use [2,4,7,8,20-22] and drug education [23] and was developed in collaboration with community members across Australia and expert collaborators. Development occurred across 3 specific phases, which are outlined below:

1. Initial consultation with end users (Australian general population, including concerned community members, people who use crystal methamphetamine, their families and friends, health professionals, and teachers) via a Web-based survey
2. Content and Web development, in consultation with the EAG and consumer experts

3. Beta testing among end users and the EAG to ascertain feedback about the acceptability and relevance of the *Cracks in the Ice Community Toolkit*.

The codevelopment process is outlined in Figure 1, and key phases are summarized in further detail below.

Phase 1: Initial End User Consultation

Design and Procedure

An anonymous Web-based self-report survey was conducted with members of the Australian community between December 2015 and January 2016. Recruitment occurred via paid Facebook advertisements over a 2-week period that invited participants to " help to develop a website to improve access to information and support about methamphetamine. " Eligible participants were individuals aged 16 years or older who currently resided in Australia, and all participants were required to provide informed consent before completing the survey. The survey sought to better understand information needs about crystal methamphetamine among the Australian community, and to gain feedback about preliminary design concepts and preferences to inform development of the Web-based toolkit. At the end of the questionnaire, all participants were given the opportunity to provide their email address to enter the draw to win an Apple iPad; email addresses were not linked to survey response data. All aspects of the study were approved by the UNSW Sydney Human Research Ethics Committee (HREC; HC15732). A full copy of the questionnaire is available on request.

Measures

Demographic data collected included gender, age, place of residence, occupation, and country of birth. Lifetime use of methamphetamine was assessed using 2 items: " Have you ever used methamphetamine (also known as ice, speed, base, crystal meth, meth, shabu, Tiny, goey or glass)? " *(Yes or No)* and " What type of methamphetamine have you used ?" *(Ice [crystal], speed or base)*. Respondents who reported crystal methamphetamine use were asked a further set of items to assess route of administration (*smoking*, *injecting*, *other*), history and frequency of use, reasons for using, and intentions to use in the future. Harms associated with crystal methamphetamine use were assessed among the whole sample using an adapted version of the Social Harm from Others Scale [24]. These items were assessed to inform development of content for the Web-based toolkit, particularly for family and friends of people who use crystal methamphetamine. Participants were also asked to indicate reasons for visiting an information website about crystal methamphetamine, information areas of most interest, and preferences for how and where to seek help related to ice use. Finally, all respondents were asked to provide feedback on preliminary design concepts (eg, logos, webpage layout, and designs) to be included in the Web-based toolkit.

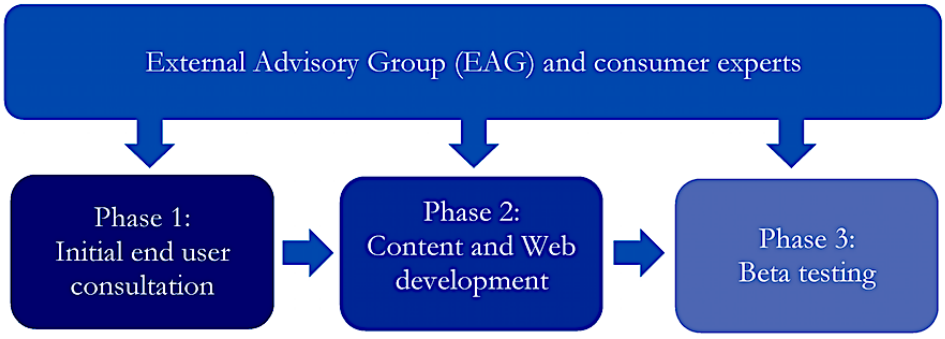
Data Analysis

Data were collated and analyzed in IBM SPSS Statistics 22 (IBM Corp, Armonk, NY, USA). Descriptive analyses were conducted to illustrate the sample characteristics and summarize interest in components of the proposed toolkit.

Phase 2: Content and Web Development

Content development occurred at multiple stages throughout the development process. First, a preliminary site structure was developed in consultation with the EAG to identify key content areas and target audiences for the Web-based toolkit. Feedback on the structure was collected during Phase 1, with results from end users confirming the key areas and target groups proposed by the EAG. A key aim of this project was to bring together the best available evidence and resources about crystal methamphetamine rather than creating entirely new material. As such, the next step in the content development process was to review existing resources developed by members of the project team for the *Positive Choices* portal [23,25]. This portal houses evidence-based drug education resources and factsheets for school students, parents, and teachers, including those related to methamphetamine, which were developed in relation to the latest available literature. These factsheets were used as the basis for the development of the *Cracks in the Ice* key webpages, with adaptations made as necessary (eg, adapting content to reflect a general population rather than a school-based audience). Scholarly databases and relevant websites were also searched using keywords related to methamphetamine (eg, "crystal methamphetamine," "ice," "ice information") to identify other relevant resources to inform development of webpage content. All new content was developed by a member of the project team with reference to existing evidence-based resources and the relevant research literature and were subject to expert review by at least two members of the EAG.

Figure 1. The codevelopment process of the *Cracks in the Ice* Community Toolkit.



Assessment of Eligibility of External Resources

Existing resources developed by individuals or groups external to the research team, such as guidelines and Web-based programs, were independently reviewed by the *Cracks in the Ice* project team. Resources were assessed for eligibility for inclusion using an adapted version of the National Health and Medical Research Centre Body of Evidence Matrix [26] against 4 specific criteria: (1) evidence base, (2) impact and utility, (3) generalizability, and (4) applicability (see Multimedia Appendix 1 for additional information). In addition, resources were only eligible for inclusion if they were less than 10 years old at the time of development (ie, developed during 2006-2016), unless a justification could be made as to why the resource should be included (eg, no other existing resources were available or the resource addresses an important area of need). To avoid duplication of content, resources were ineligible if their content substantially overlapped with other resources already included on the *Cracks in the Ice* website.

Readability Testing

To assess whether the vocabulary to be used in the developed content was appropriate, potentially problematic words, identified by 2 members of the research team, were checked for their frequency of use in the English language, as an indication of how well known and understood they would be by a general population audience. This was conducted using the Oxford English Dictionary Key to Frequency tool, where word frequency is ranked between Band 1 (extremely rare) and Band 8 (very common). All words within Bands 5 and 8 were permitted for inclusion on the website. Words in Bands 1 to 3 were excluded or replaced. Band 4 words, described by the Oxford English Dictionary as "recognisable to English speakers," were assessed on a case-by-case basis and included if they were deemed to be the most appropriate term to use. Terms that described specific mental health or physical health conditions, for example, were included and a glossary hover function was used to provide a definition for users.

Expert Review of Information for Aboriginal and Torres Strait Islander People

The preliminary site structure for the *Cracks in the Ice* toolkit included a webpage containing a directory of key support services (by state and territory) specific to Aboriginal and Torres Strait Islanders. Key support services and their relevant contact information (eg, phone number, website, email, and postal address) were collated during the scoping exercise described previously. To ensure the information was presented in a culturally appropriate manner, an Indigenous creative agency was engaged to review the content and language and to create the design elements used on the page. Recommendations made included simplifying the language used throughout the webpage, including more personal language (eg, "you" and "your"), reordering of content to reflect that much of the key toolkit information (eg, what is ice, its effects, and how to stay safe) was also relevant to Indigenous communities, and use of landscape imagery (eg, desert or beach) to represent the different states and territories across Australia.

Phase 3: Beta Testing of the Web-Based Toolkit

Design and Procedure

Following Phases 1 and 2, a beta version of the *Cracks in the Ice Community Toolkit* website was developed. Beta testing was conducted among community members and the EAG to ensure the Web-based toolkit was appealing, easy to understand, and engaging, before being launched to the general public. Individuals who participated in the initial end user consultation survey, and who agreed to being contacted in the future, were sent an email invitation to participate in the second phase of consultation. Participants were also recruited via social media channels (Facebook and Twitter) and the research team's personal and professional networks. Recruitment and beta testing took place over a 5-week period during August and September 2016. Respondents were required to be over the age of 16 years and to be living in Australia to be eligible to take part, and all participants were required to provide informed consent. All participants were asked to view a beta version of the *Cracks in the Ice* toolkit via a preview site and to complete a Web-based survey (of approximately 60 min) to provide in-depth feedback about the website. Members of the EAG (n=10) were also invited to participate in in-house beta testing via the Web-based survey. Approval was obtained from the UNSW HREC (HC15732). A full copy of the questionnaire is available on request.

Measures

Respondents were asked to provide closed and open-ended feedback about the ease of navigation, whether the content was easy to understand and informative, how much they liked or disliked the images and infographics used on the website, their likelihood of engaging with specific toolkit features (eg, a quiz or bookmarking functionality to save resources), and overall impressions.

Results

Phase 1: End User Consultation

Participants

A total of 451 participants provided consent and completed the Web-based survey. Participants ranged in age from 16 to 71 years (mean 27.97 [SD 13.58] years), and 54.8% (246/451) were female. The vast majority of participants (410/451, 91.5%) were born in Australia, with approximately one-third (151/451, 34.0%) residing in New South Wales (NSW), a quarter in Victoria (100/451, 22.5%), and 17.6% (78/451) in Queensland at the time of the survey. Most respondents were employed (279/451, 61.6%), although 10.5% (45/451) were unemployed and more than one-quarter (125/451, 27.9%) were students. The sample included a variety of different groups, including young persons aged 16 to 24 years (243/451, 53.9%), parents (138/451, 30.6%), health professionals (23/451, 5.1%), and teachers (9/451, 2.0%). A total of 4.9% (22/451) of the sample identified as Aboriginal or Torres Strait Islander.

Patterns of Methamphetamine Use

Of the 451 survey participants, 37.8% (155/451) had used some form of methamphetamine in their lifetime and 30.4% (137/451)

had used crystal methamphetamine (ice). Of those who had used crystal methamphetamine, 32.8% (44/134) reported using weekly or more, 7.5% (10/134) used monthly, 18.7% (25/134) used more than once a year but less than monthly, 10.4% (14/130) had used once in the past year, and 30.6% (41/134) had not used in the past year. The length of crystal methamphetamine use ranged from "less than 1 month" (8/130, 6.2%) to "11 years or more" (13/130, 10.0%), with 68.4% (89/130) using for 1 year or more. The most common route of administration was smoking (125/137, 91.2%); however, nearly one-quarter (32/137, 23.4%) had also injected crystal methamphetamine in the past. The majority of users (95/137, 69.3%) reported using other drugs alongside crystal methamphetamine, most commonly cannabis (70/137, 51.1%), alcohol (58/137, 49.6%), and tobacco (59/137, 43.1%).

Reasons for Using Crystal Methamphetamine

Table 1 summarizes the reasons given for using crystal methamphetamine among those who reported crystal methamphetamine use. The most commonly endorsed reasons among lifetime and weekly users were the following: "I like the feeling of being high" (lifetime: 75/137, 54.7%; weekly: 26/44, 59%) and "to party or socialize" (lifetime: 51/137, 37.2%; weekly: 25/44, 57%).

Help-Seeking Preferences

When asked where they would be comfortable seeking help if they needed help for their ice use, the most common responses were a "friend or family member" (52/137, 38.0%), counselor or psychologist (42/137, 30.7%), and general practitioner (39/137, 28.5%). Moreover, 21.9% (30/137) of crystal methamphetamine users indicated that they would be comfortable seeking help online; however, one-quarter (34/137, 24.8%) said that they would not feel comfortable asking for help at all. Additionally, 51.2% (197/385) of all participants indicated that they did not feel that effective treatments were available for people seeking help related to the use of ice.

Social Harms Resulting From Someone Else's Use of Crystal Methamphetamine

Harms associated with someone else's crystal methamphetamine use were prevalent among our sample, with 60.5% (273/451) reporting at least one social harm (mean 2.37 [SD 2.75]). The most commonly reported harms were as follows: having serious arguments or quarrels (162/451, 35.9%), friendship breakdown (149/451, 33.0%), and being insulted or humiliated (138/451, 30.6%; see Table 2).

Table 1. Reasons for using crystal methamphetamine among ice users.

Reason for use	Ever used (N=137), n (%)[a]	Used weekly or more (N=44), n (%)[a]
I like the feeling of being high	75 (54.7)	26 (59)
To escape reality	53 (38.7)	25 (57)
To party or socialize	51 (37.2)	13 (30)
To avoid dealing with issues and thoughts	46 (33.6)	19 (43)
To feel confident	45 (32.8)	16 (36)
To think more clearly	38 (27.7)	17 (39)
All my friends use it	28 (20.4)	7 (16)
I used it a bit and now I cannot stop	22 (16.1)	13 (30)
To help me focus at work	12 (8.8)	7 (16)

[a]Participants could endorse multiple reasons.

Table 2. Social harms associated with someone else's use of crystal methamphetamine (N=451).

Harm	n (%)
Ever had serious arguments or quarrels as a result of someone using ice	162 (35.9)
Ever had friendships break up as a result of someone using ice	149 (33.0)
Ever been insulted or humiliated by someone using ice	138 (30.6)
Ever had family problems or marriage difficulties because of someone using ice	130 (28.8)
Ever been a passenger with a driver who has been using ice	127 (28.2)
Ever had financial trouble as a result of someone using ice	103 (22.8)
Ever been disturbed by loud parties or the behavior of someone using ice	99 (22.0)
Ever been pushed, hit, or assaulted by someone using ice	86 (19.1)
Ever had your property vandalized by someone using ice	75 (16.6)

Table 3. Reasons for visiting a website about crystal methamphetamine (N=451).

Reason	n (%)[a]
To get information for myself	185 (41.0)
To find out how to get help for a friend or a family member	136 (30.2)
I have heard the term "ice epidemic" and want more information	121 (26.8)
To get information for a friend or a family member	123 (27.3)
To find out how to get help for myself	44 (9.8)
I am a health professional and want more information to help a client	26 (5.8)
I am interested in trying ice in the future and want to know more information before I do it	12 (2.7)
I am a teacher and am looking for educational resources to use in class	3 (0.7)

[a]Participants could endorse multiple reasons.

Information Needs About Crystal Methamphetamine

The mostly commonly endorsed reasons for visiting a website about crystal methamphetamine were to "seek information for myself" (185/451, 41.0%) and "to find out how to get help for a friend or a family member" (136/451, 30.2%; see Table 3). In terms of preferences for topic areas, respondents were most interested in obtaining information about the "effects of ice" (199/451, 44.1%), "why do people use ice?" (134/451, 29.7%), and "how many people use ice?" (125/451, 27.7%). When asked to provide open-ended feedback, participants indicated they wanted additional information about a range of topics, including how to help a family member using ice, how to protect yourself from aggressive behavior, the long-term effects of ice use, ice and the law, and warning signs of dependence.

Phase 2: Content and Web Development

Content development was informed by the Web-based survey with end users and the EAG, literature searching and scoping of evidence, and consultation with external collaborators. The beta version of the toolkit was structured to provide information for the general Australian community across 3 key areas: ice itself ("What is ice?"), its physical and mental health effects ("What are the effects of ice?"), and where and how to access support or treatment for issues related to ice ("Staying Safe"). The toolkit also included user-specific information and resources for community groups and organizations, families and friends of someone using crystal methamphetamine, health professionals and emergency services workers, and schools (parents, teachers, and students). In addition to desktop computers, the toolkit was also optimized for mobile phones, laptops, and tablet devices. A hard-copy booklet was also developed as a companion resource to promote the Web-based toolkit and to provide community groups (eg, support groups, local drug action teams), health professionals, and individuals with tangible *Cracks in the Ice* resources and information about crystal methamphetamine. The decision to develop and distribute hard-copy booklets was made in consultation with the EAG and is consistent with previous dissemination activities conducted by the research team.

Phase 3: Beta Testing of the Web-Based Toolkit

Participants

A total of 41 participants completed the Web-based survey. The mean age of participants was 34.4 years (SD 15.0) and 49% (20/41) of the sample were female. Nearly half of the sample (19/41, 46%) resided in NSW and almost one-quarter in Victoria (9/41, 22%), with 61% (25/41) of all participants living in metropolitan areas at the time of the survey and 39% (16/41) in regional or rural areas. Over two-thirds of the sample (28/41, 68%) indicated that they knew someone who uses ice, with 39% (16/41) identifying themselves as a friend of an ice user and 20% (8/41) as a family member of someone who uses ice. The sample consisted of individuals representing a variety of different groups, including parents (16/41, 39%), students (15/41, 37%), health professionals (7/41, 17%), and teachers (2/41, 5%).

Participants viewed the beta site across a variety of Web browsers (Chrome [16/41, 39%], Safari [11/41, 27%], Firefox [6/41, 15%], and Internet Explorer [5/41, 12%]) and multiple devices (mobile phone [18/41, 47%], laptop [10/41, 26%], desktop computer [5/41, 13%], and tablets [5/41, 13%]).

Feedback

Overall, feedback on the beta version of the *Cracks in the Ice Community Toolkit* was positive in terms of content, readability, layout, and aesthetic quality of the site. All community participants (41/41, 100%) rated the content as easy to understand and informative, and the vast majority (38/41, 93%) rated the site's navigation as "good" or "very good." Example qualitative feedback is provided in Multimedia Appendix 2. The EAG was also positive in its feedback about the Web-based toolkit, with the main areas for improvement relating to the need to improve the ease of navigation and layout of information on some content pages (see Multimedia Appendix 2 for example feedback). Three quarters of participants (28/37, 75%) indicated that they liked the toolkit's mission statement "Trusted, evidence-based information about crystal methamphetamine," and more than half (20/37, 54%) indicated that an evidence base was most important when looking for information about crystal methamphetamine.

Summary of Modifications

The most commonly identified areas for improvement were related to increasing the level of engagement and personal connection with the site, improving ease of navigation, and balancing the "low prevalence of use, yet high impact" message. To address these concerns, a number of modifications were made to the Web-based toolkit. To achieve greater user engagement and personal connection, additional images and infographics were included and quotes based on personal experiences related to methamphetamine use were embedded on all key pages of the website. In addition, content was modified on the "How many people use ice?" webpage to reflect the difficulties in measuring methamphetamine use in the general population and to convey the message that although rates of use might be low, the impact of crystal methamphetamine use on individuals, families, and communities can be substantial. The project team also worked in consultation with the Web developers to improve the layout and ease of navigation, for example, including "Related Content" links on each page and Show and Hide functionality to collapse large amounts of text into smaller sections. Tables 4 and 5 summarize the key content included on the final *Cracks in the Ice* website at the time of launch to the general public, and Figures 2-4 provide screenshots of key toolkit webpages.

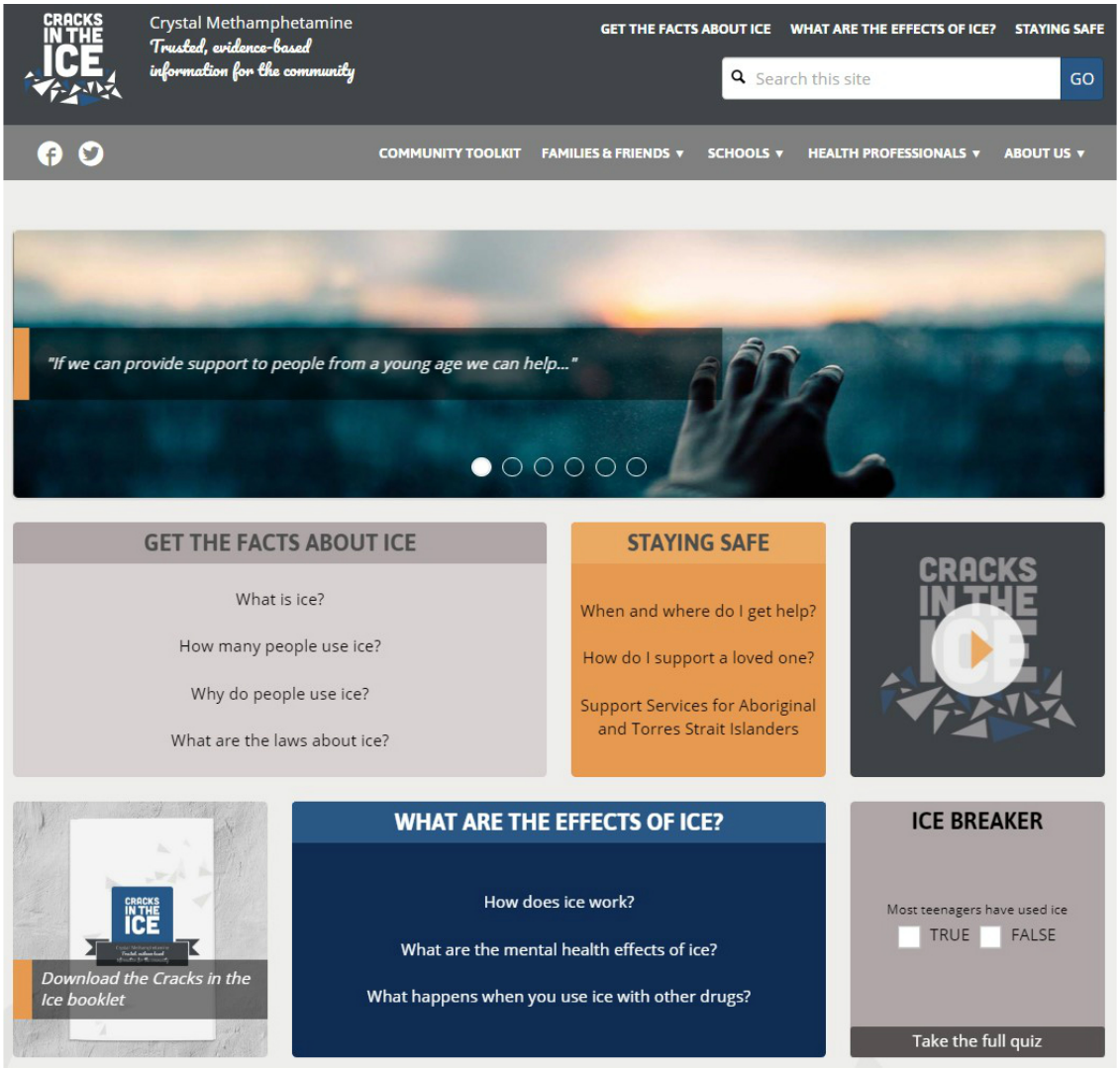
Table 4. Overview of key content on the *Cracks in the Ice* website.

Overarching topic	Content
Get the Facts about Ice	
What is ice?	• Definition of methamphetamine and its different forms ("ice," base, and speed) • Information about the appearance, route of administration, purity, and street names for methamphetamines
How many people use ice?	• Prevalence of methamphetamine use and related harms in Australia • Trends in methamphetamine use and harms in Australia
Why do people use ice?	• Commonly reported reasons for using crystal methamphetamine • Reasons young people might use drugs, such as crystal methamphetamine • Tips for being assertive and drug refusal skills
What are the laws about ice?	• Summary of the law for methamphetamine (including crystal methamphetamine)-related offences in Australia and by state and territory
What are the effects of Ice	• How methamphetamine affects the brain and body • The short- and long-term mental health effects of methamphetamine use • Using "ice" with other drugs, including reasons for polydrug use and the effects of using ice with stimulants, depressants, and with medications
Staying Safe	• When and where to get help, including a self-assessment tool to provide feedback about one's use of crystal methamphetamine • How to support a loved one who is using methamphetamine • Support services for Aboriginal and Torres Strait Islanders

Table 5. Overview of user-specific content on the *Cracks in the Ice* website.

User group	Description
Community toolkit	The community toolkit provides local councils, parents and citizen groups, community organizations, or concerned community members with the appropriate tools (including factsheets, brochures, booklets, and PowerPoint presentation and talking notes) for use at community forums and events
Families and friends	This section provides information about helping a loved one who may be using ice, including tips for starting a conversation, how to protect yourself, and where to get additional support
Health professionals	Factsheets, guidelines, and Web-based resources for professionals working across a range of sectors, including general practitioners, frontline workers in hospital settings and emergency departments, frontline workers in alcohol and other drug settings, mental health practitioners (eg, psychologists, social workers, and counselors), paramedics, and police services
Schools	Access to information and resources for parents, teachers, and students, including webinars, factsheets, and interactive games

Figure 2. The Cracks in the Ice Community Toolkit home page (at time of launch).



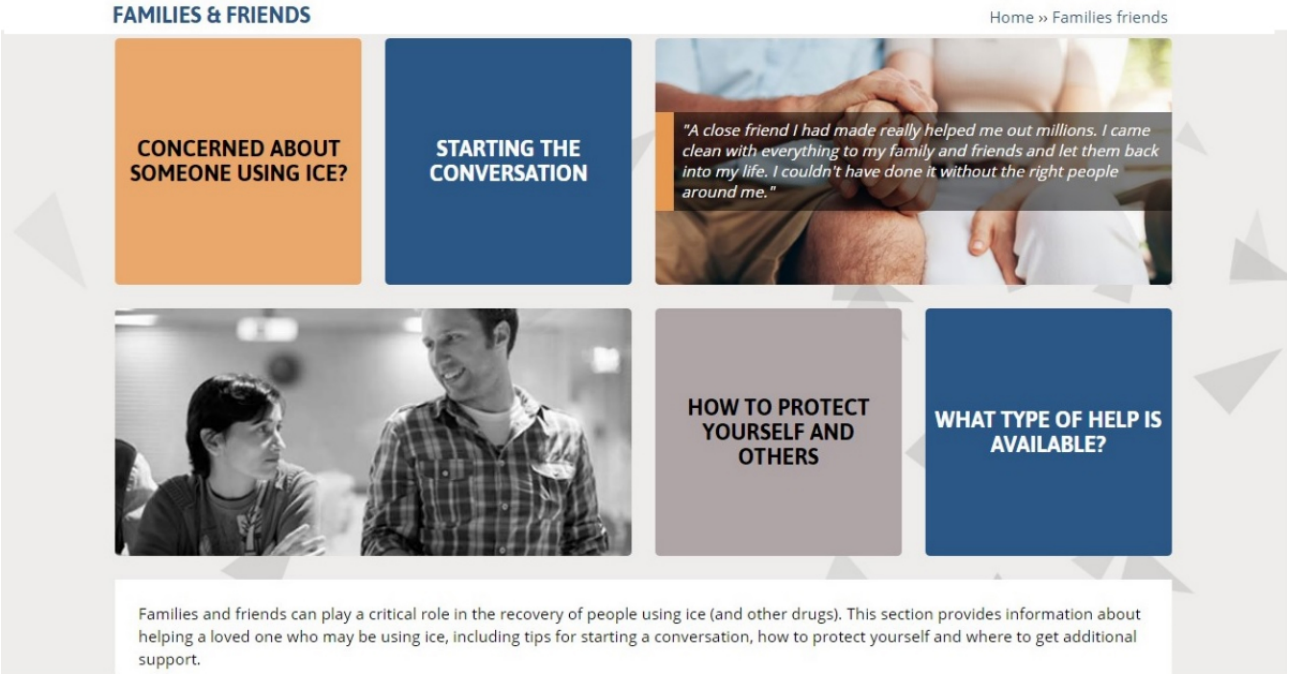
Usage Statistics

The *Cracks in the Ice Community Toolkit* was officially launched on April 3, 2017. In the 3 months immediately post launch, the toolkit received a total of 9138 visitors. Excluding the homepage, the most frequently visited toolkit pages were the following: How many people use ice?, the Community Toolkit, and What is ice?. Since launch, a total of 25,480 hard-copy *Cracks in the Ice* resources (14,040 booklets and 11,440 flyers) have been distributed to individuals, organizations, and communities across Australia. Of these resources, 60.93% (15,525/25,480) were distributed to relevant organizations and subscribers on the *Cracks in the Ice* mailing list, and 39.07% (9955/25,480) were ordered directly by individuals and organizations via the *Cracks in the Ice* website.

A full evaluation of engagement with the website is planned to determine who is visiting the website, the usefulness of the Web-based toolkit among visitors, and to better understand how people respond to the information provided in the toolkit. These data will be used to better tailor and target the information and resources on the *Cracks in the Ice Community Toolkit.*

Figure 3. Screenshot of the Community Toolkit page (at time of launch).

Figure 4. Screenshot of the Families & Friends page (at time of launch).



Discussion

Summary of Findings

This paper described the codevelopment process of *Cracks in the Ice*, a Web-based toolkit designed to provide evidence-based information and resources about crystal methamphetamine for the Australian community. The codevelopment process was broad-reaching and iterative, involving more than 450 community members across the country and expert collaborators and researchers over an 18-month period. The initial Web-based survey conducted with end users provided important insights into the information needs of the Australian community in relation to crystal methamphetamine and validated the preliminary site structure. Results indicated that community members were seeking information about crystal methamphetamine, particularly in relation to its effects and reasons for use, and were likely to visit a Web-based toolkit to search for information for themselves and to help a friend or family member. Social harms related to the use of crystal methamphetamine were considerable in our sample, with nearly one-third of the respondents reporting 1 or more harm related to someone's use of the drug. Overall, 63.6% (287/451) of the Web-based survey sample reported either having ever used crystal methamphetamine or experiencing at least one social harm from someone else's use of ice Thus, the majority of the sample had lived experience of the impacts of crystal methamphetamine use, either through their own use or that of someone else.

Consistent with previous research [27,28], participants in this study indicated that their preferred source of help would be from friends and family members. One in 4 ice users from our Web-based scoping survey said that they would not feel comfortable seeking any help for their ice use and only 21.9% (30/137) said they would be comfortable seeking help online. Additionally, just over half of the whole sample (197/385, 51.2%) said they did not feel effective treatments were available for methamphetamine use. Stigma and the belief that no effective help is available are 2 of the most commonly stated barriers to help-seeking for substance use and mental health problems [29-31]. Internet-based interventions do hold promise to overcome these barriers to care [32,33], particularly if information can be presented in a nonjudgmental and stigmatizing manner [34]. Further research is needed to clarify the reasons why some individuals do not feel comfortable seeking help online for their methamphetamine use (eg, privacy or stigma) and to understand how these concerns can be addressed in online treatment delivery. Importantly, the *Cracks in the Ice Community Toolkit* was developed to provide evidence-based information about ice, including information about when and where to get help, and what types of treatment are available, but not as a treatment intervention. Results from the beta testing survey indicated that the Web-based toolkit was well received by end users as a source of information about ice.

Overall, the beta-testing results were overwhelmingly positive and served to both reinforce the development work conducted thus far and further refine the toolkit to ensure it was as relevant, acceptable, and appealing as possible for the target audience. Three key areas for improvement emerged from the beta-testing process. First, end users indicated that they wanted an increased level of engagement and personal connection with the site. In response to this, additional images and infographics were included across the website. Specifically, photos were paired with real quotes from individuals about their experiences related to methamphetamine and prominently displayed on all key pages across the *Cracks in the Ice* site. For example, the homepage was modified to include a rotating banner of different pairs of images and quotes, for example, "If we can provide support to people form a young age we can help." Second, beta-testing data indicated that there was a clear need to improve the ease of navigation on the website to ensure that site users could easily locate the information they were seeking. To improve navigation, the project team worked in consultation with the Web developers to modify the layout across several webpages, for example, including drop-down menus on the homepage, adding "Related Content" links on each page to allow users to easily navigate to similar content, and using the Show and Hide functionality to collapse large amounts of text into smaller sections. Third, beta testing revealed that there was a need to better covey a "low prevalence of use, yet high impact" message. To address this feedback, text was modified on the How many people use ice? webpage to reflect the difficulties in measuring methamphetamine use in the general population, and additional sources of data on harms were included. In addition, an infographic was developed to convey the message that although rates of use might be low, the impact of crystal methamphetamine use on individuals, families, and communities is substantial.

Community Response and Future Directions

Importantly, beta-testing data confirmed that end users valued the toolkit's emphasis on providing evidence-based information, with more than half of participants indicating that an evidence base was the most important aspect when looking for information about crystal methamphetamine. Given the considerable focus on ice use in Australia in recent times and the potential for misinformation about crystal methamphetamine to be disseminated via the media and the internet, a key strength of the *Cracks in the Ice Community Toolkit* is the ease of access to evidence-based information and resources. To ensure that the information and resources remain evidence-based and up-to-date, important next steps for the maintenance of the website will be to review the academic literature and other relevant sources at regular intervals in the future and to update the website accordingly. Since its launch, community response has been positive, with steady increases in visitors to the *Cracks in the Ice* website and regular requests to receive hard-copy booklets and flyers. The dissemination and early demand for hard-copy resources is another strength of *Cracks in the Ice*, with booklets ordered by, and distributed to, a range of groups across the country, including drug and alcohol services, community centers, and support groups. Although developed as a companion resource to the Web-based toolkit, dissemination of hard-copy resources may be important for providing support to people who are less familiar with Web-based resources, or those without easy access to computers or the internet. Ultimately, the final *Cracks in the Ice Community Toolkit*

provides Australians, including community groups, families and friends of someone using ice, health professionals and emergency service workers, and individuals affected by crystal methamphetamine, with the much-needed evidence-based and up-to-date information and support, in one easily accessible Web-based toolkit.

Limitations

The findings presented in this paper should be considered in light of some limitations. First, the sample recruited for the initial end user consultation was not representative of the general Australian population, and prevalence of methamphetamine use (155/451, 37.8%), including ice, was significantly higher than the population rates [3]. Although we did not primarily target methamphetamine users in our recruitment advertisements, it is likely that our strategy attracted individuals with a particular concern about methamphetamine use, that is, individuals who use ice and their friends or family members. The Web-based consultation survey was also restricted to individuals who use the internet, and in particular, Facebook. Nonetheless, the survey methodology was successful in identifying key knowledge gaps and information needs in the community, as well as design and aesthetic preferences for the website, thereby directly informing the development of the Web-based toolkit. It should also be noted that the consultation survey was completed by only a small number of teachers and health professionals, 2 target audiences of the toolkit. Importantly, the content housed on *Cracks in the Ice* for these 2 groups primarily draws on existing resources that were previously developed in consultation with end users (eg, the *Positive Choices* website, which was developed with input from teachers, and guidelines developed by expert health professionals). Nonetheless, there is opportunity for future development work for the toolkit to involve further consultation with teachers and health professionals. Similarly, beta testing was conducted among a relatively small sample, via convenience sampling, and may not be representative of the general population. Fortunately, the *Cracks in the Ice Community Toolkit* contains feedback loops and opportunities for website users to submit questions and provide feedback, ensuring the continuing involvement of additional community members as the site is maintained into the future.

Conclusions

This recently developed *Cracks in the Ice Community Toolkit* involved in-depth community consultation and brings together the latest evidence and resources pertaining to crystal methamphetamine in Australia. Ultimately, the toolkit provides the Australian community with a central access point for trusted, evidence-based, and up-to-date information about crystal methamphetamine. Important next steps are to monitor engagement and use of the website, to embed the most recent evidence into the Web-based toolkit to ensure the currency of information, and to remain responsive to emerging information needs about crystal methamphetamine among the community.

Acknowledgments

This project was funded by the Australian Government Department of Health. The authors would like to thank the individuals who so generously shared their experiences with them and allowed them to use their stories on the *Cracks in the Ice* website and many community members from around the country who provided their input and feedback during the development of this resource. The authors would also like to thank the external collaborators for their contributions to the development of *Cracks in the Ice*: Professor Steve Allsop and Dr Nyanda McBride from the National Drug Research Institute, Curtin University, and Dr Caitlin Hughes from the Drug Policy Modelling Program, National Drug and Alcohol Research Centre, UNSW Sydney. The authors would like to thank Gilimbaa for their expert review and design of the webpage for Aboriginal and Torres Strait Islander People and Netfront for the overall Web development and design of the *Cracks in the Ice Community Toolkit.*

Conflicts of Interest

None declared.

Multimedia Appendix 1

Adapted version of the National Health and Medical Research Council body of evidence matrix.

[PDF File (Adobe PDF File), 36KB - mental_v5i1e21_app1.pdf]

Multimedia Appendix 2

Example feedback from end users and the Expert Advisory Group about the beta-version of Cracks in the Ice.

[PDF File (Adobe PDF File), 17KB - mental_v5i1e21_app2.pdf]

References

1. Topp L, Degenhardt L, Kaye S, Darke S. The emergence of potent forms of methamphetamine in Sydney, Australia: a case study of the IDRS as a strategic early warning system. Drug Alcohol Rev 2002 Dec;21(4):341-348. [doi: 10.1080/0959523021000023199] [Medline: 12537703]

2. Degenhardt L, Sara G, McKetin R, Roxburgh A, Dobbins T, Farrell M, et al. Crystalline methamphetamine use and methamphetamine-related harms in Australia. Drug Alcohol Rev 2017 Mar;36(2):160-170. [doi: 10.1111/dar.12426] [Medline: 27286742]
3. Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2016 Key Findings. Canberra: AIHW; 2016.
4. Australian Institute of Health and Welfare. National Drug Strategy Household Survey detailed report 2013. Canberra: AIHW; 2014.
5. Darke S, Kaye S, Duflou J. Rates, characteristics and circumstances of methamphetamine-related death in Australia: a national 7-year study. Addiction 2017 Dec;112(12):2191-2201. [doi: 10.1111/add.13897] [Medline: 28603836]
6. Darke S, Kaye S, McKetin R, Duflou J. Major physical and psychological harms of methamphetamine use. Drug Alcohol Rev 2008 May;27(3):253-262. [doi: 10.1080/09595230801923702] [Medline: 18368606]
7. McKetin R, Lubman DI, Najman JM, Dawe S, Butterworth P, Baker AL. Does methamphetamine use increase violent behaviour? Evidence from a prospective longitudinal study. Addiction 2014 May;109(5):798-806. [doi: 10.1111/add.12474] [Medline: 24400972]
8. Degenhardt L, Larney S, Chan G, Dobbins T, Weier M, Roxburgh A, et al. Estimating the number of regular and dependent methamphetamine users in Australia, 2002-2014. Med J Aust 2016 Mar 07;204(4):153. [Medline: 26937668]
9. McKetin R, Kelly E, McLaren J. The relationship between crystalline methamphetamine use and methamphetamine dependence. Drug Alcohol Depend 2006 Dec 1;85(3):198-204. [doi: 10.1016/j.drugalcdep.2006.04.007] [Medline: 16723192]
10. Final Report of the National Ice Taskforce. Canberra: Commonwealth of Australia; 2015.
11. World Telecommunication /ICT Indicators database. Switzerland: International Telecommunication Union; 2013.
12. Internet World Stats. 2017. Usage and Population Statistics 2017 URL: https://www.internetworldstats.com/stats6.htm [accessed 2018-02-21] [WebCite Cache ID 6xPBhyv7C]
13. McDaid D, Park A. BUPA Health Pulse. Online Health: Untangling the Web. London: BUPA; 2011.
14. Deady M, Kay-Lambkin F, Thornton L, Baker A, Teesson M. Social Influence, Addictions and the Internet: The Potential of Web 2.0 Technologies in Enhancing Treatment for Alcohol/Other Drug use Problems. J Addict Res Ther 2012;s8(002).
15. Cunningham JA, Gulliver A, Farrer L, Bennett K, Carron-Arthur B. Internet interventions for mental health and addictions: current findings and future directions. Curr Psychiatry Rep 2014 Dec;16(12):521. [doi: 10.1007/s11920-014-0521-5] [Medline: 25308390]
16. Strickland JC, Wagner FP, Stoops WW, Rush CR. Profile of internet access in active cocaine users. Am J Addict 2015 Oct;24(7):582-585 [FREE Full text] [doi: 10.1111/ajad.12271] [Medline: 26331803]
17. Cracks in the Ice. URL: https://cracksintheice.org.au/ [accessed 2017-08-11] [WebCite Cache ID 6se6FBjZf]
18. Happell B, Ewart SB, Platania-Phung C, Stanton R. Participative mental health consumer research for improving physical health care: An integrative review. Int J Ment Health Nurs 2016 Oct;25(5):399-408. [doi: 10.1111/inm.12226] [Medline: 27159221]
19. Linhorst DM, Eckert A. Involving people with severe mental illness in evaluation and performance improvement. Eval Health Prof 2002 Sep;25(3):284-301. [doi: 10.1177/0163278702025003003] [Medline: 12229070]
20. Roche A, McEntee A. Ice and the outback: Patterns and prevalence of methamphetamine use in rural Australia. Aust J Rural Health 2017 Aug;25(4):200-209. [doi: 10.1111/ajr.12331] [Medline: 27868256]
21. McKetin R, Black E. Methamphetamine: What you need to know about Speed, Ice, Crystal, Base and Meth. Sydney: Australian Government, Department of Health; 2014.
22. McKell D, Hordern A, Stafford J, Roxburgh A, Breen C. NSW Drug Trends 2015: Findings from the Illicit Drug Reporting System (IDRS). Sydney, Australia: NDARC; 2016.
23. Stapinski L, Lawler S, Newton N, Reda B, Chapman C, Teesson M. Empowering young people to make Positive Choices: Evidence-based resources for the prevention of alcohol and other drug use in Australian schools. LCJ 2017 Nov;21:152-167. [doi: 10.18793/LCJ2017.21.12]
24. Room R. Concepts and items in measuring social harm from drinking. J Subst Abuse 2000;12(1-2):93-111. [Medline: 11288477]
25. Positive Choices. URL: https://positivechoices.org.au/ [accessed 2017-08-11] [WebCite Cache ID 6se6tWhZp]
26. NHMRC. 2009. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines URL: https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf [accessed 2018-02-26] [WebCite Cache ID 6xVutdr52]
27. Rickwood DJ, Deane FP, Wilson CJ. When and how do young people seek professional help for mental health problems? Med J Aust 2007 Oct 1;187(7 Suppl):S35-S39. [Medline: 17908023]
28. Jorm AF, Wright A, Morgan AJ. Where to seek help for a mental disorder? National survey of the beliefs of Australian youth and their parents. Med J Aust 2007 Nov 19;187(10):556-560. [Medline: 18021042]
29. Andrade LH, Alonso J, Mneimneh Z, Wells JE, Al-Hamzawi A, Borges G, et al. Barriers to mental health treatment: results from the WHO World Mental Health surveys. Psychol Med 2014 Apr;44(6):1303-1317 [FREE Full text] [doi: 10.1017/S0033291713001943] [Medline: 23931656]

30. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. BMC Psychiatry 2010 Dec 30;10:113 [FREE Full text] [doi: 10.1186/1471-244X-10-113] [Medline: 21192795]
31. Thompson A, Hunt C, Issakidis C. Why wait? Reasons for delay and prompts to seek help for mental health problems in an Australian clinical sample. Soc Psychiatry Psychiatr Epidemiol 2004 Oct;39(10):810-817. [Medline: 15669662]
32. Boumparis N, Karyotaki E, Schaub MP, Cuijpers P, Riper H. Internet interventions for adult illicit substance users: a meta-analysis. Addiction 2017 Sep;112(9):1521-1532. [doi: 10.1111/add.13819] [Medline: 28295758]
33. Tait RJ, McKetin R, Kay-Lambkin F, Carron-Arthur B, Bennett A, Bennett K, et al. Six-month outcomes of a Web-based intervention for users of amphetamine-type stimulants: randomized controlled trial. J Med Internet Res 2015 Apr 29;17(4):e105 [FREE Full text] [doi: 10.2196/jmir.3778] [Medline: 25925801]
34. Douglass CH, Early EC, Wright CJC, Palmer A, Higgs P, Quinn B, et al. "Just not all ice users do that": investigating perceptions and potential harms of Australia's Ice Destroys Lives campaign in two studies. Harm Reduct J 2017 Jul 14;14(1):45 [FREE Full text] [doi: 10.1186/s12954-017-0175-9] [Medline: 28705259]

Abbreviations

EAG: Expert Advisory Group
HREC: Human Research Ethics Committee
NSW: New South Wales
UNSW: University of New South Wales

Edited by S Gipson; submitted 06.09.17; peer-reviewed by M Deady, S Simblett; comments to author 20.10.17; revised version received 22.11.17; accepted 09.01.18; published 20.03.18.

Please cite as:
Champion KE, Chapman C, Newton NC, Brierley ME, Stapinski L, Kay-Lambkin F, Nagle J, Teesson M
A Web-Based Toolkit to Provide Evidence-Based Resources About Crystal Methamphetamine for the Australian Community: Collaborative Development of Cracks in the Ice
JMIR Ment Health 2018;5(1):e21
URL: http://mental.jmir.org/2018/1/e21/
doi:10.2196/mental.8891
PMID:29559427

Original Paper

Cognitive and Behavioral Skills Exercises Completed by Patients with Major Depression During Smartphone Cognitive Behavioral Therapy: Secondary Analysis of a Randomized Controlled Trial

Toshi A Furukawa[1], MD, PhD; Masaru Horikoshi[2], PhD; Hirokazu Fujita[3], MD, PhD; Naohisa Tsujino[4], MD, PhD; Ran Jinnin[5], MD, PhD; Yuki Kako[6], MD, PhD; Sei Ogawa[1], MD, PhD; Hirotoshi Sato[7], MD; Nobuki Kitagawa[8], MD, PhD; Yoshihiro Shinagawa[9], MD, PhD; Yoshio Ikeda[10], MD, PhD; Hissei Imai[11], MD, PhD; Aran Tajika[11], MD, PhD; Yusuke Ogawa[11], MPH, MD, PhD; Tatsuo Akechi[1], MD, PhD; Mitsuhiko Yamada[12], MD, PhD; Shinji Shimodera[13], MD, PhD; Norio Watanabe[11], MD, PhD; Masatoshi Inagaki[14], MD, PhD; Akio Hasegawa[15], PhD

[1]Department of Psychiatry and Cognitive-Behavioral Medicine, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan
[2]Center of Cognitive-Behavior Therapy, National Center of Neurology and Psychiatry, Kodaira, Japan
[3]Center to Promote Creativity in Medical Education, Kochi Medical School, Kochi University, Nankoku, Japan
[4]Department of Neuropsychiatry, Toho University School of Medicine, Tokyo, Japan
[5]Department of Psychiatry and Neurosciences, Hiroshima University Graduate School of Biomedical & Health Sciences, Hiroshima, Japan
[6]Department of Psychiatry, Hokkaido University Graduate School of Medicine, Sapporo, Japan
[7]Harimayabashi Clinic, Kochi, Japan
[8]Hokudai-dori Mental Health Clinic, Sapporo, Japan
[9]Shiki Clinic, Nagoya, Japan
[10]Narumi Himwari Clinic, Nagoya, Japan
[11]Department of Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health, Kyoto, Japan
[12]National Institute of Mental Health, National Center of Neurology and Psychiatry, Kodaira, Japan
[13]Department of Psychiatry, Kochi Medical School, Kochi University, Nankoku, Japan
[14]Okayama University Hospital, Okayama, Japan
[15]Advanced Telecommunications Research Institute International, Kyoto, Japan

Corresponding Author:
Toshi A Furukawa, MD, PhD
Department of Psychiatry and Cognitive-Behavioral Medicine
Nagoya City University Graduate School of Medical Sciences
Kawasumi 1, Mizuho-cho, Mizuho-ku,
Nagoya, 467-8601
Japan
Phone: 81 52 753 9491
Email: furukawa@kuhp.kyoto-u.ac.jp

Abstract

Background: A strong and growing body of evidence has demonstrated the effectiveness of cognitive behavioral therapy (CBT), either face-to-face, in person, or as self-help via the Internet, for depression. However, CBT is a complex intervention consisting of several putatively effective components, and how each component may or may not contribute to the overall effectiveness of CBT is poorly understood.

Objective: The aim of this study was to investigate how the users of smartphone CBT use and benefit from various components of the program.

Methods: This is a secondary analysis from a 9-week, single-blind, randomized controlled trial that has demonstrated the effectiveness of adjunctive use of smartphone CBT (Kokoro-App) over antidepressant pharmacotherapy alone among patients with drug-resistant major depressive disorder (total n=164, standardized mean difference in depression severity at week 9=0.40, J Med Internet Res). Kokoro-App consists of three cognitive behavioral skills of self-monitoring, behavioral activation, and cognitive restructuring, with corresponding worksheets to fill in. All activities of the participants learning each session of the

program and completing each worksheet were uploaded onto Kokoro-Web, which each patient could use for self-check. We examined what use characteristics differentiated the more successful users of the CBT app from the less successful ones, split at the median of change in depression severity.

Results: A total of 81 patients with major depression were allocated to the smartphone CBT. On average, they completed 7.0 (standard deviation [SD] 1.4) out of 8 sessions of the program; it took them 10.8 (SD 4.2) days to complete one session, during which they spent 62 min (SD 96) on the app. There were no statistically significant differences in the number of sessions completed, time spent for the program, or the number of completed self-monitoring worksheets between the beneficiaries and the nonbeneficiaries. However, the former completed more behavioral activation tasks, engaged in different types of activities, and also filled in more cognitive restructuring worksheets than the latter. Activities such as "test-drive a new car," "go to a coffee shop after lunch," or "call up an old friend" were found to be particularly rewarding. All cognitive restructuring strategies were found to significantly decrease the distress level, with "What would be your advice to a friend who has a similar problem?" found more helpful than some other strategies.

Conclusions: The CBT program offered via smartphone and connected to the remote server is not only effective in alleviating depression but also opens a new avenue in gathering information of what and how each participant may utilize the program. The activities and strategies found useful in this analysis will provide valuable information in brush-ups of the program itself and of mobile health (mHealth) in general.

Trial Registration: Japanese Clinical Trials Registry UMIN CTR 000013693; https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000015984 (Archived by WebCite at http://www.webcitation.org/6u6pxVwik)

(JMIR Ment Health 2018;5(1):e4) doi:10.2196/mental.9092

KEYWORDS

major depressive disorder; smartphone; cognitive therapy; telemedicine

Introduction

Cognitive behavioral therapy (CBT) is the psychotherapy with the strongest evidence base for the treatment of depression [1-3]. CBT is indeed the only psychotherapy that has been shown to beat the pill placebo condition, the gold standard control condition in the evaluation of medical interventions [4]. It has also been demonstrated to show comparable efficacy as antidepressant pharmacotherapy, which is the mainstay of the treatment for major depression today [5].

The broad umbrella term of CBT, however, now subsumes various and different behavioral and cognitive skills such as self-monitoring, behavioral activation, cognitive structuring, assertion training, structured problem solving, mindfulness, and others [6]. The relative contributions of these various components to the overall efficacy of CBT remain uncertain and debated [7-9]. So-called dismantling studies or component studies to disentangle individual constituents of broadly conceived CBT have been largely underpowered and inconclusive, as each study can only examine the value of adding one particular component in question in a relatively limited number of patients [10,11]. Another major issue of such studies is whether the intended components are actually administered by the therapists and received by the patients, although more recent trials attempt to assure their delivery through audio or video recordings.

The development of information and communication technologies, however, is opening new opportunities to monitor the delivery of CBT skills and to study differential contribution of various components of CBT. The CBT itself can be delivered remotely [12], and the patients' progress can be remotely monitored [13,14]. Ecological momentary assessment or experience sampling enables more fine-tuned follow-up of patients' usage of and responses to the program [15,16]. We have developed a smartphone CBT app, named Kokoro-App (*kokoro* means *mind* in Japanese), with the integrated Kokoro-Web secure server to which all the activities of the patients with the app are uploaded. Kokoro-App teaches three distinctive CBT skills, namely self-monitoring, behavioral activation, and cognitive restructuring and provides interactive worksheets that the patients can fill in for each task.

The effectiveness of the system was demonstrated in a randomized controlled trial (RCT) comparing antidepressant medication switch plus Kokoro-App against antidepressant medication switch alone among patients who had been unresponsive to one or more antidepressants: the effect size of the intervention was a standardized mean difference of 0.40 in depression severity as measured by masked assessors (P<.001) [17]. This study aims to examine how the patients used the smartphone CBT app during the trial and to investigate what use characteristics differentiated the more successful users of the CBT app from the less successful ones.

Methods

Study Design

The original study was a 9-week, multicenter, parallel-group RCT comparing antidepressant medication switch plus smartphone CBT against medication switch alone among patients with antidepressant-resistant depression [17] (Japanese Clinical Trials Registry UMIN CTR 000013693). A total of 164 patients who had not responded to one or more antidepressants at adequate dosage for 4 or more weeks [18] were randomized 1:1 to the intervention or the control arm. The RCT has been registered in the Japanese trials registry (UMIN CTR 000013693).

The randomized comparison showed that the adjunctive use of smartphone CBT brought about 2.5 (95% CI 1.2-3.7, *P*<.001) points greater reduction in the Patient Health Questionnaire-9 (PHQ-9) [19] scores and 4.1 (95% CI 1.5-6.6, *P*=.002) points greater reduction in the Beck Depression Inventory-II [20] scores after 9 weeks [17]. This study focuses on the 81 patients who were randomized to the smartphone CBT arm and describes and analyzes the patients' use of Kokoro-App.

Kokoro-App

Kokoro-App is a smartphone CBT app and consists of four parts: sessions, mind maps, actions, and thoughts (Figure 1).

There are eight sessions in which several cartoon characters provide psychoeducation through easy but fun conversations. First, the welcome session explains CBT, as well as how to use iPhone and Siri (voice recognition on iPhone). Sessions 1 and 2 explain how to self-monitor one's reactions to various situations according to the cognitive behavioral model. The sessions introduce mind maps in which the patient can enter details of the situation and his reactions to it in terms of emotion and its degree, automatic thoughts, bodily reactions, and behaviors. The patient chooses between four emotions of sad or depressed, anxious or worried, angry, and happy and rates its strength in five grades between 0 and 5.

Sessions 3 and 4 explain behavioral activation according to two principles of "When the body moves, so does the mind" and "Start small and near." When the patient clicks on actions, lists of candidate activities for behavioral activation personal experiments pop up. The candidates are categorized by the usual time they require to complete into (1) less than 5 seconds, (2) less than 5 min, (3) less than 60 min, and (4) 60 min or more. The patient chooses a candidate and rates his expected mastery and pleasure levels. When the patient completes the personal experiment, he can enter his achieved mastery and pleasure levels. The patient can also enter his own personal experiment task. After his own experiments, the patient can recommend certain activities by clicking on "Nice!" button and the number of "Nice!"s will be shared by all the patients.

Sessions 5 and 6 explain cognitive restructuring. After providing a rationale for cognitive restructuring, the app provides four interactive items to guide the patient to alternative thoughts. The patient first picks up a mind map to work on. The first item, "fact glasses," asks classic questions about evidence for and evidence against the automatic thought, such as "What facts do you have to support this thought?" and "What facts are there that do not support this thought?" Then the item combines the patient's answers automatically and says, "So you believe XXX but YYY. If you think this way, how do you feel now?" and asks the patient to rerate his feeling.

Figure 1. A screenshot from Kokoro-App.

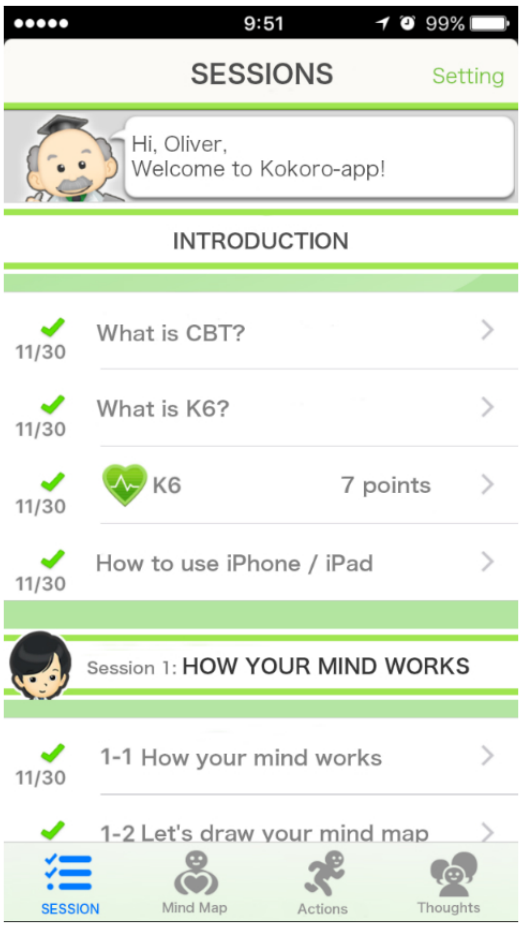
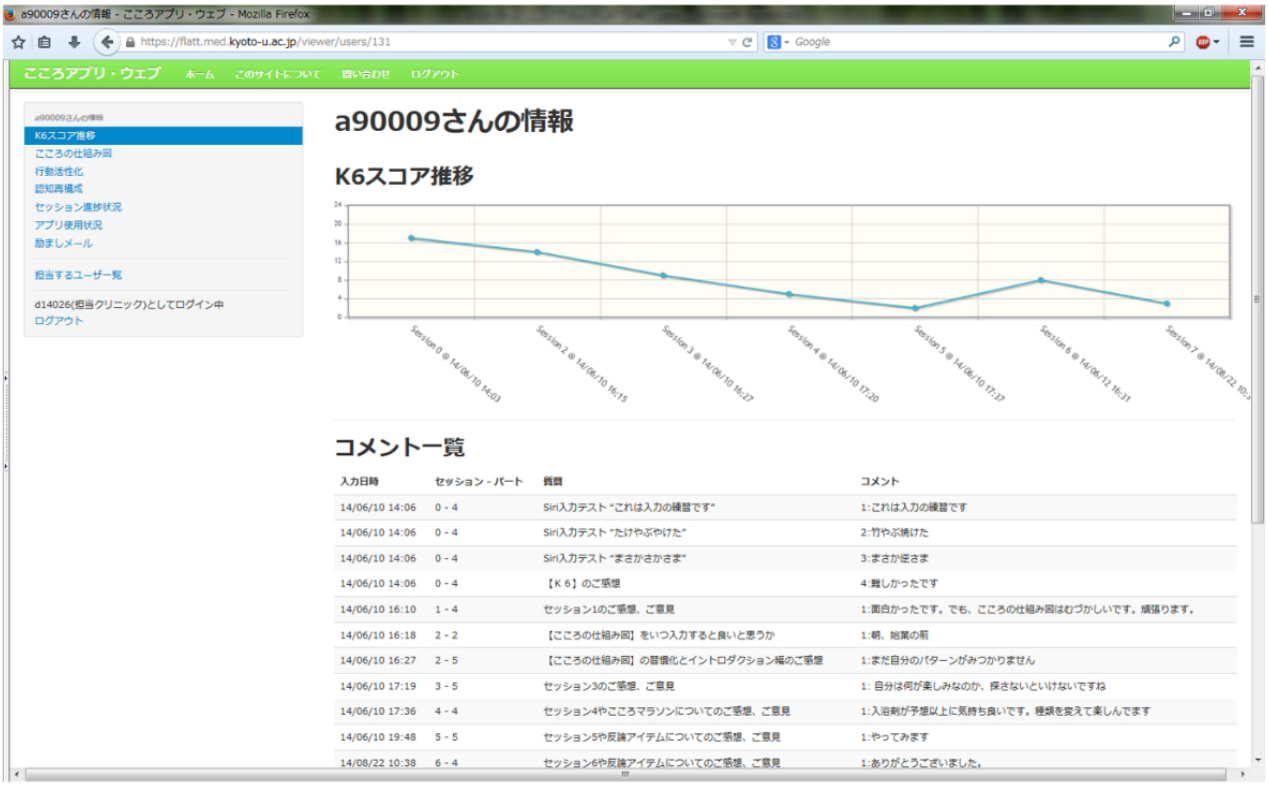


Figure 2. A screenshot from Kokoro-Web.



The second item is called "% Calculator," which does similar things as the fact glasses. It asks, "How confident are you in your thought AAA?" then lets the patient choose between 1% and 99%. Then it asks, "So you think your thought AAA is 99% correct. But then what can there be in your other 1%?" The patient will then answer XXX, and the item will then ask, "So if you think XXX, how would you feel now?" The third item is "friend's call." The item says, "Ring, ring, ring. You have just received a phone call from your best friend, saying AAA. What advice would you give to her?" The rest is the same. The last item is "What-now microphone." The item goes, "Let's just suppose that your thought AAA is true. If so, what can be done now?" The patient will then make an action statement, and the item will then ask, "What if you did do XXX, how would you be feeling?"

The epilogue session summarizes all the previous sessions and also provides tips for relapse prevention.

Each session is expected to take 1 week. The new session can be opened only a week after the last session was started and after one homework has been completed.

Kokoro-Web

All the activities of the patient with Kokoro-App are uploaded to the central server and can be viewed on Kokoro-Web (Figure 2) by the patient, as well as by his treating physician. Kokoro-Web was developed seamlessly and integratively with Kokoro-App. The communication between the app and the server through the Internet was certificated by Secure Sockets Layer.

Statistical Analyses

We first present the descriptive details of how the patients utilized Kokoro-App. The continuous outcomes are summarized by mean and SD and the dichotomous outcomes by number and percentage.

We next subdivide the patients into beneficiaries and nonbeneficiaries from Kokoro-App at the median change score of the PHQ-9 and compare each group's use of the Kokoro-App. Because the same patient contributed a variable number of mind maps, behavioral activations, or cognitive restructurings to account for the within-person clustering effect, we used the mixed effects model where appropriate. Given the observational and hypothesis-generating nature of this study, we set the threshold for statistical significance for each comparison at nominal $P<.05$ throughout. We used STATA (StataCorp) version 14.

Results

Patient Characteristics

Table 1 summarizes the baseline demographic and clinical characteristics of the cohort. Patients were typically around 40 years of age, had some higher education, slightly more than half were in some employment, and slightly less than half were married. They had had several depressive episodes, had been in the current depressive episode for almost 2 years, and were in moderately to severely depression at baseline.

Table 1. Baseline demographic and clinical characteristics of the cohort.

Characteristics	Mean SD[a] or n (%)
Demographic	
Age (years), mean (SD)	40.2 (8.8)
Women, n (%)	46 (57)
Education (years), mean (SD)	14.6 (2.5)
Employment status	
Employed full-time, n (%)	34 (42)
Employed part-time, n (%)	7 (9)
On medical leave, n (%)	21 (26)
Housewife, n (%)	6 (7)
Student, n (%)	0 (0)
Retired, n (%)	0 (0)
Not employed, n (%)	13 (16)
Marital status	
Single, never married, n (%)	34 (42)
Single, divorced, separated or widowed, n (%)	13 (16)
Married, n (%)	34 (42)
Clinical	
Age of onset at first episode (years), mean (SD)	31.8 (10.8)
Number of previous depressive episodes, mean (SD)	3.4 (4.9)
Length of current episode (months), mean (SD)	24.2 (46.3)
PHQ-9[b] at baseline, mean (SD)	13.5 (5.5)
BDI-II[c] at baseline, mean (SD)	28.2 (11.2)

[a]SD: standard deviation.

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

[c]BDI-II: Beck Depression Inventory 2nd edition.

Kokoro-App Use Statistics

Table 2 shows the use statistics of Kokoro-App by the 81 patients.

On average, the patients completed 7.0 out of 8 sessions; it took them 10.8 days to complete one session, during which they spent 62 min on the app reading the sessions and also completing their respective homework (self-monitoring, behavioral activation, or cognitive restructuring).

They filled in 10 mind maps, more often for sad or depressed, or anxious or worried feelings but also for angry or happy feelings. They performed 14 behavioral activation personal experiments through which they had anticipated and achieved moderate levels of mastery and pleasure. With respect to cognitive restructuring, they generated an average of six alternative thoughts using fact glasses, % Calculator, friend's call, or what-now microphone almost equally frequently.

Behavioral Activations

We analyzed the behavioral activations completed by the patients according to their frequencies, the level of mastery and pleasure they achieved, and how unexpectedly good they were.

The most frequently chosen behavioral activations were, in the descending order, "Listen to favorite music," "Read books and magazines," "Brew and drink coffee," and so on (Table 3). The levels of mastery or pleasure expected or achieved were typically in the range 3 to 5 on a scale of 0 to 10.

However, when selected for the levels of achieved mastery or pleasure, very different sets of activities emerged (Tables 4 and 5). These tables are limited to such activities that were reported at least three times. Activities that achieved very high levels of mastery or pleasure included "Test-drive a new car," "Go to a coffee shop after lunch," "Call up an old friend," and "Exercise."

Table 2. Use statistics of Kokoro-App.

Use statistics	Mean (SD[a]), range, and median
Overall	
Sessions completed, mean (SD), range	7.0 (1.4), 1-8
Days taken to complete one session, mean (SD), range	10.8 (4.2), 6.3-31
Actual time (min) per session, mean (SD), range, median	62.3 (96.30), 0-677, 39
Self-monitoring	
Mind maps, no. completed per person, mean (SD), range	10.4 (10.5), 0-45
Mind maps, no. completed per person, by emotion	
Sad or depressed, mean (SD), range	3.2 (3.7), 0-16
Anxious or worried, mean (SD), range	3.0 (3.3), 0-18
Angry, mean (SD), range	2.4 (3.4), 0-16
Happy, mean (SD), range	1.9 (3.1), 0-20
Level of emotion recorded (on a scale of 0-5)	
Sad or depressed, mean (SD)	3.4 (1.3)
Anxious or worried, mean (SD)	3.5 (1.3)
Angry, mean (SD)	3.5 (1.3)
Happy, mean (SD)	3.2 (1.3)
Behavioral activation	
Behavioral activations, no. completed per person, mean (SD), range	13.8 (17.3), 0-118
Level of mastery or pleasure by behavioral activation (on a scale of 0-10)	
Mastery expected, mean (SD)	4.5 (2.8)
Mastery achieved, mean (SD)	4.3 (3.0)
Pleasure expected, mean (SD)	4.8 (2.7)
Pleasure achieved, mean (SD)	4.7 (2.9)
Cognitive restructuring	
Cognitive restructuring, no. completed per person, mean (SD), range	6.2 (6.3), 0-31
Cognitive restructuring items used, per person	
Fact glasses, mean (SD), range	2.0 (2.0), 0-11
% Calculator, mean (SD), range	1.5 (1.8), 0-10
Friend’s call, mean (SD), range	1.5 (1.6), 0-7
What-now microphone, mean (SD), range	1.4 (1.5), 0-7

[a]SD: standard deviation.

Table 3. Behavioral activations: top 10 activities in terms of frequency and their mastery or pleasure levels.

Activity	Frequency (number of reports)	Mastery		Pleasure	
		Expected Mean (SD[a])	Achieved Mean (SD)	Expected Mean (SD)	Achieved Mean (SD)
Listen to favorite music	95	5.2 (3.0)	5.0 (3.3)	5.9 (2.7)	5.7 (2.9)
Read books and magazines	71	4.9 (3.0)	4.5 (3.3)	5.3 (2.7)	4.8 (2.8)
Brew and drink coffee	50	3.5 (3.2)	3.1 (2.6)	3.8 (2.2)	3.8 (2.5)
Hum a tune	41	2.9 (2.5)	2.3 (1.9)	3.8 (2.1)	3.4 (2.2)
Take a long bath	36	3.6 (2.0)	3.9 (2.5)	4.4 (1.9)	4.5 (2.4)
Throw away something you don’t need from the drawer	33	4.3 (1.9)	3.9 (2.4)	3.6 (2.0)	3.5 (2.1)
Go to a coffee shop after lunch	27	8.4 (1.8)	8.3 (2.2)	8.4 (1.8)	8.3 (2.1)
Put some bath powder in the bathtub	24	2.9 (2.0)	3.3 (2.1)	4.1 (2.0)	4.4 (2.0)
Close your eyes for 3 min	21	2.9 (1.7)	2.6 (2.2)	2.7 (1.1)	2.5 (2.3)
Take a different route on the way back home	20	3.0 (1.4)	3.4 (2.3)	3.1 (1.1)	3.3 (2.2)

[a]SD: standard deviation.

Table 4. Behavioral activations: top 10 activities in mastery achieved and their frequencies.

Activity	Frequency (number of reports)	Mastery achieved, mean (SD[a])
Test-drive a new car	3	9.7 (0.6)
Go to a coffee shop after lunch	27	8.3 (2.2)
Exercise	3	8.3 (2.9)
Call up an old friend	4	7.8 (2.9)
Go to yoga with a friend	6	7.2 (1.2)
Go to a hairdresser	3	6.7 (1.5)
Go to a gym	7	6.6 (3)
Walking	8	6.5 (0.8)
Get a haircut	4	6.5 (3)
Go to a meal with a friend	13	6.3 (2.8)

[a]SD: standard deviation.

Table 5. Behavioral activations: top 10 activities in pleasure achieved and their frequencies.

Activity	Frequency (number of reports)	Pleasure achieved, mean (SD[a])
Test-drive a new car	3	9.7 (0.6)
Call up an old friend	4	9.0 (1.4)
Exercise	3	8.7 (2.3)
Go to a coffee shop after lunch	27	8.3 (2.1)
Go to yoga with a friend	6	7.8 (1)
Call up a family and hear their voice	5	7.4 (1.5)
Go to a meal with a friend	13	7.2 (2.3)
Go out for a luxurious lunch	17	6.8 (2.9)
Take a walk	8	6.6 (2)
Nail art	4	6.3 (3.8)

[a]SD: standard deviation.

Some activities brought greater levels of mastery and pleasure than initially expected. Such pleasant surprises included "Exercise," "Do a makeup," "Buy a comic book at a convenience store," "Call up an old friend," or "Go out for a luxurious lunch" (Tables 6 and 7).

Cognitive Restructurings

All the cognitive restructuring items showed statistically significant reductions in sad or depressed, anxious or worried, or angry feelings when the emotion levels were compared pre-post within each situation that the patient worked on (Table 8). Typically, the level of emotion went down from approximately 3.5 to 2.1, showing a reduction greater than 1 point, on a scale of 0 to 5.

When the four tools were compared against each other, again within each situation, friend's call and % Calculator both outperformed fact glasses. The average change in emotion level was −1.6 (SD 1.3), −1.5 (SD 1.3), −1.4 (SD 1.3), and −1.3 (1.3), respectively, for friend's call, what-now microphone, % calculator, and fact glasses.

Contrasts Between Beneficiaries and Nonbeneficiaries of Kokoro-App

The median of the final change score on PHQ-9 was 4. We therefore split the cohort into beneficiaries from Kokoro-App (change greater than 4: n=31) and nonbeneficiaries (change of 4 or less: n=49, including six who showed deterioration from baseline).

Although the beneficiaries tended to complete more sessions, need fewer days to complete one session, and spent more time per session, the group differences were not statistically significant (Multimedia Appendix 1).

Neither did the numbers of mind maps completed, overall and by emotion differ between the two groups, although the beneficiaries tended to report a slightly higher level of happy emotion.

Table 6. Behavioral activations: top 10 activities in unexpected mastery and their frequencies.

Activity	Frequency (number of reports)	Mastery achieved-expected, mean (SD[a])
Exercise	3	1.3 (2.3)
Buy a comic book at a convenience store	4	1.0 (1.4)
Call up an old friend	3	1.0 (1.7)
Do a makeup	5	0.8 (1.3)
Call up a family and hear their voice	5	0.8 (1.3)
Go see a movie	4	0.8 (1.0)
Test-drive a new car	3	0.7 (0.6)
Nail art	3	0.7 (2.1)
Take a long bath	32	0.6 (1.7)
Put some bath powder in the bathtub	21	0.5 (1.0)

[a]SD: standard deviation.

Table 7. Behavioral activations: top 10 activities in unexpected pleasure and their frequencies.

Activity	Frequency (number of reports)	Pleasure achieved-expected, mean (SD[a])
Do a makeup	5	1.0 (1.7)
Call up an old friend	3	1.0 (1.7)
Test-drive a new car	3	0.7 (0.6)
Go out for a luxurious lunch	15	0.6 (1.9)
Say hurray!	9	0.6 (0.7)
Borrow and watch a DVD	8	0.6 (2.7)
Go to a gym	7	0.6 (2.9)
Put some bath powder in the bathtub	21	0.5 (1.0)
Take a long bath	31	0.4 (1.2)
Throw away something you don't need from the drawer	25	0.4 (1.7)

[a]SD: standard deviation.

Table 8. Changes in emotion levels by cognitive restructuring items. The statistical test was done with within-situation paired *t* test.

Item and emotion	Before, mean (SD[a])	After, mean (SD)	Change, mean (SD)	*P* value
Fact glasses				
Sad or depressed (n=68)	3.5 (1.3)	2.4 (1.3)	−1.5 (1.3)	<.001
Anxious or worried (n=61)	3.7 (1.1)	2.2 (1.4)	−1.5 (1.2)	<.001
Angry (n=44)	3.8 (1.2)	2.3 (1.3)	−1.1 (1.3)	<.001
% Calculator				
Sad or depressed (n=48)	3.5 (1.3)	2.2 (1.2)	−1.3 (1.3)	<.001
Anxious or worried (n=49)	3.7 (1.1)	2.1 (1.4)	−1.6 (1.2)	<.001
Angry (n=33)	3.8 (1.3)	2.2 (1.1)	−1.5 (1.3)	<.001
Friend's call				
Sad or depressed (n=50)	3.6 (1.3)	2.1 (1.2)	−1.5 (1.3)	<.001
Anxious or worried (n=46)	3.7 (1.2)	2.1 (1.2)	−1.7 (1.3)	<.001
Angry (n=30)	3.4 (1.3)	2.0 (1.1)	−1.4 (1.3)	<.001
What-now microphone				
Sad or depressed (n=41)	3.4 (1.3)	2.0 (1.2)	−1.4 (1.3)	<.001
Anxious or worried (n=45)	3.9 (1.1)	2.1 (1.2)	−1.8 (1.2)	<.001
Angry (n=30)	3.6 (1.3)	2.4 (1.2)	−1.2 (1.3)	<.001

[a]SD: standard deviation.

The use of behavioral activation differed significantly in many aspects between the successful users and the less successful ones. The former conducted almost twice as many behavioral activations and expected and achieved greater levels of mastery or pleasure. The kinds of behavioral activation tasks chosen were significantly different: differences by more than 3% were found for activities such as "Listen to favorite music," "Read books and magazines," "Go to a coffee shop after lunch" (all more frequent among the beneficiaries), and "Take a long bath" (more frequent among nonbeneficiaries). The time categories of activities chosen were also different: the beneficiaries chose activities likely to require 60 min, whereas the nonbeneficiaries chose activities requiring 5 min or less.

The successful users of Kokoro-App also conducted more cognitive restructuring than the less successful ones, especially those using fact glasses and % Calculator. The decrease in emotion levels, however, was significantly different between the two groups only when using % Calculator.

Discussion

Summary of Findings

Kokoro-App was well accepted among the patients who had been unresponsive to one or more antidepressants and were moderately to severely depressed at baseline. The patients proceeded with the sessions in Kokoro-App at their own pace, spending approximately 60 min across 10 days for each session. Over the course of 9 weeks, on average, they completed 10 mind maps for self-monitoring own emotions and thoughts, conducted 14 behavioral activation personal experiments, and filled in six cognitive restructuring worksheets.

To the best of our knowledge, this study is the first study to examine specific details of behavioral activation or cognitive restructuring tasks conducted by the patients undergoing remote CBT or face-to-face CBT among a sizable number of clinical patients. Very interesting pictures emerged. Although patients often conducted activities with expected and achieved mastery or pleasure levels, around 4 to 5, a number of candidate activities emerged that achieved higher than expected mastery or pleasure. Such activities included, among others, "Test-drive a new car," "Go to a coffee shop after lunch," "Exercise," "Call up an old friend," "Do a makeup," and "Go out for a luxurious lunch." All the cognitive restructuring items were able to reduce the emotion levels significantly.

The study is also the first to compare details of the behavioral and cognitive skills practiced by the patients with regard to the outcome. The successful users of Kokoro-App conducted twice as many behavioral experiments of different kinds and of different time requirements than those who were less successful. The former also conducted significantly more cognitive restructuring tasks, especially using % Calculator.

Limitations of the Study

These are several caveats in the interpretation of the current findings. First, although the original study was an RCT examining the value of adjunctive use of Kokoro-App, this study is by nature an observational study of the users of Kokoro-App. The current results therefore indicate association but not necessarily causation. The amount and nature of behavioral activation tasks or cognitive restructuring worksheets are potential mediators in the causative process from using the smartphone CBT to reduction in depressive symptomatology. It is possible that the beneficiaries of Kokoro-App got better

because they engaged in more behavioral activations, or it is also possible that they conducted more behavioral activations because they had already felt better and had more energy. Second, in accordance with the observational nature of the study, we did not correct for multiple statistical testing and the analyses remain hypothesis-generating rather than confirmatory. The insights gained need be examined in future confirmatory experiments to provide ultimate guidance on how to conduct CBT. Third, strictly speaking, the findings only apply to Kokoro-App and the Japanese patients with moderate to severe depression on an antidepressant treatment. Whether they would apply to other smartphone or Internet CBT (iCBT), or whether they apply to Japanese nonclinical populations or to non-Japanese patients when they use Kokoro-App cannot be taken for granted. For example, “Take a long bath” or “Put some bath powder in the bathtub” may be particularly comforting for the Japanese people who traditionally take great pleasure in taking baths and may not necessarily apply to people living in different cultural traditions. The candidate activities list must certainly be culturally adapted when Kokoro-App is transferred to different countries. It must also be emphasized that app contents need be contextualized for each user’s age, sex, personal relationships, disabilities, and so on to make them more specific.

Implications of the Study Findings

Nonetheless, our findings have important implications at three levels. First, they suggest how Kokoro-App can be improved in the next upgrade. Currently Kokoro-App lists the candidate activities according to the number of “Nice!”s that the patients have voted. This is probably a good feature of the app, creating an atmosphere of a therapeutic community. The next version of Kokoro-App can probably add another dimension to the recommendation by highlighting such activities that may not have been experimented by many but which turned out to produce great mastery or pleasure. The next version of Kokoro-App may also choose to emphasize % Calculator, and possibly do away with fact glasses as the latter has been found to be less effective than the other items. % Calculator and fact glasses aim to derive the same kinds of information, namely evidence for and evidence against the automatic thoughts but through different Socratic questions. % Calculator may be easier to understand for the users.

Second, they provide some insight on how iCBT and CBT in general can be better practiced. Our results suggest that behavioral activation best distinguishes the more from the less successful users of smartphone CBT. This finding is in line with a growing number of RCTs showing similar effectiveness of behavioral activation in comparison with the full CBT package, including cognitive restructuring [7-9]. However, these studies compared the different versions of CBT in the face-to-face settings. Whether the iCBT may as well consist only of behavioral activation or need to include cognitive restructuring is an empirical question warranting a direct randomized comparison.

Third, they also provide suggestions for the next generation of mobile health (mHealth). Providing the mHealth intervention on the Web or via a smartphone increases accessibility of the intervention but is only taking advantage of one aspect of the technology. The program can be used to collect valuable information of what the users of the program do or feel. It may also be combined with habit formation activities. Development of such an e-monitoring system has its own difficulties and complexities, including privacy, integration, and customization [21] but our Kokoro-Web presents one successful example and our study an example of how such a system enables collection of important and fertile information.

Acknowledgments

The study was funded by the Ministry of Health, Labor, and Welfare, Japan (H-22-Seishin-Ippan-008) from April 2013 to March 2014 and thereafter by the Japan Foundation for Neuroscience and Mental Health (JFNMH). The JFNMH received donations from Asahi Kasei, Eli-Lilly, GSK, Janssen, MSD, Meiji Seika, Mitsubishi-Tanabe, Mochida, Otsuka, Pfizer, Shionogi, and Taisho. The study was supported in part by JSPS KAKENHI (Grant-in-Aid for Scientific Research) grant number 17K19808 to TAF. A complete list of participating centers and investigators in the Fun to Learn to Act and Think through Technology (FLATT) trial appears in Multimedia Appendix 2.

Authors' Contributions

TAF conceived the study. TAF, MH, and NY designed the study. KF, NT, RJ, YK, SO, HS, NK, YS, YI, HI, AT, YO, NT, TA, MY, SS, NW, MI, and AH carried out the study. TAF conducted the analyses and wrote the first draft manuscript. All authors contributed to the critical revision of the draft and read and approved the final manuscript.

Conflicts of Interest

TAF has received lecture fees from Eli Lilly, Janssen, Meiji, MSD, Otsuka, Pfizer, and Tanabe-Mitsubishi and consultancy fees from Takeda Science Foundation. He has received royalties from Igaku-Shoin and Nihon Bunka Kagaku-sha publishers. He has received research support from Mochida and Tanabe-Mitsubishi. He is diplomate of the Academy of Cognitive Therapy. MH has received royalties from Igaku Shoin, Shogakukan Shuei-sha Production, Shindan-to-Chiryo-sha, Sogen-sha, Kango-Kyokai, Kitaoji-Shobo, and Kongo-Shuppan publishers. HF has received lecture fees from Meiji and Mochida. NT has received speaking fees from Astellas, Shionogi, Novartis, FUJIFILM RI Pharma, Meiji, Mochida, Janssen, Eli Lilly, and Dainippon-Sumitomo. He has received royalties from Igaku-Shoin, Nanzando, Medical View, and Kanehara publishers. YK has received speaking fee from Otsuka, Yoshitomi, Tanabe-Mitsubishi, Dainippon-Sumitomo, and Eli Lilly. SO has received speaking fee from Eli Lilly and

Mochida. He has received royalties from Igaku-Shoin and Nihon-Hyoron-sha publishers. NK has received lecture fees from Eli Lilly, Janssen, Dainippon-Sumitomo, and Otsuka and consultancy fees from Meiji and Otsuka. He has received royalties from Igaku-Shoin, Nakayama-Shoten, Seronjihou-sha, and Iwasakigakujutu-Shuppan publishers. He has received research funds from Shionogi, Pfizer, and Meiji-Seika. YO has received honoraria for speaking at meetings sponsored by Eli Lilly. NT has received lecture fees from Otsuka and Meiji. AT has received honoraria for speaking at a meeting sponsored by Eli Lilly and Tanabe-Mitsubishi. He has received royalties from Kagaku-Hyoron-sha. TA has received speaking fees or research funds from Daiichi-Sankyo, Eizai, Hisamitsu, Lilly, MSD, Meiji, Mochida, Otsuka, Pfizer, Novartis, and Terumo. He has received royalties from Igaku-Shoin, Nanzando, and Nankodo publishers. MY has received speaking fees from Meiji and has contracted research with Nippon Chemiphar. MI has received lecture fees from Pfizer, Mochida, Shionogi, Daiichi-Sankyo, Meiji, Takeda, and Sumitomo Dainippon Pharma. He has received royalties from Nippon-Hyoron-Sha, Nanzando, Seiwa-Shoten, Igaku-Shoin, and Technomics. SS has received lecture fees from Otsuka, MSD, Meiji, Eli Lilly, Mochida, Pfizer, and Tanabe-Mitsubishi. He has received royalties from Seiwa-Shoten. He has received royalties from Sentan-Igaku-sha, Chuohoki, and Medical Review publishers. NW has received royalties from Sogen-sha, Paquet and Akatsuki publishers.

Multimedia Appendix 1

Beneficiaries and nonbeneficiaries of Kokoro-App.

[PDF File (Adobe PDF File), 63KB - mental_v5i1e4_app1.pdf]

Multimedia Appendix 2

FLATT investigators and committee members.

[PDF File (Adobe PDF File), 29KB - mental_v5i1e4_app2.pdf]

References

1. Cuijpers P, van Straten A, Andersson G, van Oppen P. Psychotherapy for depression in adults: a meta-analysis of comparative outcome studies. J Consult Clin Psychol 2008 Dec;76(6):909-922. [doi: 10.1037/a0013075] [Medline: 19045960]
2. Baardseth TP, Goldberg SB, Pace BT, Wislocki AP, Frost ND, Siddiqui JR, et al. Cognitive-behavioral therapy versus other therapies: redux. Clin Psychol Rev 2013 Apr;33(3):395-405. [doi: 10.1016/j.cpr.2013.01.004] [Medline: 23416876]
3. Barth J, Munder T, Gerger H, Nüesch E, Trelle S, Znoj H, et al. Comparative efficacy of seven psychotherapeutic interventions for patients with depression: a network meta-analysis. PLoS Med 2013;10(5):e1001454 [FREE Full text] [doi: 10.1371/journal.pmed.1001454] [Medline: 23723742]
4. Furukawa TA, Weitz ES, Tanaka S, Hollon SD, Hofmann SG, Andersson G, et al. Initial severity of depression and efficacy of cognitive-behavioural therapy: individual-participant data meta-analysis of pill-placebo-controlled trials. Br J Psychiatry 2017 Mar;210(3):190-196. [doi: 10.1192/bjp.bp.116.187773] [Medline: 28104735]
5. Weitz ES, Hollon SD, Twisk J, van Straten A, Huibers MJH, David D, et al. Baseline depression severity as moderator of depression outcomes between cognitive behavioral therapy vs pharmacotherapy: an individual patient data meta-analysis. JAMA Psychiatry 2015 Nov;72(11):1102-1109. [doi: 10.1001/jamapsychiatry.2015.1516] [Medline: 26397232]
6. Churchill R, Moore T, Caldwell D, Davies P, Jones H, Furukawa T, et al. Cognitive behavioural therapies versus other psychological therapies for depression. Cochrane Database Syst Rev 2010(9) [FREE Full text] [doi: 10.1002/14651858.CD008698] [Medline: 25411559]
7. Jacobson NS, Dobson KS, Truax PA, Addis ME, Koerner K, Gollan JK, et al. A component analysis of cognitive-behavioral treatment for depression. J Consult Clin Psychol 1996 Apr;64(2):295-304. [Medline: 8871414]
8. Dimidjian S, Hollon SD, Dobson KS, Schmaling KB, Kohlenberg RJ, Addis ME, et al. Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. J Consult Clin Psychol 2006 Aug;74(4):658-670. [doi: 10.1037/0022-006X.74.4.658] [Medline: 16881773]
9. Richards DA, Ekers D, McMillan D, Taylor RS, Byford S, Warren FC, et al. Cost and outcome of behavioural activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. Lancet 2016 Aug 27;388(10047):871-880 [FREE Full text] [doi: 10.1016/S0140-6736(16)31140-0] [Medline: 27461440]
10. Cuijpers P. Are all psychotherapies equally effective in the treatment of adult depression? The lack of statistical power of comparative outcome studies. Evid Based Ment Health 2016 Dec;19(2):39-42. [doi: 10.1136/eb-2016-102341] [Medline: 26984413]
11. Bell EC, Marcus DK, Goodlad JK. Are the parts as good as the whole? A meta-analysis of component treatment studies. J Consult Clin Psychol 2013 Aug;81(4):722-736. [doi: 10.1037/a0033004] [Medline: 23688145]
12. Karyotaki E, Riper H, Twisk J, Hoogendoorn A, Kleiboer A, Mira A, et al. Efficacy of self-guided internet-based Cognitive Behavioral Therapy in the treatment of depressive symptoms: a meta-analysis of individual participant data. JAMA Psychiatry 2017 Apr 01;74(4):351-359. [doi: 10.1001/jamapsychiatry.2017.0044] [Medline: 28241179]

13. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
14. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of web-based and mobile health interventions. J Med Internet Res 2011;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
15. Armey MF, Schatten HT, Haradhvala N, Miller IW. Ecological momentary assessment (EMA) of depression-related phenomena. Curr Opin Psychol 2015 Aug 1;4:21-25. [doi: 10.1016/j.copsyc.2015.01.002] [Medline: 25664334]
16. aan het Rot M, Hogenelst K, Schoevers RA. Mood disorders in everyday life: a systematic review of experience sampling and ecological momentary assessment studies. Clin Psychol Rev 2012 Aug;32(6):510-523. [doi: 10.1016/j.cpr.2012.05.007] [Medline: 22721999]
17. Mantani A, Kato T, Furukawa TA, Horikoshi M, Imai H, Hiroe T, et al. Smartphone cognitive-behavior therapy as adjunct to pharmacotherapy for refractory depression: a randomized controlled trial. J Med Internet Res 2017 Nov 03;19(11):e373 [FREE Full text] [doi: 10.2196/jmir.8602] [Medline: 29101095]
18. Thase ME, Rush AJ. When at first you don't succeed: sequential strategies for antidepressant nonresponders. J Clin Psychiatry 1997;58(Suppl 13):23-29 [FREE Full text] [Medline: 9402916]
19. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary care evaluation of mental disorders. Patient Health Questionnaire. J Am Med Assoc 1999 Nov 10;282(18):1737-1744. [Medline: 10568646]
20. Beck A, Steer R, Brown G. BDI-II: Beck Depression Inventory, Second Edition. San Antonia: The Psychological Corporation; 1996.
21. Sundram F, Hawken SJ, Stasiak K, Lucassen MF, Fleming T, Shepherd M, et al. Tips and traps: lessons from codesigning a clinician e-monitoring tool for computerized cognitive behavioral therapy. JMIR Ment Health 2017 Jan 11;4(1):e3 [FREE Full text] [doi: 10.2196/mental.5878] [Medline: 28077345]

Abbreviations

CBT: cognitive behavioral therapy
iCBT: Internet cognitive behavioral therapy
mHealth: mobile health
SD: standard deviation

Edited by G Eysenbach; submitted 03.10.17; peer-reviewed by N Bragazzi, S Aggarwal; comments to author 08.11.17; revised version received 16.11.17; accepted 17.11.17; published 11.01.18.

Please cite as:
Furukawa TA, Horikoshi M, Fujita H, Tsujino N, Jinnin R, Kako Y, Ogawa S, Sato H, Kitagawa N, Shinagawa Y, Ikeda Y, Imai H, Tajika A, Ogawa Y, Akechi T, Yamada M, Shimodera S, Watanabe N, Inagaki M, Hasegawa A
Cognitive and Behavioral Skills Exercises Completed by Patients with Major Depression During Smartphone Cognitive Behavioral Therapy: Secondary Analysis of a Randomized Controlled Trial
JMIR Ment Health 2018;5(1):e4
URL: http://mental.jmir.org/2018/1/e4/
doi:10.2196/mental.9092
PMID:29326098

Original Paper

Web-based Therapy Plus Support by a Coach in Depressed Patients Referred to Secondary Mental Health Care: Randomized Controlled Trial

Simon Hatcher[1], MBBS, MMedSc, MRCPsych; Robyn Whittaker[2], MBChB, PhD; Murray Patton[3], MBChB, FRANZCP; Wayne Sylvester Miles[4], MBChB, FRANZCP; Nicola Ralph[5]; Katharina Kercher[4], BSc; Cynthia Sharon[5], MSc (Hons), PGDip HealthPsych

[1]Brain and Mind Research Institute, Department of Psychiatry, The University of Ottawa, Ottawa, ON, Canada

[2]National Institute for Health Innovation, The University of Auckland, Auckland, New Zealand

[3]Mental Health and Addiction Services, Northland District Health Board, Whangarei, New Zealand

[4]Mental Health Services, Waitemata District Health Board, Auckland, New Zealand

[5]Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand

Corresponding Author:
Simon Hatcher, MBBS, MMedSc, MRCPsych
Brain and Mind Research Institute
Department of Psychiatry
The University of Ottawa
Room 4418
501 Smyth Road
Ottawa, ON, K1H 8L6
Canada
Phone: 1 (613) 798 5555
Email: shatcher@uottawa.ca

Abstract

Background: The evidence for the effectiveness of Web-based therapies comes mainly from nonclinical populations, with a few studies in primary care. There is little evidence from patients referred to secondary mental health care with depression. Adherence to Web-based therapies is often poor. One way to increase this is to create a new health service role of a coach to guide people through the therapy.

Objective: This study aimed to test in people referred to secondary care with depression if a Web-based therapy (The Journal) supported by a coach plus usual care would be more effective in reducing depression compared with usual care plus an information leaflet about Web-based resources after 12 weeks.

Methods: We conducted a randomized controlled trial with two parallel arms and a process evaluation that included structured qualitative interviews analyzed using thematic analysis. The coach had a background in occupational therapy. Participants were recruited face-to-face at community mental health centers.

Results: We recruited 63 people into the trial (intervention 35, control 28). There were no statistically significant differences in the change from baseline in Patient Health Questionnaire-9 (PHQ-9) scores at 12 weeks comparing The Journal with usual care (mean change in PHQ-9 score 9.4 in the intervention group and 7.1 in the control group, t_{41}=1.05, P=.30; mean difference=2.3, 95% CI −2.1 to 6.7). People who were offered The Journal attended on average about one less outpatient appointment compared with usual care, although this difference was not statistically significant (intervention mean number of visits 2.8 (SD 5.5) compared with 4.1 (SD 6.7) in the control group, t_{45}=−0.80, P=.43; mean difference=1.3, 95% CI −4.5 to 2.0). The process evaluation found that the mean number of lessons completed in the intervention group was 2.5 (SD=1.9; range=0-6) and the number of contacts with the coach was a mean of 8.1 (SD=4.4; range=0-17). The qualitative interviews highlighted the problem of engaging clinicians in research and their resistance to recruitment: technical difficulties with The Journal, which prevented people logging in easily; difficulty accessing The Journal as it was not available on mobile devices; participants finding some lessons difficult; and participants saying they were too busy to complete the sessions.

Conclusions: The study demonstrated that it is feasible to use a coach in this setting, that people found it helpful, and that it did not conflict with other care that participants were receiving. Future trials need to engage clinicians at an early stage to articulate where Web-based therapies fit into existing clinical pathways; Web-based therapies should be available on mobile devices, and logging in should be easy. The role of the coach should be explored in larger trials.

Trial Registration: Australian New Zealand Clinical Trials Registry (ACTRN): 12613000015741; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=363351&isReview=true (Archived by WebCite at http://www.webcitation.org/6wEyCc6Ss).

(JMIR Ment Health 2018;5(1):e5) doi:10.2196/mental.8510

KEYWORDS

Internet; major depressive disorder; secondary care; randomized controlled trial; New Zealand

Introduction

Depression is a common mental disorder [1] with significant impacts on quality of life and with a high social burden [2]. It is also a significant risk factor for suicide [3]. Most treatment of depression occurs in primary care. However, there is limited availability of psychological therapies despite them being recommended as first line treatments for mild to moderate depression. Additionally, access to specialized care is difficult with long waiting lists [4].

There is increasing evidence that Web-based treatments, which deliver psychological therapy based on cognitive behavioral principles, can reduce symptoms of depression [5]. Randomized controlled trials (RCTs) have demonstrated the effectiveness of Web-based cognitive behavior therapy [6], problem solving therapy [7], interpersonal therapy [8], and psychodynamic therapy [9]. However, most RCTs of Web-based therapy have been in "community samples" often recruited from the Internet. These populations are self-selecting, and although their scores on depression rating scales may be comparable to clinical populations, they often differ in comorbidity, duration of symptoms, and impact on everyday activities.

A second problem is whether the Internet interventions should be provided with or without support from a coach or therapist (referred to as guided interventions). The role of the coach is to provide support for the patient progressing through the Web-based therapy, answering both technical questions about how the program works, as well as providing support and encouraging the patient to progress through the program. The computer provides the therapy, whereas the coach provides guidance and advice. To date, coaches have come from a variety of backgrounds including psychology, social work, as well as "technicians" [10,11]. Several systematic reviews have demonstrated that Internet-based interventions for depression provided with human support have effect sizes that are comparable with face-to-face interventions, whereas nonguided interventions have smaller effect sizes [12,13]. However, the evidence is inconsistent with head-to-head comparisons of guided versus unguided interventions showing mixed results. For example, three recent studies on depression showed no significant differences between guided and unguided therapy. The participants were recruited by newspaper or television adverts [14], by a telephone helpline [15], or from US academic internal medicine clinics [16]. In contrast, a head-to-head comparison of guided versus unguided Web-based problem solving therapy in a population of mildly depressed participants recruited via newspaper and television adverts in the Netherlands found that the guided therapy was significantly better than the waiting list control group [17]. These differences could be explained by differences in the Web-based therapy, the population, the type or intensity of support, the different qualifications of the coach, or choice of control group. There have been no trials of guided compared with unguided Web-based therapy in secondary care.

The largest study of guided versus unguided therapy has been the Randomised Evaluation of the Effectiveness, cost-effectiveness and Acceptability of Computerised Therapy (REACT) study [18], which was an RCT of 691 patients with depression in UK primary care. Participants were randomized to treatment as usual, a guided commercial Web-based program "Beating the Blues," and a guided free Web program "MoodGYM." The study found no difference in depression outcomes between the three groups. A major criticism of this study is the minimal exposure to the intervention in the Web-based therapy groups; participants only completing a median of 1 or 2 sessions and receiving only 6 min technical support time from the coaches, 5 emails, and almost no text messages (short message service, SMS). About one in 5 participants randomized to Web-based therapy did not access the Web-based programs at all.

The most probable reason that guided Web-based treatments are likely to be effective is that human support increases adherence to the intervention, which results in better outcomes [11]. Unguided Internet interventions have high dropout rates with few people completing the entire course. Mean rates of adherence for unguided interventions are about 26% compared with 72% for guided interventions [19]. The components of effective coaching are unclear; as to date, most of the literature emphasizes the technical aspects of the Internet intervention. It is not clear whether the professional background of the coach makes a difference, what is the optimal frequency of contact, and what the content of the coaching should be.

"The Journal" [20] is a free Web-based program for the self-management of depression developed in New Zealand by the Ministry of Health. It capitalizes on the social marketing appeal of Sir John Kirwan, an ex All Black rugby player who has described his experiences of depression to help destigmatize mental illness. The program is based on the cognitive behavioral techniques of behavioral activation and problem solving. Usage

data shows that the depression.org.nz website was visited by 700,000 people in its first year with 20,000 registered with The Journal and 13,000 active users. About 1500 people a month register to start the program, with about three-quarters of people recording significant improvement. There is no data on who uses the program, but peaks in registration coincide with TV adverts promoting the www.depression.org.nz site. Although the program was designed for depression of mild to moderate severity, the evidence shows that nearly a third of people who access the program have more severe depression. However, only one in twenty people who start the program complete all six lessons, and one in ten report no change or a worsening of symptoms. The data do not show who these people are, how to improve the rate of completion, or whether the improvement would have happened without The Journal. The Journal has not been subjected to any clinical trials, and its effectiveness is unproven.

In New Zealand, there is universal health care, with most people having a family doctor. Mental health care is generally provided by community mental health teams based outside hospitals. Each community mental health team provides care to a population of 80,000 to 100,000 people. The teams consist of several disciplines including nurses, psychiatrists, and social workers. People with depression are generally referred by their family doctor.

We report on an RCT and process evaluation of The Journal using a coach compared with a pamphlet that included descriptions of Web-based self-help therapy for depression that participants could choose to use how they liked. We did this in people referred to secondary mental health services with depression. We chose giving an information pamphlet as a control because this seemed like a low cost, low risk alternative that services could easily implement, and we wanted to see if providing guided therapy added anything to this pamphlet. We hypothesized that patients who received guided Web-based therapy would improve quicker and require fewer face-to-face appointments with clinicians than people who received the pamphlet.

Methods

Trial Design

The design of the trial was an RCT with two parallel groups.

Participants

Potential participants were patients attending community mental health centers in Waitemata District Health Board (DHB) who had been referred with a problem of depression or dysthymia. We aimed to involve one community mental health center in an urban area, one in a mixed rural urban area, and the Maori mental health service, Moko. The main exclusion criteria were inability to read and write English or cognitive difficulties, meaning that potential participants would be unable to use a computer. The presence of other comorbid conditions such as anxiety, suicidal thoughts, alcohol, or drug disorders were not exclusion criteria. Potential participants were approached in person face-to-face after triage at the community mental health center to ask for their consent to take part in the trial.

Interventions

The control group received their normal clinical care. They were also given a pamphlet describing different websites that provide support for people with depression, including The Journal, and told that they could decide for themselves the best way to use the information.

For those participants in the intervention group, the intervention consisted of the following:

1. An invitation to use *The Journal* supported by a coach who provided patients with weekly email, text message, or telephone contact. The coach had a guideline script for each lesson of *The Journal* to reinforce the topic of each lesson, help identify and support patients in their goals, and to coach them in goal setting and the techniques of problem solving. The coach provided a brief summary for the clinicians at each face-to-face appointment, including details of the goals selected by the patients. The coach who had a background in occupational therapy received weekly supervision from an experienced clinician.
2. A brief training program for the clinicians in using *The Journal* with their patients. This familiarized the clinicians in the content of *The Journal* and the clinical concepts embedded in it.
3. A short checklist for clinicians to use to check progress through *The Journal* during scheduled outpatient appointments.

If participants did not have access to a computer at home, one was provided in the mental health center.

Outcomes

The primary outcome measure was the PHQ-9 [21], a brief self-rating scale for depression that is built into The Journal, measured at 12 weeks (scores of 0-9 on the PHQ-9 indicate minimal or mild depression, 10-14 is moderate depression, 15-19 is moderately severe depression, and 20-27 is severe depression). Secondary outcome measures included the short form-36 (SF-36) [22], the EuroQol-5D (EQ-5D) [23], medication use, time to first outpatient appointment, and the number of outpatient appointments. We administered the rating scales at baseline, after 2 weeks, 6 weeks, and 12 weeks. For measures other than the PHQ-9 in the intervention arm, participants were mailed questionnaires to return in prepaid envelopes or they completed the questionnaires over the phone. Service use within the DHB was obtained from the electronic medical record of each participant.

Sample Size

Using the PHQ-9 in this patient group based on other studies, we expected the mean pretreatment score to be about 17 with an SD of 4. To detect a difference in score between the two groups of 3 points, an established minimal clinically important difference [24], would need 30 people in each group with a two-sided alpha of .05 and a power of 80%. Allowing for a 25% (20/80) dropout rate, we aimed to recruit 80 participants.

Randomization

Randomization was by computer, with allocations kept in sequential sealed envelopes at the study base. There were no

restrictions. We contacted potential participants by post or telephone. After giving their consent to be in the study, participants were allocated by the study coordinator to one of the groups according to the allocation in the sealed envelopes.

Blinding

The clinicians were not blind to whether their patients were using The Journal. Research assistants who collected study outcomes were blind to treatment allocation.

Statistical Methods

Group differences in demographic, pre- and posttreatment measures were analyzed with analysis of variance (ANOVA). We planned to assess changes in participants' scores from pretreatment to follow-up at 12 weeks by paired sample two-tailed t tests. The summary statistics and the one-way ANOVA were generated in R version 3.0.2 for Windows (R Foundation for Statistical Computing, Vienna, Austria). We planned to use a repeated measure model to account for missing PHQ-9 values. This model analyzed the scores with gender (female and male), ethnicity (Pakeha [non-Maori New Zealanders], Asian, and Maori), age, PHQ-9 (four different times baseline, week 2, week 6, and week 12), group (control and intervention) and their interaction as fixed effects, and PHQ-9 by each patient as a repeated effect. Statistical analysis was conducted using the PROC MIXED procedure in SAS version 9.3 for Windows. A significance level of 0.05 was used in hypothesis testing. Shapiro-Wilk tests were used to assess normal distribution.

We also planned to calculate numbers needed to treat (NNTs) for two measures: (1) the NNT to achieve remission, which we define as a PHQ-9 score of 9 or below at 12 weeks and (2) the NNT to demonstrate a significant reduction in symptoms, which we define as a score of 9 or less or a 50% decrease in individual PHQ-9 scores from baseline to 12-week follow-up. Chi-square was used to test differences in proportions.

Process Evaluation

We conducted a process evaluation to explore the implementation, receipt, and context of the intervention to help understand the results following the Medical Research Council's guidelines on assessing complex interventions [25]. We documented the number of lessons completed and the number of email and phone contacts from the coach. We also conducted structured qualitative interviews that asked open-ended questions about participants' experience of the website, the content of the program, and the experience of having a coach. Interviews were analyzed using thematic analysis using two independent reviewers. The female interviewer was not part of the team that conducted the RCT. We planned to interview a purposive sample of participants with an even gender balance. We would stop interviews once no new themes were identified. We also planned focus groups to interview clinicians in the community mental health teams about their experience of seeing participants who had used The Journal with a coach. The coach provided feedback on her role.

We received signed informed consent from participants, and the study received ethical approval from the New Zealand Central Health and Disability Ethics Committee ref 12/CEN/53.

Results

Participants

We recruited participants from February to October 2013. Over the 9 months, 132 people were screened, and 63 consented to take part in the trial (47.7% [63/132] of those screened). Of those who declined to consent for the study, 26 preferred not to take part (6 of whom had a private psychotherapist); 17 we could not contact, 5 needed an interpreter, and one had already completed the Journal. Most of the participants (54 of 63) came from two community mental health teams: North One, which covers the southern urban part of the North Shore of Waitemata DHB and Rodney, which covers the more rural northern part of the DHB. Figure 1 shows the flow of participants through the study, and Table 1 describes the baseline data of the participants.

Primary Outcome

The mean and median PHQ-9 scores were lower in the intervention group than in control at all time points (Table 2). There were more missing values of PHQ-9 scores in the intervention group than in the control group except at baseline. There were high rates of missing scores at 6 and 12 weeks. Shapiro-Wilk tests of normal distribution were not significant apart from the control PHQ-9 scores at week 12 (Shapiro-Wilk statistic 0.91, df=22, P=.04).

The one-way ANOVA (Table 2) showed that PHQ-9 scores did not differ significantly between control and intervention groups at any of the time points. Due to the nonnormality of PHQ-9 scores in the control group at week 12, we also tested statistical significance of the difference in mean PHQ-9 scores at week 12 with a Mann-Whitney test. This confirmed that the difference was not statistically significant (Mann-Whitney U=193, Z=−1.15, P=.25).

The mean change from baseline in PHQ-9 score at 12 weeks was 9.4 (SD 6.7) in the intervention group and 7.1 (7.5) in the control group (t_{41}=1.05, P=.30; mean difference=2.3, 95% CI −2.1 to 6.7).

The repeated measures modeling showed the scores on the PHQ-9 were not statistically significantly associated with gender (F_{60}=0.65, P=.42), ethnicity (F_{60}=0.74, P=.39), age (F_{60}=0.79, P=.46), group (F_{60}=1.26, P=.27), and the interaction between group and PHQ9 (F_{205}=0.46, P=.71). The scores of PHQ-9 differed statistically at the different time points (F_{186}=40.66, P<.001).

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

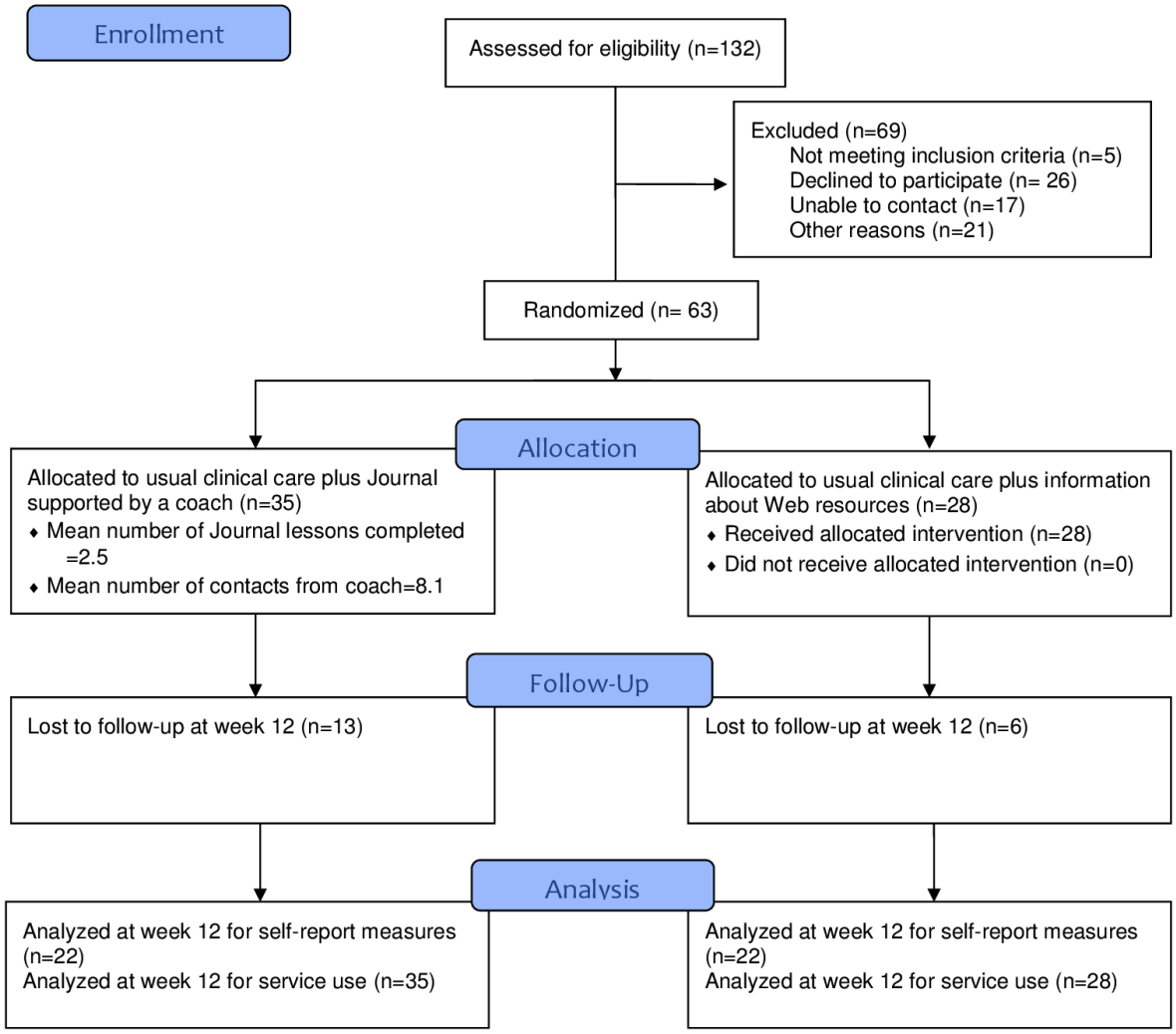


Table 1. Baseline data.

Variable	Intervention (N=35)	Control (N=28)
Gender, n		
Male	16	13
Female	19	15
Age in years, mean (range)	43 (21-65)	42 (23-64)
Ethnicity, n		
European New Zealander	21	20
Maori	2	2
Other	12	6
Referral source, n		
Primary care	26	14
Other	9	14
PHQ-9[a] (SD)	17.1 (5.2)	18.0 (5.7)
SF-36[b] physical function (SD)	78 (21)	74 (27)
SF-36 social function (SD)	31 (19)	27 (19)
EQ-5D[c] (SD)	8.0 (1.8)	8.0 (1.7)

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

[b]SF-36: short form-36.

[c]EQ-5D: EuroQol-5D.

Table 2. Summary scores of Patient Health Questionnaire-9 (PHQ-9) at four time points.

Summary statistic	Baseline		2 weeks		6 weeks		12 weeks	
	Control (N=28)	Intervention (N=35)	Control (N=28)	Intervention (N=35)	Control (N=28)	Intervention (N=35)	Control (N=28)	Intervention (N=35)
Mean (SD)	18.0 (5.2)	17.1 (5.7)	12.4 (6.4)	11.5 (5.2)	11.5 (7.2)	10.1 (5.9)	10.4 (7.7)	7.3 (4.9)
Median	19	17.5	12	11	13	10	7	7
Missing values (%)	1 (3.6)	1 (2.9)	3 (10.7)	6 (17.1)	5 (17.9)	10 (28.6)	6 (21.4)	13 (37.1)
Difference in mean scores (95% CI) and results of one way analysis of variance	0.9 (3.6 to −0) F_{60}=0.37 P=.55		0.9 (4.1 to −2.2) F_{53}=0.37 P=.55		1.4 (5.2 to −2.5) F_{47}=0.51 P=.48		3.1 (7.1 to −0.8) F_{43}=2.61 P=.11	

At 12 weeks, 16 (73%, 16/22) of the intervention group scored 9 or below on the PHQ compared with 12 (55%, 12/22) in the control group (χ^2=1.57, P=.21). To assess a significant reduction in symptoms, we used the last observation carried forward for those participants who had at least two measures on the PHQ-9. This showed that 22 of the intervention group (69%, 22/32) and 15 of the control group (58%, 1/26) had achieved scores of 9 or less or had a 50% improvement in PHQ-9 scores by week 12 (χ^2=0.76, P=.39).

Secondary Outcomes

Participants in the intervention group attended one fewer outpatient appointments with the mental health teams compared with the control group. This difference was not statistically significant (intervention: n=33, mean number of visits=2.8, SD=5.5 compared with mean=4.1, SD=6.7, n=24 in the control group; t_{45}=−0.80, P=.43; mean difference=1.3, 95% CI −4.5 to 2.0). They also made fewer phone calls to the mental health teams (intervention: n=35, mean=2.4, SD=3.1 compared with mean=2.8, SD=4.1, n=28 in the control group; t_{61}=−0.50, P=.62; mean difference=−0.5, 95% CI −2.3 to 1.4). Participants in the intervention group reported fewer appointments with general practitioners (intervention: n=26, mean number of appointments=1.5, SD=1.2 compared with mean=2.1, SD=2.7, n=22 in the control group; t_{46}=−0.96, P=.35; mean difference=−0.6, 95% CI −1.7 to 0.6).

At 12 weeks, there were no significant differences in mean SF-36 scores between the intervention and control groups (intervention group: n=22, mean SF-36 physical function=87, SD=19; control group: n=22, mean=81, SD=24; t_{42}=0.9, P=.40, 95% CI for difference −7 to 19. Intervention group: n=22, mean SF-36 social function=60, SD=22; control group: n=22, mean=59, SD=30; t_{42}=0.14, P=.90, 95% CI for difference −15

to 17). There were also no significant differences in mean EQ-5D scores at 12 weeks (intervention group: n=22, mean EQ-5D=6.5, SD=1.4; control group: n=22, mean=7.2, SD=1.8; t_{42}=−1.4, *P*=.16, 95% CI for the difference −1.7 to 0.3).

At the end of the study, 22 out of 26 (85%) people in the intervention group reported they had been prescribed medication compared with 16 out of 22 (73%) in the control group. In the control group, 13 of 22 participants took a mean of 2.4 days off work at 12 weeks compared with 12 of 22 participants in the intervention group who took a mean of 1.5 sick days (t_{42}=−0.9, *P*=.40, 95% CI for the difference −2.8 to 1.1 days).

Process Evaluation

The mean number of lessons completed in the intervention group in the 12 weeks was 2.5 (SD=1.9; range=0-6); the number of contacts with the coach was a mean of 8.1 (SD=4.4; range=0-17). Seven people in the intervention group did not complete any of the Journal lessons, although 5 of these did have some contact with the coach. There was no correlation between the number of lessons completed and change in PHQ-9 scores at 12 weeks (Spearman rho, ρ=.1, *P*=.60) or between the number of contacts with the coach and change in PHQ-9 scores at 12 weeks (ρ=.4, *P*=.07).

We conducted nine structured qualitative interviews with 5 male and 4 female participants who had been randomized to The Journal. Interviews took place at a mutually convenient location, which in most cases was a community mental health team base or the person's place of work. The themes that arose from peoples' experience of using the website included technical difficulties with access and not being able to view future lessons as barriers to engagement. Furthermore, at the time of the trial, The Journal could not be used fully on a mobile phone or tablet, which participants found limited their use of the program. The participants liked the layout of The Journal, the suggested activities, and the alerts, as illustrated in the following quote:

> *I liked the one where you had to think about a problem and try and come up with solutions to solve that problem. So chose wanting to spend more quality time with my children and so I found that that really got me thinking about it and to figure out how I could do it.* [034;3]

Participants found some lessons too long and complicated. They found the coach was helpful for motivation and support, as illustrated in the following quote:

> *I think that if I had been doing it on my own I would have struggled…but when I got a bit mixed up with it she (E-therapy Coach) was able to say well ok this is what this is and...so I thought the combination of the two (the Journal and coaching) was great.* [013;4]

However, the process of using a coach was different to a face-to-face appointment, and participants thought education around this would be helpful. Some participants reported avoiding the coach and feeling judged if they felt they had done something "wrong" such as not completing a lesson, as illustrated in the following quote:

> *One of the lessons I did have a bit of a relapse because she said that I had done it all wrong, and I got quite upset...And so she went away and it was a bit open ended and all I could think of was that I had done it all wrong.* [039;6]

The feedback from the coach was that some people were not in a "therapeutic space" when accessing help online. When seeing clinicians face-to-face, the act of going prepares individuals to enter a psychological as well as physical space to seek support, explore, open up, and learn. Being online or at home was providing help in a different context that wasn't necessarily therapeutic. Follow-up by phone was similar as participants often were not available for follow-up when they said they would be or were in places such as supermarkets where coaching conversations were difficult. The coach used email and text messages mainly to check whether people had time to visit the website and to arrange times to call. The coach also found staff in secondary services did not appreciate Internet information and support as part of a skill set and resources they could offer clients.

We conducted two focus groups with clinicians. The main findings were that clinicians wanted to know more about The Journal but thought there were barriers to using it (access to broadband and computers) and that navigating the program was "a bit clunky." The clinicians also thought it was difficult introducing the program at triage and preferred to use it as an extra resource at discharge from their service.

Discussion

Principal Findings

In a trial of usual care plus a guided Web-based therapy compared with usual care plus information about Web-based therapies, in a depressed secondary care population, we found no statistically significant differences in outcomes.

Limitations

The strength of the study is that it is one of the first trials of a guided therapy compared with unguided therapy in a secondary care setting. It also showed that it was feasible to use a coach in this setting. The main weakness was the trial was underpowered for the outcomes based on self-rating scales because of the large number of dropouts from the study at 12 weeks and because of difficulties recruiting the planned sample size in a clinical setting.

There was also the problem of contamination: (1) the clinicians could use The Journal with patients allocated to the usual care group and (2) The Journal is freely available online, so any participant in the study could access it. There was little we could do to prevent clinicians and patients from using The Journal who were not in the intervention group. However, our experience is that clinicians or patients in secondary care do not widely use The Journal. Furthermore, the problem with contamination is likely to bias the study to showing no-difference (as the control group could use The Journal unguided), so any differences that are found are likely to be more "believable."

Comparison With Prior Work

The findings in this study are similar to the REACT study [18], which found no difference between guided and unguided therapies in UK primary care. As in the REACT study, we found low engagement with the Web-based program, although in our study there was greater engagement with the coach.

A problem with The Journal during the study was there were difficulties with ease of access as it was not available on mobile devices and there were problems logging in. The process evaluation identified these as major obstacles, which are similar to problems of losing trust in face-to-face therapy and barriers to access preventing use of services. If patients are to use Web-based therapies as alternatives to face-to-face therapy, then they need to be easily accessible and do what they promise.

This study also indicates that training for patients in the use of a remote coach would be helpful. The training should include explaining the purpose of the coach, state that patients will not be "judged" if they do not complete or miss lessons, what to do if lessons are missed, and the need to be in an appropriate physical place when engaged in coaching. Future studies could include tests of technological ability as a predictor of adherence. Not everyone navigates around the Web-based environment in the same way or with the same level of skill. These tests could include simple timed tasks to see how easily people navigate around Web-based programs on their chosen platform. Additionally, assessments of motivation to complete the program from both the coach and participants could be investigated as predictors of completion of Web-based programs.

Conclusions

Larger studies in clinical populations in primary and secondary care need to be done. Researchers need to consider when and how Web-based therapies should be used in existing clinical pathways.

Acknowledgments

This work was supported by Health Research Council—Research Partnership in New Zealand Health Delivery fund (grant number 12-188). The funders had no role in the review or approval of the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 846KB - mental_v5i1e5_app1.pdf]

References

1. Wang PS, Aguilar-Gaxiola S, Alonso J, Angermeyer MC, Borges G, Bromet EJ, et al. Use of mental health services for anxiety, mood, and substance disorders in 17 countries in the WHO world mental health surveys. Lancet 2007 Sep 8;370(9590):841-850 [FREE Full text] [doi: 10.1016/S0140-6736(07)61414-7] [Medline: 17826169]
2. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med 2006 Nov;3(11):e442 [FREE Full text] [doi: 10.1371/journal.pmed.0030442] [Medline: 17132052]
3. Zalsman G, Hawton K, Wasserman D, van Heeringen K, Arensman E, Sarchiapone M, et al. Suicide prevention strategies revisited: 10-year systematic review. Lancet Psychiatry 2016 Jul;3(7):646-659. [doi: 10.1016/S2215-0366(16)30030-X] [Medline: 27289303]
4. Slomp M, Bland R, Patterson S, Whittaker L. Three-year physician treated prevalence rate of mental disorders in Alberta. Can J Psychiatry 2009 Mar;54(3):199-203. [doi: 10.1177/070674370905400308] [Medline: 19321024]
5. Stéphan F, Le Galudec M, Tritschler-Le Maitre M, Berrouiguet S, Walter M. Revue des différents programmes de thérapies cognitivo-comportementales sur Internet dans le traitement de la dépression. Journal de Thérapie Comportementale et Cognitive 2014 Dec;24(4):138-143. [doi: 10.1016/j.jtcc.2014.05.002]
6. Andrews G, Cuijpers P, Craske MG, McEvoy P, Titov N. Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: a meta-analysis. PLoS One 2010 Oct 13;5(10):e13196 [FREE Full text] [doi: 10.1371/journal.pone.0013196] [Medline: 20967242]
7. van Straten A, Cuijpers P, Smits N. Effectiveness of a web-based self-help intervention for symptoms of depression, anxiety, and stress: randomized controlled trial. J Med Internet Res 2008 Mar 25;10(1):e7 [FREE Full text] [doi: 10.2196/jmir.954] [Medline: 18364344]
8. Donker T, Bennett K, Bennett A, Mackinnon A, van Straten A, Cuijpers P, et al. Internet-delivered interpersonal psychotherapy versus internet-delivered cognitive behavioral therapy for adults with depressive symptoms: randomized controlled noninferiority trial. J Med Internet Res 2013 May 13;15(5):e82 [FREE Full text] [doi: 10.2196/jmir.2307] [Medline: 23669884]

9. Zwerenz R, Becker J, Johansson R, Frederick RJ, Andersson G, Beutel ME. Transdiagnostic, psychodynamic web-based self-help intervention following inpatient psychotherapy: results of a feasibility study and randomized controlled trial. JMIR Ment Health 2017 Oct 16;4(4):e41 [FREE Full text] [doi: 10.2196/mental.7889] [Medline: 29038094]
10. Titov N, Andrews G, Davies M, McIntyre K, Robinson E, Solley K. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PLoS One 2010 Jun 8;5(6):e10939 [FREE Full text] [doi: 10.1371/journal.pone.0010939] [Medline: 20544030]
11. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing human support to enhance adherence to eHealth interventions. J Med Internet Res 2011 Mar 10;13(1):e30 [FREE Full text] [doi: 10.2196/jmir.1602] [Medline: 21393123]
12. Andersson G, Cuijpers P, Carlbring P, Riper H, Hedman E. Guided Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis. World Psychiatry 2014 Oct;13(3):288-295 [FREE Full text] [doi: 10.1002/wps.20151] [Medline: 25273302]
13. Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on Internet-based mental health interventions - a systematic review. Internet Interv 2014;1(4):205-215 [FREE Full text] [doi: 10.1016/j.invent.2014.08.003]
14. Berger T, Hämmerli K, Gubser N, Andersson G, Caspar F. Internet-based treatment of depression: a randomized controlled trial comparing guided with unguided self-help. Cogn Behav Ther 2011;40(4):251-266. [doi: 10.1080/16506073.2011.616531] [Medline: 22060248]
15. Farrer L, Christensen H, Griffiths KM, Mackinnon A. Internet-based CBT for depression with and without telephone tracking in a national helpline: randomised controlled trial. PLoS One 2011;6(11):e28099 [FREE Full text] [doi: 10.1371/journal.pone.0028099] [Medline: 22140514]
16. Mohr DC, Duffecy J, Ho J, Kwasny M, Cai X, Burns MN, et al. A randomized controlled trial evaluating a manualized TeleCoaching protocol for improving adherence to a web-based intervention for the treatment of depression. PLoS One 2013 Aug 21;8(8):e70086 [FREE Full text] [doi: 10.1371/journal.pone.0070086] [Medline: 23990896]
17. Kleiboer A, Donker T, Seekles W, van Straten A, Riper H, Cuijpers P. A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety. Behav Res Ther 2015 Sep;72:63-71. [Medline: 26188373]
18. Gilbody S, Littlewood E, Hewitt C, Brierley G, Tharmanathan P, Araya R, REEACT Team. Computerised cognitive behaviour therapy (cCBT) as treatment for depression in primary care (REEACT trial): large scale pragmatic randomised controlled trial. BMJ 2015 Nov 11;351:h5627 [FREE Full text] [Medline: 26559241]
19. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clin Psychol Rev 2012 Jun;32(4):329-342. [Medline: 22466510]
20. Depression. Depression and anxiety affects us all differently URL: https://depression.org.nz/ [accessed 2017-07-12] [WebCite Cache ID 6ruA0HVsG]
21. Wittkampf KA, Naeije L, Schene AH, Huyser J, van Weert HC. Diagnostic accuracy of the mood module of the Patient Health Questionnaire: a systematic review. Gen Hosp Psychiatry 2007;29(5):388-395. [doi: 10.1016/j.genhosppsych.2007.06.004] [Medline: 17888804]
22. Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992 Jun;30(6):473-483. [Medline: 1593914]
23. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med 2001 Jul;33(5):337-343. [Medline: 11491192]
24. Kroenke K, Wu J, Yu Z, Bair MJ, Kean J, Stump T, et al. Patient Health Questionnaire Anxiety and Depression Scale: initial validation in three clinical trials. Psychosom Med 2016;78(6):716-727 [FREE Full text] [doi: 10.1097/PSY.0000000000000322] [Medline: 27187854]
25. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015 Mar 19;350:h1258. [Medline: 25791983]

Abbreviations

ANOVA: analysis of variance
DHB: district health board
EQ-5D: EuroQol-5D
NNT: number needed to treat
PHQ-9: Patient Health Questionnaire-9
RCT: randomized controlled trial
SF-36: short form-36

Edited by D Gratzer; submitted 19.07.17; peer-reviewed by J Apolinário-Hagen, M Thirumalai, L Bohleber; comments to author 26.08.17; revised version received 19.10.17; accepted 05.11.17; published 23.01.18.

Please cite as:
Hatcher S, Whittaker R, Patton M, Miles WS, Ralph N, Kercher K, Sharon C
Web-based Therapy Plus Support by a Coach in Depressed Patients Referred to Secondary Mental Health Care: Randomized Controlled Trial
JMIR Ment Health 2018;5(1):e5
URL: http://mental.jmir.org/2018/1/e5/
doi:10.2196/mental.8510
PMID:29362207

Original Paper

Youth Codesign of a Mobile Phone App to Facilitate Self-Monitoring and Management of Mood Symptoms in Young People With Major Depression, Suicidal Ideation, and Self-Harm

Sarah Elisabeth Hetrick[1,2], BA, MA, PGCertHSc, DPsych (Clin); Jo Robinson[1,3], BSc (Hon), MSc, PhD; Eloise Burge[4], BA, LLB, GradDipPLT; Ryan Blandon[4], BDes; Bianca Mobilio[5], BDes (DigMedia); Simon M Rice[1,3], MPsych (Clin), PhD; Magenta B Simmons[1,3], BA (Psych), PhD; Mario Alvarez-Jimenez[1,3], DClinPsych, PhD; Simon Goodrich[4], BA, BGenoME (Hons); Christopher G Davey[1,3], MBBS (Hons), MPsych, PhD, FRANZCP

[1]Centre for Youth Mental Health, University of Melbourne, Melbourne, Australia

[2]Department of Psychological Medicine, University of Auckland, Auckland, New Zealand

[3]Orygen, The National Centre of Excellence in Youth Mental Health, Melbourne, Australia

[4]Portable, Web Innovation Company, Melbourne, Australia

[5]Royal Melbourne Institute of Technology University, Melbourne, Australia

Corresponding Author:
Sarah Elisabeth Hetrick, BA, MA, PGCertHSc, DPsych (Clin)
Centre for Youth Mental Health
University of Melbourne
Locked Bag 10
Parkville, Victoria
Melbourne, 3052
Australia
Phone: 61 3 9342 2880
Fax: 61 3 9342 2941
Email: shetrick@unimelb.edu.au

Abstract

Background: Effective treatment of depression in young people is critical, given its prevalence, impacts, and link to suicide. Clinical practice guidelines point to the need for regular monitoring of depression symptom severity and the emergence of suicidal ideation to track treatment progress and guide intervention delivery. Yet, this is seldom integrated in clinical practice.

Objective: The objective of this study was to address the gap between guidelines about monitoring and real-world practice by codesigning an app with young people that allows for self-monitoring of mood and communication of this monitoring with a clinician.

Methods: We engaged young people aged 18 to 25 years who had experienced depression, suicidal ideation including those who self-harm, as well as clinicians in a codesign process. We used a human-centered codesign *design studio* methodology where young people designed the features of the app first individually and then as a group. This resulted in a minimal viable product design, represented through low-fidelity hand-drawn wireframes. Clinicians were engaged throughout the process via focus groups.

Results: The app incorporated a mood monitoring feature with innovative design aspects that allowed customization, and was named a “well-being tracker” in response to the need for a positive approach to this function. Brief personalized interventions designed to support young people in the intervals between face-to-face appointments were embedded in the app and were immediately available via pop-ups generated by a back-end algorithm within the well-being tracker. Issues regarding the safe incorporation of alerts generated by the app into face-to-face clinical services were raised by clinicians (ie, responding in a timely manner) and will need to be addressed during the full implementation of the app into clinical services.

Conclusions: The potential to improve outcomes for young people via technology-based enhancement to interventions is enormous. Enhancing communication between young people and their clinicians about symptoms and treatment progress and increasing access to timely and evidence-based interventions are desirable outcomes. To achieve positive outcomes for young

people using technology- (app) based interventions, it is critical to understand and incorporate, in a meaningful way, the expectations and motivations of both young people and clinicians.

(JMIR Ment Health 2018;5(1):e9) doi:10.2196/mental.9041

KEYWORDS

depression; suicidal ideation; suicide, attempted; self-injurious behavior; adolescent; young adult; cell phone

Introduction

Depressive disorders affect up to 25% of young people by the age of 18 years and account for the greatest global burden of disease in young people [1]. If untreated, there are high risks of developing further psychiatric disorders and impairments in occupational and social functioning [2,3]. Critically, depressive disorders confer a significant risk for suicidal ideation and suicide [4], the leading cause of death and disability in young people [5]. Early intervention is essential, and clinical practice guidelines recommend cognitive behavioral therapy or interpersonal therapy as first-line treatments, with fluoxetine as an adjunctive pharmacotherapeutic treatment when there is poor response to psychological treatment or when the depression is particularly severe and complex [6,7].

Symptom Monitoring

Treatment recommendations within clinical practice guidelines are predicated on establishing the severity of depression symptoms and highlight the importance of monitoring depression symptom severity as a way to monitor treatment progress and inform ongoing treatment decision making. Specific depression symptom measurement tools have been suggested [6] to ensure the accurate reporting of symptoms. Moreover, clinicians are specifically instructed to monitor the emergence of suicidal ideation once a week for 4 weeks, and biweekly thereafter, upon commencing antidepressant medication, due to the known risks of this adverse outcome for young people taking antidepressants [6,8]. The accurate reporting of symptoms facilitates therapeutic monitoring [9] in terms of enhancing clinicians' knowledge about the clients' symptoms and risk, which can have a positive impact on treatment planning [10,11]. Young people have been shown to have faster symptom improvement when their clinicians receive feedback about treatment progress [12,13]. Furthermore, even without the clinician having this information, there is evidence that self-monitoring can improve outcomes across a range of health conditions [14-20].

However, there are significant challenges to implementing routine and meaningful monitoring [21-23]. Specific depression and suicidal ideation symptom measurement tools and regular timing of monitoring are often not incorporated into the processes and procedures in services; thus, monitoring is often not routine or meaningful. Time and resource constraints and relying on what can be irregular face-to-face client appointments (including clients who struggle to engage in treatment) also have an impact on the frequency and reliability of monitoring [21].

Self-Monitoring

Self-monitoring offers a potential solution; this involves a young person regularly completing a symptom measurement tool in between their face-to-face appointments. This allows the capture of information about current depression and suicidal ideation symptoms. Self-monitoring is increasingly becoming part of self-management programs in general health areas [14-17] and has been shown to be effective in improving symptoms in adults with depression [24]. Self-monitoring overcomes problems with retrospective recall and captures the natural fluctuation in symptoms. It helps to overcome barriers to spontaneous reporting such as help-negation—a process of help avoidance or refusal [25-27]. Self-monitoring also serves as a feedback mechanism assisting individuals to notice fluctuations in their symptoms and how this might relate to changes in circumstances or life events. It can educate individuals about the conditions under which symptoms deteriorate or improve and thus can increase self-efficacy in relation to managing symptoms [20,28].

Utilizing Technology

Web-based technology accessible via handheld devices offers the opportunity to implement real-time symptom self-monitoring. Such interventions have the potential to be more flexible, nonstigmatizing, accessible, and cost-effective [29] and to have significantly greater reach than traditional forms of treatment [30-34]. The use of technology in clinical practice has been shown to be acceptable to users and health professionals [35,36]. There is emerging evidence that young people may, in some circumstances, be more comfortable with technology over face-to-face intervention with therapists [37], and studies have shown that rates of disclosure of mental health difficulties and suicidal ideation are higher when paper and pencil or Web-based approaches are used relative to face-to-face assessment [9,10,38-42]. Similarly, young people are particularly enthusiastic users of smartphones and various mobile phone apps [43,44], and consider smartphones an acceptable form of support [45-47]. Technology thus has the potential to extend service delivery and improve treatment engagement and outcomes [9,48,49]. One study has developed monitoring within a self-directed online cognitive behavioral therapy (CBT) intervention (SPARX: Smart, Positive, Active, Realistic, X-Factor thoughts) [50] for young people with depression, showing this to be acceptable to users. We have developed and tested an online monitoring tool, delivered via a tablet, which was completed by young persons immediately before their face-to-face client appointment. Both young people and clinicians rated the tool favorably and found it useful for facilitating the timely exchange of information about symptoms and risks [10]. The results of the study indicated the potential for this intervention to be extended to allow symptom monitoring via a mobile phone app [10].

Mobile Phone Apps

There are a large number of existing apps that monitor mood, although with a few notable exceptions [9,10,51,52], these have not been subject to research on their efficacy and safety, which has been highlighted as a major limitation of most apps that provide interventions for mental health issues [49,53]. Also emerging on the market are suicide prevention apps [54,55], particularly those that make Stanley and Brown's safety planning intervention [56] available via an app [57,58]. A suite of recommendations are appearing with regard to the features that suicide prevention apps should include [57]. These include features such as immediate access to crisis helplines [59,60], a "hope box" [61], integrated safety planning that reminds people of their internal and external coping resources [57,59,62], and automated interventions [59]. Recommendations also include the ability to personalize the app, to pay attention to the potential impact of the colors used [60], and to ensure that the app is simple to use [57].

However, few apps to date have integrated self-monitoring of mood and suicidal ideation with brief interventions, including those recommended for suicide prevention apps, and apps that are designed to be integrated within clinical services have not been tested. Furthermore, few, if any, apps of this kind have been designed specifically with, and for, young people. We are aware of a very small body of research that has investigated the features young people would like to have incorporated in such an app [47,63], and of an app developed and beta-tested by Paul Stallard and colleagues in the United Kingdom in consultation with young people [55].

Consumer involvement in the concept development and design of apps for young people has been cited as crucial to ensure that app design better matches the needs and preferences of stakeholders [64], and participatory design is the epitome of this [65-67]. In this paper, we describe the codesign process and methodology and outcomes of designing a self-monitoring tool delivered via an app for young people receiving face-to-face clinical management of major depression.

Methods

Study Design

We used an overarching participatory design framework [66] and studio design methodology [68] to develop the app. This process goes beyond consultation and testing of already developed sketches or interventions; rather, we sought the active participation of users as codesigners throughout the design process [66]. This follows human-centered design principles, seeking to understand the needs of users and designing a solution with them to meet those needs. This approach recognizes the expertise of young people due to their age and, in this project, their lived experience of mental ill health. This expertise is valued just as much as the expertise of team members with formal qualifications (eg, researchers, clinicians). By using the principles of youth partnerships in research [69], the codesign process described below was undertaken within overarching complementary youth participation principles, including ensuring clear expectations from team members about the scope of each person's contribution; being flexible, providing resources, and supporting involvement to limit barriers to participation; valuing diverse forms of experience (as previously described); involving more than one young person; reimbursing young people for their time; ensuring that all parties are benefiting from the experience (eg, skill development); avoiding tokenism to promote meaningful involvement; and providing feedback so that all team members are aware of what has been achieved.

Setting and Participants

The study was undertaken in the Youth Mood Clinic (YMC) [70] at Orygen Youth Health (OYH); in a tertiary mental health service; and in secondary mental health services, headspace [71], all located in Melbourne, Australia. OYH is a public mental health service for young people aged 15-24 years. headspace services provide outpatient clinic-based assessment and individual face-to-face psychological and psychiatric treatment to young people aged 12-25 years [72]. Both OYH and headspace centers incorporate youth advisory groups, who facilitate youth participation in the design and delivery of services. In partnership with a digital design and technology company (Portable) and a youth participant who was a digital design student at a local university and being mentored by Portable, the study was undertaken with young people who were eligible to participate if they were aged 18 to 25 years and were current or former clients within these services for the treatment of depression (any level of severity), which may have also included suicidal ideation as well as self-harm (suicide-related behaviors). However, we excluded those who had experienced these suicide-related behaviors in the past 3 months.

Design for mental health technology must consider both young people and their clinicians [64]. All clinicians working within the YMC and headspace were eligible to participate.

Participant Recruitment

Young people were informed of the study by their clinicians or by the coordinator of their youth advisory group. We also recruited via a chain-referral sampling method whereby participants informed young people they knew who might be eligible for the study. Those interested were directed to a Web page that contained information about the study and included an expression of interest form to complete. One of the investigators (SH), a clinical psychologist, then contacted those young people to further describe the study, ensure they met eligibility criteria, and provide details of the codesign workshop times and locations. Young people were able to attend as many or as few of the codesign workshops as they wanted to. All youth participants were reimbursed for their time (AU $30 per hour).

App Design

On the basis of our previous study of an online monitoring tool, which was undertaken in the same clinical settings [10], and evidence that young people want technologies to enhance, not replace existing mental health services [73], it was proposed that the app would be designed to fit within and extend existing face-to-face services for young people with depression, including those at risk of suicide-related behaviors. On the basis

of our previous study, it was proposed that the app would include the following:

- Onboarding (introduces the app, familiarizes the user with the purpose and functions of the app, and allows user registration)
- Monitoring of mood with feedback for young people and their clinicians
- An algorithm that generates automatic alerts at prespecified mood levels to encourage users to access help
- Prompts for the young person to complete a depression rating scale, the patient health questionnaire (PHQ-9) [74], and the 3-item suicide risk screener, which we developed in our pilot study [10], just before their appointment with their clinician.

Codesign Workshops: Young People

The principal researcher (SH) and designers (EB, RB), along with the digital design student (BM), conducted 4 codesign workshops with young people and 2 focus groups with clinicians. Codesign workshops are designed to immerse participants and build a shared understanding of an issue to allow generation of concepts based on personal experience as well as previous research [66]. The methodology used was Design Studio [68], which is a key method within the user-centered agile design development field [75,76]. It involves the following: (1) young people individually sketching what they thought the app might look like and the features it should have; (2) young people presenting these sketches back to the group and gaining feedback on their design; (3) the group engaging in a team design using the best ideas (a process referred to as "feature prioritization") from the individual design phase; (4) the "feature prioritization" from each workshop informing the following rounds of codesign; and (5) consolidating the best ideas into a final design that represents a minimal viable product design (a product developed with sufficient features for those involved in early testing), represented through wireframes.

Codesign Workshops: Clinicians

One clinician workshop was held before the codesign workshops with young people, and one was held after the final codesign workshop. The initial clinician workshop was used to present the results of our online monitoring tool [10] and scope the needs and concerns of clinicians with regard to routine monitoring of their clients via an app. In the second workshop with clinicians, a young person who had participated in the codesign workshops presented the wireframes for the app. Feedback was sought on the design of the app as well as how it could be integrated with the face-to-face clinical services.

Data Analysis

A general inductive approach was used for analysis, which allows findings to be derived in the context of focused objectives [77]. Thus, the analysis procedures have no specific label but are guided by the research objectives with the purpose of condensing the raw data. Although the objectives guide the analysis, findings are derived from analysis of the raw data rather than from a priori expectations driven by the objectives. The raw data were in the form of field notes from the focus groups and codesign workshops, as well as photographs of individual and team designs (photographs were not taken of participants to maintain anonymity). These raw data were summarized for the purposes of designing the app and highlighting the potential issues that need to be considered with regard to its use. The lead author as well as the app designers read the field notes and examined the photographs several times, and the lead author listened to audio recordings of the codesign workshops and focus groups, and a coding frame was developed via discussion. As new codes emerged, these were incorporated and field notes and photographs were re-examined. These codes were then organized into categories, which were conceptualized as themes. We were able to establish the trustworthiness of the data due to the iterative nature of the codesign workshops, and we sent the wireframes, as well as the results of the qualitative analysis, to young people and clinicians for comment.

Risk Management

All young people were required to complete "a wellness plan" before participation, and robust procedures for ensuring the safety and well-being of participants were developed and implemented.

Ethics Approval and Consent

Ethics approval was obtained from Melbourne Health Human Research Ethics Committee (Reference: HREC/15/MH/340; 2015.207), and written informed consent was gained from each clinician and young person.

Results

Codesign Workshops With Young People

A total of 8 young people attended at least 1 of the 4 codesign workshops: 5 attended 1 codesign workshop, 2 attended 2 workshops, 3 attended 3 workshops, and 1 young person attended all 4 workshops.

Of the participants, 3 identified as male and 8 as female. The mean age of participants was 21.4 years; the age of the youngest codesigner was 18 years and that of the oldest was 25 years.

Young people quickly developed a shared vision of what the app's purpose was and of the key features it would include. They were enthusiastic about the idea of monitoring their mood: "Need some kind of pop-up—where you can note how you feel—are you in a good or bad place"; however, their overwhelming motivation was driven by the potential to develop something that would allow young people to access support in real time, when they needed it in between their face-to-face sessions, noting the limitations of current services, including telephone and online-based crisis support services: "If feeling really like [I] want to self-harm...need something that is immediately available."

Young people were asked about key features that should be in the app. There was strong support for 5 key features that are described in detail below.

Onboarding

The onboarding process is the users' first experience of an app and has to be designed so that it is easy to understand and use.

Young people in the codesign workshops identified the importance of being able to customize the app. This included having the option to use the app as a guest or as a registered user. Young people highlighted the importance of being able to choose the welcome message and the color palate that was used in the app (highlighting that some colors might trigger negative mood states: "Childish colors...don't like brown...characters too bold...need something calm") . Young people also discussed the need to customize the frequency and timing of mood monitoring and the distraction and care package activities that were available to them . They wanted to be able to choose who their support people were and customize a preprogramed default message that could be sent to a support person when they were very distressed or experiencing suicidal ideation. They also wanted to be able to customize the way that the mood monitoring ratings were calibrated and how mood monitoring feedback was presented (see below under Mood Monitoring).

Young people agreed that the onboarding process should be done with their clinician ("app should be opened up and started with the clinician") and wanted the customization to allow the young person to modify and add new distraction and brief intervention activities as they learnt them: "make it an option to add to your list of things that help."

Mood Monitoring

Young people wanted the app to include a feature to monitor their mood. They highlighted that generic descriptors of mood and generic numerical ratings of mood were not necessarily useful or relevant across the population of young people who might use the app. They were clear that the app should not over simplify mood states, instead preferring a more nuanced monitoring approach: "I don't like sad, happy or in-between faces...there's so much more to emotions." Thus, a key innovation for this mood monitoring feature, and again in line with recommendations about customization [60], was to establish both a preferred color system for mood that for each young person equated with their own customized ratings and, with involvement of their clinician, "trigger points"' for high distress, and possible onset of suicide-related behaviors: "realized for me a 9 might be like super high...for someone else 6 might be really high...or I might consistently press a 4 every day and that is ok for me...so we've sort of made it customizable" (see Figures 1 and 2).

Young people described the importance of having a feature where they could enter potential influences on their mood: "space to write comments about what happened that day...you can record your thoughts." However, they were clear that the annotations about what had impacted their negative mood should not be automatically displayed but go in a separate section that they could open if they wanted to, stating that it might not be helpful to dwell on this if something negative had happened. This highlighted again that the app should ensure a positive approach to monitoring, allowing rating of positive mood states with a potential further innovation being to provide notifications about what appears to improve mood "I don't want to see an unhappy face on the calendar everyday" or "don't use the word crisis." Thus, this feature became known as a "well-being check." They were also clear that various approaches to displaying the mood "ratings" over time should be provided so that young people would have choice about how they saw this (eg, a graph or calendar displaying colors over time).

Figure 1. Customization of mood monitoring feature (well-being check) using colors.

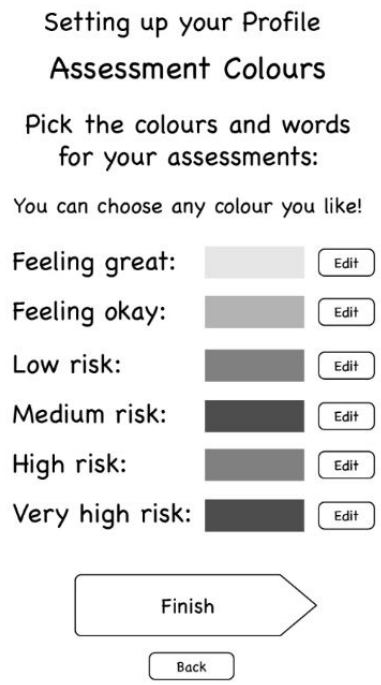


Figure 2. Well-being check.

Finally, young people designed an algorithm that was built into the mood monitoring feature that linked, via a pop-up, to appropriate levels of intervention (described below) corresponding to their mood state including for "trigger points" that indicate moderate and high levels of distress, which is individualized and quantified according to the young person's own criteria. Table 1 describes a potential algorithm that is subject to further testing and validation.

Distraction

Young people were unanimous in wanting real-time distractions that provided an immersive experience and diversion from intense and distressing mood states, including suicidal ideation. As stated above, they highlighted the need to ensure customization of these distraction interventions to suit the varying needs of different young people. The types of distractions young people discussed as being useful included the following: meditation with simple tips given to calm the user, games, music, breathing exercises, and videos (eg, inspirational, funny, or of their support people providing support messages).

This feature represents the "internal coping strategies" element of the Stanley and Brown's safety planning app [56]. Distraction is also a core intervention in dialectical behavioral therapy (DBT) [78], an evidence-based intervention for young people engaging in self-harm [79].

Brief Interventions

These brief interventions were designed by young people to be something that could be used regularly, rather than only when they were experiencing high distress. They could include all of the distraction interventions described above and also include features such as a photo album that contained meaningful photos, or photos that induced a positive emotion, supportive messages from friends and loved ones and messages that induced positive emotions, links to music playlists (eg, Spotify), and inspirational quotes (with the option of quotes generated by the user or app generated).

This feature is consistent with the interventions designed to increase distress tolerance, such as DBT and CBT, both evidence-based interventions for young people engaging in self-harm [78-80]. It is also reminiscent of the concept of a "hope box," which is a technique used in DBT and CBT that has been recommended for inclusion in apps that have a suicide prevention function [61].

Table 1. Algorithm of "interventions" made available according to mood monitor ratings.

Well-being rating	Levels of intervention
Low risk	Positive affirmation
Low to medium risk	Positive affirmation
	Link to care package
Medium risk	Positive affirmation
	Link to care package
Medium to high risk	Link to distraction
	Prompt to ask if user wants to talk to a friend or support person
	Prompt to ask if user wants to fix an appointment with a clinician
High risk	*If user responds to the prompt stating they feel safe:*
	Prompt to ask if user wants to fix an appointment with a clinician
	Prompt them to schedule another self-assessment
	Link to distraction
	If user responds to the prompt stating they are unsure if safe:
	Prompt to ask if user needs support line: if yes, preprogramed text message to support person and 24-hour crisis support line number selected; clinician notified that user has accessed support. If no, user prompted to fix an appointment with a clinician and schedule another self-assessment
	Link to distraction

Safety Features

In line with recommendations [59,60], young people agreed that it was important that on every screen of the app there was a one-touch option to access emergency services for immediate crisis intervention, as well as a one-touch option to call or message (using a preprogramed default message) their support person, and a one-touch option to see their list of support contact people. Young people provided a compelling rationale for this one-touch option that allows a preprogramed default message to be sent to their support person. They clearly stated that it was very difficult to both scroll through contact lists to find a phone number and to construct a message about their distress and need for help in times when they were experiencing intense levels of distress and suicidal ideation: "even just like if you just preprogrammed into the app just you know like a list of people you care about, care about you, people you feel safe with...it comes up as an option"; "it will come up with 'do you need to call a family member or friend or selected member' who knows you are using this app and knows your history."

Young people showed insight into the constraints of the services in which they were engaged. They were aware of the working hours of clinicians and did not expect clinicians to respond to distress messages after their working hours. They were keenly aware that crisis services, such as telephone helplines, were not always able to provide a timely service. Young people did think it was important that their clinician had access to the information generated from their mood monitoring in their face-to-face sessions, including when they had accessed the distraction function, contacted their support person, or used emergency or crisis services:

> *The idea isn't that you have access to your clinicians at all times of day...it is very clear that this is not what this is...the idea is that it is to be a log so you and your clinician can see over the past month what has been good, what has been bad, what has been happening...*

Clinician Workshops

In total, 16 clinicians participated in the workshops. These clinicians were from a range of professional backgrounds including clinical psychologists, psychiatrists, social workers, and occupational therapists. They all had considerable experience working with young people with severe mood disorders. Many of them worked across both the YMC and a headspace clinical service.

Clinician Responsibility in Responding to Mood Monitoring

Clinicians at both workshops expressed concerns regarding the clinical responsibilities that would ensue after being informed by the app about high levels of distress and suicidal ideation. They articulated that once this information was known, action would need to be taken to mitigate the risk of suicide. They were uncomfortable about receiving these notifications when they were not present in their clinical roles (ie, in the evenings, on weekends, and while they were on leave). Clinicians expressed concerns that developing a mechanism for being notified of a young person's distress and responding to this would require significant additional clinical resourcing.

Managing Expectations

Clinicians highlighted the importance of clarifying and managing the expectations of young people using the app. Unmet expectations, for example, if a young person did not receive an immediate response from a support person, has the potential to result in unintended harm. Suggestions to manage

this included ensuring that clinicians had choice over which clients they would use the app with and working closely with the young people in the onboarding stage to familiarize the young person with the app. They highlighted how important it was to ensure that young people were clear about when and what sort of response they should expect from their clinician. In this regard, they highlighted that receiving emails documenting the mood monitoring results for a client would not be appropriate because it was not possible to guarantee a timely response due to workload or circumstances such as the clinician being on leave. The preference of clinicians was to view the mood monitoring information only in their face-to-face sessions with young people. They emphasized that they wanted knowledge of any suicidal crisis and related intervention via traditional means such as notification from other clinicians, as well as from the information within the app that they would view during the face-to-face session with their client. They did note that it would be clinically useful to incorporate a discussion of the mood monitoring results and the potential influences on mood states, as well as what and how young people had used the distraction and care package interventions into their face-to-face clinical sessions. They also suggested that it might be useful to ensure a printable version of the mood monitoring results, for example, a PDF document that could be used in sessions and included in the clinical record. It was the clinician's view that, although the app allowed the young person to monitor his or her mood in real time, it would not be feasible for clinicians to have access to or respond to these data in real time. They suggested that the app should be considered as, and more appropriately named, a "digital diary" rather than "mood monitoring," a term that gives the impression that it is a live monitoring device.

The clinician interface tool that was designed as part of the app was designed to be utilized as a separate Web app tool through which clinicians could view the young people under their care and their details. In this tool, clinicians would be able to view the young person's mood through a calendar or chart function to visually see details of mood ratings over time. Clinicians would also be able to see if any emergency calls were made, what interventions (either from the care packages or distractions) were utilized, and their impact on mood ratings. Allowing the clinician to see this information in the clinician's own time allows them to access the information quickly and alleviates the perception that a young person could rely on the digital diary as a source of immediate or on-demand treatment.

With regard to managing the expectations of young people, they also made the point that young people also needed to be made aware that their support people may not always be available, for example, if there was a delay in the message being sent due to network problems, if their support person's phone was not charged, if they were away from their phone, or if they were unwell. Clinicians raised some concerns at both workshops about the potential burden on the support person and how this person needed to be carefully selected and made aware that they were going to be contacted by the young person in this way.

Potential Adverse Therapeutic Effects of the App

Clinicians highlighted a potentially counterproductive effect of one feature of the app (the function allowing a preprogramed default message to be sent when a young person was distressed), in that it could create a learned helplessness with regard to help seeking. Clinicians were concerned that young people might develop an expectation that others should respond and initiate supportive contact when they were in distress, discouraging the young person to learn active help-seeking skills.

Discussion

Principal Findings

The development of this app utilized a codesign process, predominantly with young people but also involving clinicians. Young people and clinicians were enthusiastic about the app including mood monitoring as a key function. Young people wanted a positive approach to this and developed a creative and innovative approach to this function that allowed an individual to customize their well-being scale to indicate when and what type of intervention was needed [50]. The provision of real-time support as well as issues with the accessibility to timely response in times of crisis were considered critical. One way of addressing this was to design embedded interventions to enable young people to manage their own distress. The development of the app, using a codesign process, is a significant advance on many of the currently available apps (and other technology-based interventions) that have been designed to address mental ill health because of the incorporation of the youth perspective. The inclusion of both clinicians and young people in a codesign process highlighted disparate needs, motivations, and intentions for the app, and by incorporating the views of both, the app has promise as a tool to assist both clinicians and young people in the management of depression and suicide-related behaviors.

Limitations

The codesign process used in this study has been undertaken with help-seeking young people who were predominantly recruited via their clinicians or the coordinator of the youth advisory group in which they were involved. To ensure we could safely manage risk, we imposed criteria on inclusion that required that we only include older adolescents and young adults who had not experienced suicide-related behaviors within the previous 3 months. We acknowledge that some young people may have been unwilling to participate given their participation in the codesign workshops meant others would be aware of their history of depression and suicide-related behaviors. Thus, the app may not be relevant or acceptable to all young people or to those accessing different kinds of services. Young people in the codesign workshops had some awareness of this and highlighted the need for customization because "young people" are not a homogenous group, but all have different needs and preferences. Customization has been highlighted as important by adolescents in similar codesign processes [50]. It is important to note that the app has not been designed for young people who are not engaged in face-to-face treatment.

Although our app conforms to clinical practice guideline recommendations with regard to routine monitoring of

symptoms (depression) and medication side effects (suicidal ideation) and its prototype has been beta-tested [10], there is a need to robustly test the app for efficacy and safety, including testing that the innovative mood rating function is a reliable and valid measure of mood compared with validated measures such as the PHQ-9 and our 3-item suicide risk screener [10].

Through the process of codesign, we have been made aware of some of the barriers to implementing this app into face-to-face clinical care. Further work will be required to tailor implementation of the app into various service settings and governance structures. This is potentially challenging, given the different processes used across various services, and highlights that health providers and young people have different expectations and preferences with regard to the use of technology in mental health care.

Comparison With Prior Study

The functionality of the app is consistent with prototypes developed for adults experiencing depression [9,51,52], with recommendations for suicide and self-harm prevention apps [57,59-62], with what young people in other studies of app development have described as potentially useful [47,63], and with a recently developed app developed in the United Kingdom for young people at risk of self-harm [55]. That young people and clinicians wanted mood monitoring as a key function is consistent with the previous finding that mood monitoring is an acceptable and safe function for users [9,10]. Young people highlighted the need for a positive approach to mood monitoring, which also aligns with previous findings [65,51], and resulted in this function being named a "well-being tracker."

The inclusion of distractions, which are essentially self-soothing interventions or "internal coping strategies" as well as one-touch access to personal support, is consistent with Stanley and Brown's widely used safety planning intervention [56]. These interventions are also consistent with emotional regulation strategies used in DBT, an intervention with evidence of its efficacy in reducing self-harm [79,81,82]. Overall, the key features that young people wanted to include in the app are consistent with the recommendations for apps in the field of suicide prevention and are evidence based, thus addressing concerns raised in the literature about the types of nonevidence-based interventions that are provided in many commercially available apps [49].

Young people clearly expressed a need to have mechanisms to overcome help-seeking barriers when they were very distressed, consistent with what is described as help-negation in the literature [25]. This echoes findings relevant to the development of monitoring in the context of the SPARX intervention [50]. Young people in our study developed an innovative approach whereby preprogramed messages could be developed for automated delivery to the young person's support person. However, clinicians were concerned that this function could be counter-therapeutic in terms of preventing young people taking an active role in their help seeking. This highlights the need to ensure that innovation is undertaken in the context of high-quality evaluation to ensure that there are no unintended adverse therapeutic impacts [50,65] and to document whether these clinical concerns are founded.

Clinicians also raised significant concerns about the implications of real-time mood monitoring with regard to ensuring the safety of their clients, consistent with concerns raised in similar studies [50]. They highlighted that there was no capacity for clinicians to receive or respond to mood monitoring data from their clients, except within their scheduled face-to-face client appointments, where both young people and clinicians agreed the information was potentially clinically useful. Our previous study and results from the development of monitoring for SPARX highlight the potential for monitoring to enhance communication between young people and clinicians and engagement in treatment [10,50].

A key issue is balancing the needs of young people with the potential clinical burden, and the need for moderation in a landscape where mental health services are already underfunded and overstretched. Although in Australia the integration of technology into clinical care is a national priority [83], the additional resourcing to ensure this is done in a safe and effective way has not followed this policy direction. Greater resourcing of mental health services would, for example, ensure that the full advantage of real-time mood monitoring could be realized in terms of identifying and intervening with young people in real time to deal with acute risk of suicide rather than using the app as a digital diary.

Conclusions

Extending and enhancing treatment services for young people with depression are important goals given the necessity to ensure that early and evidence-based interventions are delivered to this group. There is significant potential to improve the lives of young people experiencing depression via the provision of technology-based enhancement to interventions, although it may mean significant redesign of current mental health service systems. Our findings have highlighted the critical need to ensure both clinicians and young people are involved in the development of these kinds of interventions to ensure the needs of young people as well as clinicians, and the services in which they are working, are addressed in the design of the intervention.

For clinicians, the app has been designed to assist with ensuring guideline concordant care (symptom monitoring). For young people, it addresses their need for support when they experience distress and suicidal ideation in between their face-to-face appointments. Thus, the app has the potential to enhance communication between young people and their clinicians about symptoms and treatment progress and increase access to timely and evidence-based interventions. Understanding and incorporating the expectations and motivations of both young people and their clinicians are critical to ensure that this can be done.

Acknowledgments

The investigators would like to acknowledge the young people who participated in the codesign process. JR is supported by a National Health and Medical Research Council (NHMRC) Early Career Fellowship. MA was supported via a Career Development Fellowship (APP1082934) by the NHMRC. The authors would also like to thank the young people who participated in the design workshops.

Conflicts of Interest

None declared.

References

1. Gore F, Bloem P, Patton G, Ferguson J, Joseph V, Coffey C, et al. Global burden of disease in young people aged 10-24 years: a systematic analysis. Lancet 2011 Jun;377(9783):2093-2102 [FREE Full text] [Medline: 21652063]
2. Ebmeier K, Donaghey C, Steele J. Recent developments and current controversies in depression. Lancet 2006 Jan;367(9505):153-167 [FREE Full text] [Medline: 16413879]
3. Brent DA, Birmaher B. Clinical practice. Adolescent depression. N Engl J Med 2002 Aug 29;347(9):667-671. [doi: 10.1056/NEJMcp012249] [Medline: 12200555]
4. Cash SJ, Bridge JA. Epidemiology of youth suicide and suicidal behavior. Curr Opin Pediatr 2009 Oct;21(5):613-619 [FREE Full text] [doi: 10.1097/MOP.0b013e32833063e1] [Medline: 19644372]
5. World Health Organization. Preventing Suicide: A Global Imperative. Geneva, Switzerland: World Health Organization; 2014.
6. National Institute for Health and Clinical Excellence. Leicester, UK: The British Psychological Society; 2005. Depression in children and young people: identification and management in primary, community and secondary care (updated March 2015) URL: https://www.nice.org.uk/guidance/cg28 [accessed 2018-01-16] [WebCite Cache ID 6wVW2O6Wq]
7. BeyondBlue. Clinical practice guidelines: depression in adolescents and young adults. Melbourne; 2011.
8. Hetrick SE, McKenzie JE, Cox GR, Simmons MB, Merry SN. Newer generation antidepressants for depressive disorders in children and adolescents. Cochrane Database Syst Rev 2012 Nov 14(11):CD004851. [doi: 10.1002/14651858.CD004851.pub3] [Medline: 23152227]
9. Torous J, Staples P, Shanahan M, Lin C, Peck P, Keshavan M, et al. Utilizing a personal smartphone custom app to assess the patient health questionnaire-9 (PHQ-9) depressive symptoms in patients with major depressive disorder. JMIR Ment Health 2015;2(1):e8 [FREE Full text] [doi: 10.2196/mental.3889] [Medline: 26543914]
10. Hetrick S, Goodall J, Yuen H, Davey C, Parker A, Robinson J, et al. Comprehensive online self-monitoring to support clinicians to manage risk of suicide in youth depression: a pilot study. Crisis 2017 May;38(3):147-157 [FREE Full text] [Medline: 27659516]
11. Lambert M, Whipple J, Smart D, Vermeersch D, Nielsen S, Hawkins E. The effects of providing therapists with feedback on patient progress during psychotherapy: are outcomes enhanced. Psychother Res 2001;11(1):49-68. [Medline: 25849877]
12. Bickman L, Kelley S, Breda C, Andrade A, Reimer M. Effects of routine feedback to clinicians on mental health outcomes of youths: Results of a randomized trial. Psychiatr Serv 2011 Dec;62(12):1423-1429 [FREE Full text] [Medline: 22193788]
13. Timimi S, Tetley D, Burgoine W, Walker G. Outcome orientated child and adolescent mental health services (OO-CAMHS): a whole service model. Clin Child Psychol Psychiatry 2013 Apr;18(2):169-184. [doi: 10.1177/1359104512444118] [Medline: 22548827]
14. Bodenheimer T. Patient self-management of chronic disease in primary care. JAMA 2002 Nov 20;288(19):2469. [doi: 10.1001/jama.288.19.2469]
15. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, part 2. JAMA 2002 Oct 16;288(15):1909-1914. [doi: 10.1001/jama.288.15.1909] [Medline: 12377092]
16. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA 2002 Oct 09;288(14):1775-1779. [doi: 10.1001/jama.288.14.1775] [Medline: 12365965]
17. Foster G, Taylor SJ, Eldridge SE, Ramsay J, Griffiths CJ. Self-management education programmes by lay leaders for people with chronic conditions. Cochrane Database Syst Rev 2007 Oct 17(4):CD005108. [doi: 10.1002/14651858.CD005108.pub2] [Medline: 17943839]
18. Miller K, Beck R, Bergenstal R, Goland R, Haller M, McGill J. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D Exchange clinic registry participants. Diabetes Care 2013 Jul;36(7):2009-2014 [FREE Full text] [Medline: 23378621]
19. Welschen LM, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WA, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Diabetes Care 2005 Jun;28(6):1510-1517. [Medline: 15920083]
20. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns 2002 Oct;48(2):177-187 [FREE Full text] [Medline: 12401421]

21. Hetrick SE, Simmons M, Thompson A, Parker AG. What are specialist mental health clinician attitudes to guideline recommendations for the treatment of depression in young people? Aust N Z J Psychiatry 2011 Nov;45(11):993-1001. [doi: 10.3109/00048674.2011.619161] [Medline: 21999241]
22. Hetrick SE, Thompson A, Yuen K, Finch S, Parker AG. Is there a gap between recommended and 'real world' practice in the management of depression in young people? A medical file audit of practice. BMC Health Serv Res 2012 Jun 27;12:178 [FREE Full text] [doi: 10.1186/1472-6963-12-178] [Medline: 22738436]
23. Morrato E, Libby A, Orton H, Degruy FV, Brent D, Allen R, et al. Frequency of provider contact after FDA advisory on risk of pediatric suicidality with SSRIs. Am J Psychiatry 2008 Jan;165(1):42-50. [doi: 10.1176/appi.ajp.2008.165.7.A42] [Medline: 17986680]
24. Ludman E, Katon W, Bush T, Rutter C, Lin E, Simon G, et al. Behavioural factors associated with symptom outcomes in a primary care-based depression prevention trial. Psychol Med 2003 Aug;33(6):1061-1070 [FREE Full text] [Medline: 12946090]
25. Wilson C, Deane F. Help-negation and suicidal ideation: the role of depression, anxiety and hopelessness. J Youth Adolesc 2010 Mar;39(3):291-305. [doi: 10.1007/s10964-009-9487-8] [Medline: 19957103]
26. Wilson CJ, Deane FP, Marshall KL, Dalley A. Adolescents' suicidal thinking and reluctance to consult general medical practitioners. J Youth Adolesc 2010 Apr;39(4):343-356 [FREE Full text] [doi: 10.1007/s10964-009-9436-6] [Medline: 20229227]
27. Stellrecht NE, Joiner TE, Rudd MD. Responding to and treating negative interpersonal processes in suicidal depression. J Clin Psychol 2006 Sep;62(9):1129-1140. [doi: 10.1002/jclp.20298] [Medline: 16924679]
28. Clum G, Curtin L. Validity and Reactivity of a system of self-monitoring suicidal ideation. J Psychopathol Behav Assess 1993 Dec;15(4):375-385 [FREE Full text] [doi: 10.1007/BF00965039]
29. van Spijker AJ, Majo MC, Smit F, van Straten A, Kerkhof AJ. Reducing suicidal ideation: cost-effectiveness analysis of a randomized controlled trial of unguided web-based self-help. J Med Internet Res 2012 Oct 26;14(5):e141 [FREE Full text] [doi: 10.2196/jmir.1966] [Medline: 23103835]
30. Silenzio V, Duberstein P, Tang W, Lu N, Tu X, Homan C. Connecting the invisible dots: Reaching lesbian, gay, and bisexual adolescents and young adults at risk for suicide through online social networks. Soc Sci Med 2009 Aug;69(3):469-474 [FREE Full text] [Medline: 19540641]
31. Bower P, Gilbody S. Stepped care in psychological therapies: access, effectiveness and efficiency. Narrative literature review. Br J Psychiatry 2005 Jan;186:11-17 [FREE Full text] [doi: 10.1192/bjp.186.1.11] [Medline: 15630118]
32. Christensen H. Increasing access effectiveness: using the internet to deliver low intensity CBT. In: Bennett-Levy J, Richards DA, Farrand P, Christensen H, Griffiths KM, Kavanaugh DJ, et al, editors. Low Intensity CBT Interventions. Oxford: Oxford University Press; 2010:53-67.
33. Gerhards SA, de Graff LE, Jacobs LE, Severens JL, Huibers MJ, Arntz A, et al. Economic evaluation of online computerised cognitive-behavioural therapy without support for depression in primary care: randomised trial. Br J Psychiatry 2010 Apr;196(4):310-318 [FREE Full text] [doi: 10.1192/bjp.bp.109.065748] [Medline: 20357309]
34. Kerkhof A, van Spijker B, Mokkenstorm J. Reducing the burden of suicidal thoughts through online cognitive behavioural therapy self help. In: Mishara BL, Kerkhof AJ, editors. Suicide Prevention and New Technologiesvidence Based Practice. New York: Palgrave MacMillan; 2013:50-62.
35. Montague A, Varcin K, Parker A. Putting Technology Into Practice: Eevidence and Opinions on Integrating Technology with Youth Health Services. Melbourne: Young and Well Cooperative Research Centre; 2014.
36. Robinson J, Rodrigues M, Fisher S, Bailey E, Herrman H. Social media and suicide prevention: findings from a stakeholder survey. Shanghai Arch Psychiatry 2015 Feb 25;27(1):27-35 [FREE Full text] [doi: 10.11919/j.issn.1002-0829.214133] [Medline: 25852253]
37. Abeles P, Verduyn C, Robinson A, Smith P, Yule W, Proudfoot J. Computerized CBT for adolescent depression ("Stressbusters") and its initial evaluation through an extended case series. Behav Cogn Psychother 2009 Mar;37(2):151-165 [FREE Full text] [doi: 10.1017/S1352465808005067] [Medline: 19364416]
38. Scott MA, Wilcox HC, Schonfeld IS, Davies M, Hicks RC, Turner JB, et al. School-based screening to identify at-risk students not already known to school professionals: the Columbia suicide screen. Am J Public Health 2009 Feb;99(2):334-339. [doi: 10.2105/AJPH.2007.127928] [Medline: 19059865]
39. Gardner W, Klima J, Chisolm D, Feehan H, Bridge J, Campo J, et al. Screening, triage, and referral of patients who report suicidal thought during a primary care visit. Pediatrics 2010 May;125(5):945-952. [doi: 10.1542/peds.2009-1964] [Medline: 20385642]
40. Grover K. Sfx.unimelb.hosted.exlibrisgroup. 2012. Agreement between measures of suicide attempt among adolescent inpatients URL: https://tinyurl.com/yazq8e3o
41. Bradford S, Rickwood D. Acceptability and utility of an electronic psychosocial assessment (myAssessment) to increase self-disclosure in youth mental healthcare: a quasi-experimental study. BMC Psychiatry 2015 Dec;15(1):305-317 [FREE Full text] [doi: 10.1186/s12888-015-0694-4]

42. Fein JA, Pailler ME, Barg FK, Wintersteen MB, Hayes K, Tien AY, et al. Feasibility and effects of a web-based adolescent psychiatric assessment administered by clinical staff in the pediatric emergency department. Arch Pediatr Adolesc Med 2010 Dec;164(12):1112-1117. [doi: 10.1001/archpediatrics.2010.213] [Medline: 21135339]
43. Boschen M, Casey L. The use of mobile telephones as adjuncts to cognitive behavioral psychotherapy. Prof Psychol Res Pr 2008;39(5):546-552. [doi: 10.1037/0735-7028.39.5.546]
44. Andrews S, Ellis D, Shaw H, Piwek L. Beyond self-report: Tools to compare estimated and real-world smartphone use. PloS one 2015 Oct;10(10):e0139004 [FREE Full text] [Medline: 26509895]
45. Matthews M, Doherty G, Coyle D, Sharry J. Designing mobile applications to support mental health interventions. In: Lumsden J, editor. Handbook of research on user interface design and evaluation for mobile technology. New York: Information Science Reference; 2008:635-656.
46. Kenny R, Dooley B, Fitzgerald A. Feasibility of "copesmart": a telemental health app for adolescents. JMIR Ment Health 2015 Aug;2(3):e22 [FREE Full text] [doi: 10.2196/mental.4370] [Medline: 26552425]
47. Kennard B, Biernesser C, Wolfe K, Foxwell A, Craddock LS, Rial K, et al. Developing a brief suicide prevention intervention and mobile phone application: a qualitative report. J Technol Hum Serv 2015;33(4):345-357. [doi: 10.1080/15228835.2015.1106384]
48. Griffiths K, Farrer L, Christensen H. Clickety-click: e-mental health train on track. Australasian Psychiatry 2007;15(2):100-108. [doi: 10.1080/10398560601123716]
49. Torous J, Roberts LW. Needed innovation in digital health and smartphone applications for mental health. JAMA Psychiatry 2017 May 01;74(5):437-438. [doi: 10.1001/jamapsychiatry.2017.0262] [Medline: 28384700]
50. Sundram F, Hawken SJ, Stasiak K, Lucassen MF, Fleming T, Shepherd M, et al. Tips and traps: lessons from codesigning a clinician e-monitoring tool for computerized cognitive behavioral therapy. JMIR Ment Health 2017 Jan 11;4(1):e3. [doi: 10.2196/mental.5878] [Medline: 28077345]
51. Drake G, Csipke E, Wykes T. Assessing your mood online: acceptability and use of moodscope. Psychol Med 2013 Jul;43(7):1455-1464. [doi: 10.1017/S0033291712002280:1-10] [Medline: 23149120]
52. Rickard N, Arjmand H, Bakker D, Seabrook E. Development of a mobile phone app to support self-monitoring of emotional well-being: a mental health digital innovation. JMIR Ment Health 2016 Nov 23;3(4):e49 [FREE Full text] [doi: 10.2196/mental.6202] [Medline: 27881358]
53. Proudfoot J. The future is in our hands: the role of mobile phones in the prevention and management of mental disorders. Aust N Z J Psychiatry 2013 Feb 04;47(2):111-113. [doi: 10.1177/0004867412471441]
54. Franklin JC, Fox KR, Franklin CR, Kleiman EM, Ribeiro JD, Jaroszewski AC, et al. A brief mobile app reduces nonsuicidal and suicidal self-injury: evidence from three randomized controlled trials. J Consult Clin Psychol 2016 Jun;84(6):544-557. [doi: 10.1037/ccp0000093] [Medline: 27018530]
55. Stallard P, Porter J, Grist R. Safety, acceptability, and use of a smartphone app, blueice, for young people who self-harm: protocol for an open phase i trial. JMIR Res Protoc 2016 Nov 16;5(4):e217 [FREE Full text] [doi: 10.2196/resprot.6525] [Medline: 27852560]
56. Stanley B, Brown G. Safety planning intervention: a brief intervention to mitigate suicide risk. Cogn Behav Pract 2012 May;19(2):256-264 [FREE Full text] [doi: 10.1016/j.cbpra.2011.01.001]
57. Pauwels K, Aerts S, Muijzers E, De Jaegere E, van Heeringen K, Portzky G. BackUp: development and evaluation of a smart-phone application for coping with suicidal crises. PLoS one 2017;12(6):e0178144 [FREE Full text] [Medline: 28636617]
58. Nuij C, Van Ballegooijen W, Ruwaard J, de Beurs D, O'Connor R, Smit J, et al. Smartphone-based safety planning and self-monitoring for suicidal patients: a conceptual basis for the CASPAR (continuous assessment for suicide prevention and research) study. Preprints (www.preprints.org) 2017 Apr:1-10. [doi: 10.20944/preprints201704.0103.v1]
59. Luxton DD, June JD, Chalker SA. Mobile health technologies for suicide prevention: feature review and recommendations for use in clinical care. Curr Treat Options Psychiatry 2015 Dec;2(4):349-362. [doi: 10.1056/NEJM196803212781204] [Medline: 5637250]
60. Aguirre RTP, McCoy MK, Roan M. Development guidelines from a study of suicide prevention mobile applications (apps). J Technol Hum Serv 2013;31(3):269-293. [doi: 10.1080/15228835.2013.814750]
61. Bush NE, Dobscha SK, Crumpton R, Denneson LM, Hoffman JE, Crain A, et al. A virtual hope box smartphone app as an accessory to therapy: proof-of-concept in a clinical sample of veterans. Suicide Life Threat Behav 2015 Feb;45(1):1-9. [doi: 10.1111/sltb.12103] [Medline: 24828126]
62. Labelle R, Bihoud-de-Serre A, Leblanc F. Innovating to treat depressionprevent suicide: the Iphone@PSY ASSISTANCE application. In: Mishara B, Kerkhof AJ, editors. Suicide Prevention and New Technologies: Evidence Based Practice. Basingstoke, England: Palgrave Macmillan; 2013:166-180.
63. Gritton J, Rushing S, Stephens D, Kerr B, Moreno M. "People care": recommendations from native youth to address concerning mental health displays on social media. J Adolesc Health 2016;58(2):S58. [doi: 10.1016/j.jadohealth.2015.10.128]
64. Coyle D, Doherty G, Matthews M, Sharry J. Computers in talk-based mental health interventions. Interact Comput 2007;19(4):545-562 [FREE Full text] [doi: 10.1016/j.intcom.2007.02.001]

65. Wadley G, Lederman R, Gleeson J, Alvarez-Jimenez M. Participatory design of an online therapy for youth mental health. 2013 Presented at: 25th Australian Computer-Human Interaction Conference: Augmentation, Application, Innovation, Collaboration; November 25-29, 2013; Adelaide, Australia. [doi: 10.1145/2541016.2541030]
66. Hagan P, Collins P, Metcalf A, Nicholas M, Rahilly K, Swainston N. Participatory design of evidence-based online youth mental health promotion, intervention and treatment: a Young and Well Cooperative Research Centre innovative methodologies guide. Melbourne, Australia: Young and Well Cooperative Research Centre; 2012.
67. Bannon L. Reimagining HCI: toward a more human-centered perspective. Interactions 2011 Jul;18(4):50-57 [FREE Full text] [doi: 10.1145/1978822.1978833]
68. Warfel T. Prototyping: a practitioner's guide. New York: Rosenfeld Media; 2009.
69. Orygen. 2017. Youth partnership toolkit URL: https://www.orygen.org.au/About/Youth-Engagement/Resources/YouthPartnershipToolkit.aspx [accessed 2017-09-25] [WebCite Cache ID 6tkxNoHl6]
70. Rice SM, Halperin S, Cahill S, Cranston I, Phelan M, Hetrick SE, et al. The youth mood clinic: an innovative service for the treatment of severe and complex depression. Australas Psychiatry 2017 Apr;25(2):112-116. [doi: 10.1177/1039856216689002] [Medline: 28135816]
71. Rickwood DJ, Telford NR, Parker AG, Tanti CJ, McGorry PD. headspace - Australia's innovation in youth mental health: who are the clients and why are they presenting? Med J Aust 2014 Feb 3;200(2):108-111. [doi: 10.5694/mja13.11235] [Medline: 24484115]
72. McGorry P. The specialist youth mental health model: strengthening the weakest link in the public mental health system. Med J Aust 2007;187(7 Suppl):S53-S56. [Medline: 17908028]
73. Alvarez-Jimenez M, Bendall S, Lederman R, Wadley G, Chinnery G, Vargas S, et al. On the HORYZON: moderated online social therapy for long-term recovery in first episode psychosis. Schizophr Res 2013 Jan;143(1):143-149 [FREE Full text] [Medline: 23146146]
74. Spitzer RL, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary care evaluation of mental disorders. Patient health questionnaire. JAMA 1999 Nov 10;282(18):1737-1744. [Medline: 10568646]
75. Bertholdo A, Kon F, Gerosa M. Agile usability patterns for user-centered design final stages. 2016 Jul Presented at: International Conference on Human-Computer Interaction; July 17-22, 2016; Toronto, Ontario, Canada. [doi: 10.1007/978-3-319-39510-4_40]
76. Caballero L, Moreno A, Seffah A. How agile developers integrate user-centered design into their processes: a literature review. Int J Soft Eng Knowl Eng 2016 Oct;26(08):1175-1201 [FREE Full text] [doi: 10.1142/S0218194016500418]
77. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. Am J Eval 2006 Jun 01;27(2):237-246. [doi: 10.1177/1098214005283748]
78. Linehan M. DBT skills training manual, 2nd ed. New York: Guilford; 2014.
79. Ougrin D, Tranah T, Stahl D, Moran P, Asarnow JR. Therapeutic interventions for suicide attempts and self-harm in adolescents: systematic review and meta-analysis. J Am Acad Child Adolesc Psychiatry 2015 Feb;54(2):97-107.e2 [FREE Full text] [doi: 10.1016/j.jaac.2014.10.009] [Medline: 25617250]
80. Robinson J, Hetrick S, Martin C. Preventing suicide in young people: systematic review. Aust N Z J Psychiatry 2011 Jan;45(1):3-26. [doi: 10.3109/00048674.2010.511147] [Medline: 21174502]
81. Mehlum L, Ramberg M, Tørmoen AJ, Haga E, Diep LM, Stanley BH, et al. Dialectical behavior therapy compared with enhanced usual care for adolescents with repeated suicidal and self-harming behavior: outcomes over a one-year follow-up. J Am Acad Child Adolesc Psychiatry 2016 Apr;55(4):295-300 [FREE Full text] [doi: 10.1016/j.jaac.2016.01.005] [Medline: 27015720]
82. Carter G, Page A, Large M, Hetrick S, Milner A, Bendit N, et al. Royal Australian and New Zealand College of Psychiatrists clinical practice guideline for the management of deliberate self-harm. Aust N Z J Psychiatry 2016 Oct;50(10):939-1000 [FREE Full text] [Medline: 27650687]
83. National Mental Health Commission. Mental Health Commission. 2014. The national review of mental health programmes and services URL: http://www.mentalhealthcommission.gov.au/media-centre/news/national-review-of-mental-health-programmes-and-services-report-released.aspx [accessed 2018-01-16] [WebCite Cache ID 6wVkLlnEZ]

Abbreviations

CBT: cognitive behavioral therapy
DBT: dialectical behavioral therapy
OYH: Orygen Youth Health
PHQ: patient health questionnaire
SPARX: Smart, Positive, Active, Realistic, X-Factor thoughts
YMC: Youth Mood Clinic

Edited by J Lipschitz; submitted 26.09.17; peer-reviewed by D Newman, A Radovic-Stakic, M Acosta; comments to author 27.10.17; revised version received 31.10.17; accepted 23.11.17; published 23.01.18.

Please cite as:
Hetrick SE, Robinson J, Burge E, Blandon R, Mobilio B, Rice SM, Simmons MB, Alvarez-Jimenez M, Goodrich S, Davey CG
Youth Codesign of a Mobile Phone App to Facilitate Self-Monitoring and Management of Mood Symptoms in Young People With Major Depression, Suicidal Ideation, and Self-Harm
JMIR Ment Health 2018;5(1):e9
URL: http://mental.jmir.org/2018/1/e9/
doi:10.2196/mental.9041
PMID:29362208

Original Paper

Facilitating Factors and Barriers to the Use of Emerging Technologies for Suicide Prevention in Europe: Multicountry Exploratory Study

Juan-Luis Muñoz-Sánchez[1], MD; Carmen Delgado[2], PhD; Andrés Sánchez-Prada[2], PhD; Esther Parra-Vidales[3], MSc, Psych (Clin); Diego de Leo[4], MD, PhD, DSc; Manuel Franco-Martín[1], MD, PhD

[1]Department of Psychiatry, Zamora Hospital, Zamora, Spain

[2]Faculty of Psychology, Universidad Pontificia de Salamanca, Salamanca, Spain

[3]Intras Foundation, Zamora, Spain

[4]Australian Institute for Suicide Research and Prevention, Griffith University, Queensland, Australia

Corresponding Author:
Juan-Luis Muñoz-Sánchez, MD
Department of Psychiatry
Zamora Hospital
Av Hernán Cortes, 44
Zamora, 49021
Spain
Phone: 34 980521816
Fax: 34 980548572
Email: jlmusa@icloud.com

Abstract

Background: This study provides an analysis on the use of emerging technologies for the prevention of suicide in 8 different European countries.

Objective: The objective of this study was to analyze the potentiality of using emerging technologies in the area of suicide prevention based on the opinion of different professionals involved in suicide prevention.

Methods: Opinions of 3 groups of stakeholders (ie, relevant professionals in suicide field) were gathered using a specifically designed questionnaire to explore dimensions underlying perceptions of facilitating factors and barriers in relation to the use of emerging technologies for suicide prevention.

Results: Goal 1 involved facilitating factors for the use of emerging technologies in suicide prevention. Northern European countries, except for Belgium, attach greater relevance to those that optimize implementation and benefits. On the other hand, Southern European countries attach greater importance to professionally oriented and user-centered facilitating factors. According to different stakeholders, the analysis of these facilitating factors suggest that professionals in the field of social work attach greater relevance to those that optimize implementation and benefits. However, professionals involved in the area of mental health, policy makers, and political decision makers give greater importance to professionally oriented and user-centered facilitating factors. Goal 2 was related to barriers to the usability of emerging technologies for suicide prevention. Both countries and stakeholders attach greater importance to barriers associated with resource constraints than to those centered on personal limitations. There are no differences between countries or between stakeholders. Nevertheless, there is a certain stakeholders-countries interaction that indicates that the opinions on resource constraints expressed by different stakeholders do not follow a uniform pattern in different countries, but they differ depending on the country.

Conclusions: Although all countries and stakeholders agree in identifying resource constraints as the main barrier to the use of emerging technologies, factors facilitating their use in suicide prevention differ among countries and among stakeholders.

(JMIR Ment Health 2018;5(1):e7) doi:10.2196/mental.7784

KEYWORDS

suicide; prevention; technology

Introduction

The use of emerging technologies involving Internet surfing, virtual social networks, videogames, or mobile phones has led to significant changes in the way people interact, especially the younger population [1]. Applied to health sciences, emerging technologies offer advantages such as easy access to resources and information, personalized medical care, and real-time communication [2,3]. The usefulness of mobile communication technologies in the health area has been known for a number of years [4-7]. Telemedicine has proven effective in various health sectors through the use of apps to treat patients and by facilitating interactions among health professionals [8].

In the area of mental health, the use of emerging technologies has proven effective in the treatment of different mental disorders [9,10], especially anxiety and depression [11,12]. Indeed, interventions in mental health through the Internet have appeared as more cost-effective than traditional interventions [13,14]. However, acceptance by patients and professionals of emerging technologies in the treatment of mental disorders is currently limited, but it could be increased by providing more information about it [15,16]. In any case, it seems clear that these technologies represent an opportunity to supplement many of the treatments carried out in the mental health area by increasing contact and accessibility to therapies, especially for patients living in rural areas and those who usually avoid, for different reasons, mental health facilities [17-19].

Suicide is a serious public health issue, representing one of the main causes of unnatural death worldwide [20]. More than 800,000 people die each year by suicide, the global suicide rate being 11.4 per 100,000 population (15.0 men and 8.0 women) [21]. Although the overall suicide rate in Europe is high, its epidemiology differs considerably among countries [22]. Suicide rates are higher in northern and eastern European countries, the highest being detected in Finland, Hungary, and the Baltic countries, alongside Russia and Belarus, whereas the lowest correspond to southern European countries, such as Italy, Spain, and Greece [23].

It is known that suicidal behaviors are usually preceded by thoughts of death or suicide ideation [24]. Addressing risk factors and an early detection are essential to reduce suicide rates [25]. Currently, there is an awareness of a number of risk factors for suicide, which include neurobiological factors [26], socioeconomic factors [27], and personality traits [28]. Likewise, suffering from or having a history of mental illness and previous suicide attempts are the main risk factors among the general population [29-31]. In this regard, affective disorders, and major depressive disorder in particular, are the mental conditions that involve the highest risk for suicide [32], especially in the elderly [33].

Development of strategies to counteract suicide is one of the priorities of European and worldwide public health systems [34]. In recent years, this has led to the establishment of a growing number of intervention programs in many health care networks [35-37]. However, the stigma associated with mental health care and the difficulties in early detection of the risk for suicide have led to considering the possibility of using emerging technologies to facilitate the access of young people, an at-risk population, to these services while combating the stigma that obstacles help-seeking [38,39].

Suicide prevention programs using emerging technologies [40-42] have also proven effective in the detection of suicide risk [38,43] and in reducing suicide ideation [18,44,45]. Young people look at the Internet also as a useful and accessible tool to express suicidal feelings, seek support, or even try to help other young people having thoughts of suicide [46,47]. This is why technologies such as Twitter, Facebook, forums, text messages, and mobile apps can be of relevance in the area of suicide prevention [48-56]. However, their use is still far from being widespread, and it would be important to be aware of the barriers and limitations that hinder generalized usage.

The purpose of this study was to analyze the potentiality of using emerging technologies in the area of suicide prevention based on the opinion of different professionals involved in addressing this public health issue, as well as possible differences between European countries. The objective was to assess the disposition of professionals to incorporate such resources into the design of a suicide prevention program for the health area of Zamora (Spain). This investigation is encompassed within the European project entitled European Regions Enforcing Actions against Suicide (EUREGENAS), which includes 11 regions with diverse experiences and attempts to advance in the field of suicide prevention in Europe. In particular, we wanted to explore the perception of facilitating factors and barriers related to the use of emerging technologies. So, our goals were as follows:

1. To explore the structure behind the assessment of the facilitating factors for using emerging technologies and compare the relevance attached to them by different countries and stakeholders.
2. To group the barriers to the use of emerging technologies into clusters to determine the importance attached to them and to compare the assessments between countries and between stakeholders.

Methods

Participants

Pursuing the aim of efficient intervention in suicide and effective courses of action to be followed for its prevention, a study of the needs at European level was conducted in the context of the Euregenas project. This project brought together 11 European regions with diverse experiences in an attempt to advance the area of suicide prevention in Europe. We wanted to understand the different points of view of those involved in suicide prevention (stakeholders) and the courses of action that could be taken.

First, a consultation with the partners involved in the project and an in-depth review of the literature, and a list of possible stakeholders of interest was proposed. Three main categories of stakeholders were established with different subcategories. The first category corresponded to stakeholders in the political and public management context, designating this category as decision and policy makers (DPM). The second category of

stakeholders corresponded to professionals working in the area of mental health, designated as mental health professionals (MHP), and the third one corresponded to professionals related to the social area and nongovernmental organizations (NGOs), designated as NGO/social area (Table 1).

A total of 416 participants were recruited in 11 regions of 8 different European countries according to the following inclusion criteria:

- Workers belonging to the 3 professional groups selected for this study: DPM, MHP, and NGO.
- High professional experience in the field of suicide.
- Age between 18 and 65 years.

Variables and Instruments

Customized questionnaires including questions on the use of emerging technologies for suicide prevention were prepared for each stakeholder category as tools to gather the necessary information to assess the needs. They included closed questions about the use of emerging technologies for the prevention of suicide. These technologies applied to suicide prevention were defined in the questionnaires as follows: *Technology-based suicide prevention is a form of e-mental health aimed at suicide prevention, making use of information and computer technology*. Some examples of emerging technologies applied to suicide prevention were provided in the questionnaires (Textbox 1).

The sociodemographic data collected in the questionnaires were gender, age, and professional category. The questionnaires were elaborated by some project partners and, subsequently, these questionnaires were revised by all the members of the project. They were drafted in English; each project partner was responsible for translating them into their own language and sending an appropriate number of questionnaires (approximately 60). Questionnaires were mainly administered as face-to-face surveys or via email.

Table 1. Categories and subcategories of stakeholders.

Category	Subcategory
Decision and policy makers	European networks focusing on mental health promotion
	Decision and policy makers from local and regional authorities (dealing with mental health, care, welfare, family matters, youth)
	Decision and policy makers in public health institutions (mental health care centers, hospitals)
	Private companies influencing policy (health insurance)
	Media
	Educational setting, policy makers
	Professionals working in financial services and human resources
Mental health professionals (for youth, adult and elderly)	General practitioners
	Psychologists (inpatient, outpatient)
	Psychiatrists (inpatient, outpatient)
	Emergency physicians (on call doctors in Accident and Emergency units)
	Nursing staff who work with suicidal patient (primary health nurse, mental health nurse, emergency room nurse)
	Rescue personnel (paramedic – ambulance crew)
	Work setting (private companies and prevention advisors in occupational medicine)
	Educational setting (schools, school counselors)
Nongovernmental organizations (NGOs)/social area	Professionals in the social area (community social workers, home help workers, youth workers, social welfare services)
	Staff of NGOs and agencies working in the following areas: youth, marital counseling, family and life counseling, welfare
	Educational setting: teachers
	Staff of suicide helplines
	Representatives of religious group
	Support groups with survivors
	Work setting: employers, human resources, union representatives
	Criminal justice stakeholders (police, penitentiary police, coroners)
	Pharmacists

Textbox 1. Examples of emerging technologies applied to the suicide prevention provided in the questionnaires.

There are many forms of technology-based suicide prevention. Here you can find some examples of what we mean by technology-based suicide prevention:

1. Informative websites (ie, websites that offer information on suicide, including warning signs, risk factors, and what to do when someone is suicidal).
2. Web-based self-help interventions (ie, Web-based interventions that aim at helping (mild to moderate) suicidal people at decreasing their symptoms through self-help).
3. e-therapy interventions (ie, Web-based interventions in which a suicidal person is being guided by a counselor either through a form of self-help in which the counselor is there when needed, or through Web-based and maybe face-to-face therapy).
4. Chat websites (ie, online discussion in a chat room aimed at helping suicidal people through a crisis).
5. Internet forums on suicide and suicide prevention in which suicidal and nonsuicidal people share their thoughts.
6. Social networking websites on suicide prevention (eg, Facebook, Twitter).
7. Apps (ie, apps from the iTunes or Android store on suicide prevention).

In Spain, 154 out of 213 questionnaires facilitated to the stakeholders (72.0 %) were correctly completed. The predominant way of administration was face-to-face (187 questionnaires via face-to-face and 25 questionnaires via email). The most frequent reasons for nonperformance of questionnaires were the incorrect filling of the questionnaire and the absence of a reply by the stakeholder.

Two questions from the survey have been selected for the purpose of this research; both questions aimed at exploring the use of emerging technologies applied to the suicide based on perceived barriers to be removed and facilitating factors to be promoted. These are listed below.

Facilitating Factors

What would encourage you to use/recommend suicide prevention based on emerging technologies?

(1=not at all; 5=absolutely):

- Further information through training
- Further information through newsletters
- More automated apps
- Easy access
- Guaranteed anonymity
- Time-saving
- Cost-saving
- Free, with no extra costs

Barriers

What prevents you from using/recommending suicide prevention based on emerging technologies?

(1=yes; 0=no):

- Lack of availability
- Too expensive
- Too time-consuming
- Lack of reliable apps
- I do not know their uses
- I am not interested
- I lack the skills
- I lack the knowledge

The questionnaire was administered to a total of 416 participants from 8 European countries. Among this, Spain provided 37.0% of questionnaires; Finland 14.2%; Belgium 11.5%; both Italy and Romania 7.7%; Sweden 7.5%; and lastly, both Germany and Slovenia 7.2% (Table 2).

The gender distribution was 39.7% (165/416) men and 60.3% (251/416) women. According to age, 61.8% (257/416) were aged between 40 to 59 years, 26.9% (112/416) were aged between 20 to 39 years, and 11.3% (47/416) were over 60 years.

Statistical Analysis

The data analysis of the questionnaires was performed through 2 different statistical methods. First, a multidimensional scaling (MDS) PROXimity SCALing (PROXSCAL) was used to detect the underlying dimensions of the facilitating factors for the use of emerging technologies in suicide prevention. PROXSCAL is a computer program for MDS and individual differences scaling (IDS) of proximities. The program, PROXSCAL, performs MDS of proximity data to find the least squares' representation of the objects in a low-dimensional Euclidean space. The analysis of the structure underlying the usability barriers of emerging technologies for suicide prevention was performed through hierarchical cluster analysis. Finally, multivariate analysis of variance (MANOVA) was used to estimate the differences between countries and stakeholders. The data analysis was performed using the statistical software IBM SPSS version 19.

Table 2. Questionnaires administered by country.

Country	DPM[a]	MHP[b]	NGO[c]	Percentage (%)
Belgium	14	19	15	11.5
Finland	7	21	31	14.2
Germany	9	9	12	7.2
Italy	10	13	9	7.7
Romania	10	19	3	7.7
Slovenia	10	11	9	7.2
Spain	17	92	45	37.0
Sweden	10	13	8	7.5
Total	87	197	132	100

[a]DMP: decision and policy makers.

[b]MHP: mental health professionals.

[c]NGO: nongovernmental organizations.

Results

Goal 1: Factors Facilitating the Use of Emerging Technologies

MDS PROXSCAL was applied to identify the underlying dimensions of facilitating factors for using emerging technologies in suicide prevention. This analysis provides a display of how the facilitating factors are structured and their weight in the different target populations.

The starting point is the exploration of a common space that reveals a structure in the assessments of the interviewees. If a common structure is found, the underlying criteria used for the assessments can be identified, which are not explicit, but deducible from the way in which the assessments accorded to the facilitating factors relate to each other. This technique is useful to identify the criteria used when assessing the aspects related to the use of emerging technologies. In this case, beyond specific assessments for each aspect, the interest lies in exploring the underlying criteria so that the actions to stimulate the use of emerging technologies can be linked to the aspects that are most relevant to each group of the target population.

The perceptual map resulting from this analysis reveals that there is indeed an identifiable structure the indices of which indicate a very good fit to the empirical data. A scatterplot matrix of coordinates of the common space is displayed in Figure 1. The structure presents a good fit to the obtained dimensions (Stress=.05; Tucker's Coefficient of Congruence=.973>.90).

As shown in Figure 1, Dimension 1 on the right-hand area of the chart brings together aspects related to cost for professionals: training costs (*Training*), cost in time (*Time and Automated*), and economic cost (*Cost*). At the opposite end are the facilitating factors related to aspects that are convenient for the user, which are as follows: *Anonymity*, *Accessible*, and *Free*. Therefore, Dimension 1 opposes professionally oriented facilitating factors and user-centered facilitating factors.

On the right-hand upper area of the graph, Dimension 2 brings together the aspects related to the implementation of emerging technologies, which are as follows: *Training*, *Anonymity*, *Accessible*, and *Automated*. The lower area includes facilitating factors related to the benefits from their use, which are as follows: *Cost*, *Time*, and *Free*. Therefore, Dimension 2 opposes facilitating factors that optimize implementation and facilitating factors that optimize the benefits.

Thus, the following 2 dimensions can be identified in the common space:

- Dimension 1: professionally oriented facilitating factors and user-centered facilitating factors.
- Dimension 2: facilitating factors that optimize implementation and facilitating factors that optimize the benefits.

Once the structure or common space has been defined, the weight of each dimension in the different target populations is obtained. In this case, the weight or relevance of each dimension was obtained for different countries and different stakeholders. Figure 2 shows the different weights for the different countries studied.

As shown in the chart, Dimension 2 (implementation-benefits) has greater weight than Dimension 1 (professional-user) in Sweden, Finland, and Germany, in that order. Thus, in these countries, emphasis should be placed on the adaptation of the characteristics involved in the implementation of emerging technologies (*Training*, *Accessible*, *Anonymity*, and *Automated*) and on the variety of benefits they provide (*Cost*, *Time*, and *Free*) because they attach higher relevance to these criteria in their assessments. On the other hand, in Spain, Belgium, Italy, Slovenia, and Romania, in that order, Dimension 1 (professional–user) has higher weight than Dimension 2 (implementation–benefits). Thus, it is appropriate for these countries to emphasize the benefits to be obtained by the use of emerging technologies, both for professionals and for users.

Figure 1. Common space of the facilitating factors in the multicountry sample.

Category	Subcategory
Decision and Policy Makers	European networks focusing on mental health promotion
	Decision and policy makers from local and regional authorities (dealing with mental health, care, welfare, family matters, youth…)
	Decision and policy makers in public health institutions (eg, mental health care centers, hospitals)
	Private companies influencing policy (eg, health insurance)
	Media
	Educational setting, policy makers
	Professionals working in financial services and human resources
Mental Health Professionals (youth, adult and elderly focused MHPs)	General practitioners
	Psychologists (inpatient, outpatient)
	Psychiatrists (inpatient, outpatient)
	Emergency physicians (on call doctors in Accident & Emergency)
	Nursing staff who work with suicidal patient (primary health nurse, mental health nurse, emergency room nurse)
	Rescue personnel (paramedic – ambulance crew)
	Work setting (eg, private companies and prevention advisors in occupational medicine)
	Educational setting (eg, schools, school counselors)
NGOs/ Social Area	Professionals in the social area (community social workers, home help workers, youth workers, social welfare services)
	Staff of NGOs and agencies working in the following areas: youth, marital counseling, family and life counseling, welfare
	Educational setting: teachers
	Staff of suicide helplines
	Representatives of religious group
	Support groups with survivors
	Work setting: employers, human resources, union representatives
	Criminal justice stakeholders (eg, police, penitentiary police, coroners)
	Pharmacists

Figure 2. Dimension Weights of the facilitating factors for suicide prevention in the different countries.

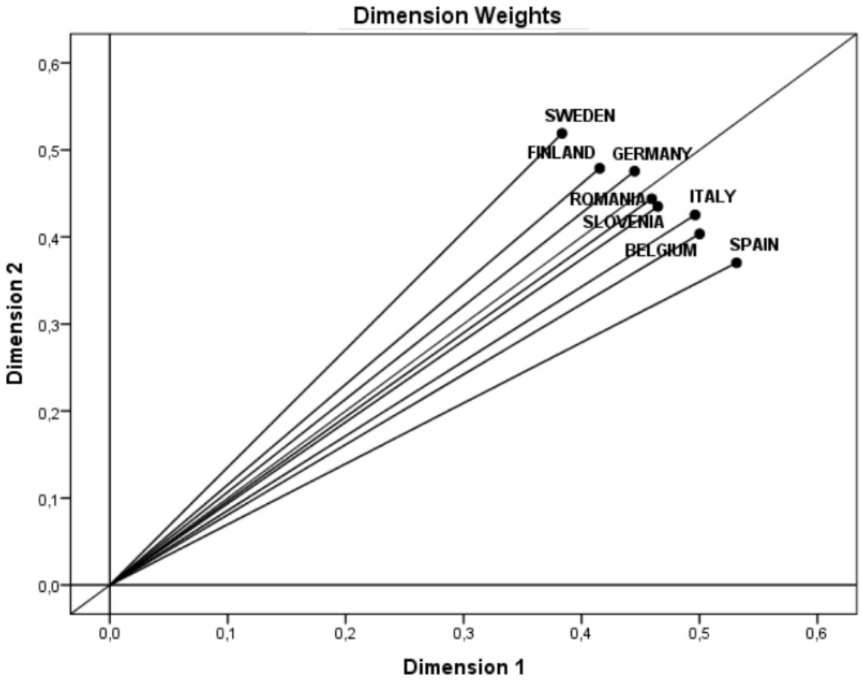
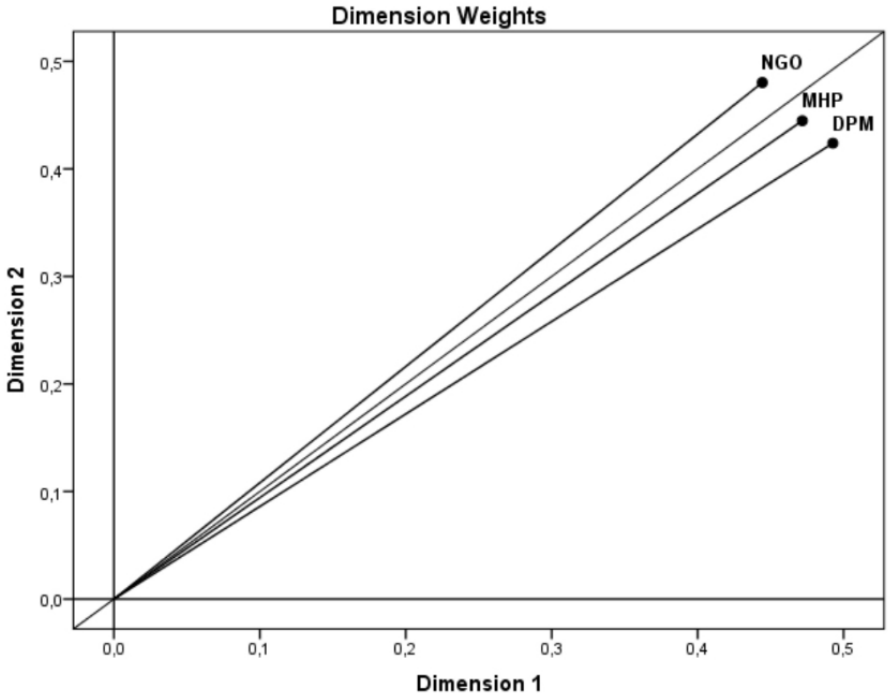


Figure 3. Dimension weights of the facilitating factors in the different stakeholders.



The comparison of weights by stakeholders also reveals differences in the relevance attached to these 2 dimensions, as shown in Figure 3.

NGOs attach greater weight to Dimension 2 (implementation–benefits) than to Dimension 1 (professional–user). To promote the use of emerging technologies by NGOs and achieve greater usability, emphasis should be placed on the conditions for the implementation of such resources and the benefits they bring. On the other hand, DPMs and MHPs, in that order, attach greater relevance to Dimension 1 (professional–user) than to Dimension 2 (implementation–benefits). To promote the use of emerging technologies by these stakeholders and achieve greater usability, emphasis should be placed on the aspects related to the benefits they bring to both professionals and users.

Goal 2: Barriers to the Use of Emerging Technologies

The analysis of the structure underlying the barriers hindering the use of emerging technologies for suicide prevention was carried out through hierarchical cluster analysis (Figure 4). As shown in the chart, the barriers were gathered into the following 2 large groups or differentiated clusters:

- Barriers focused on resource constraints: expensive, time-consuming, not interesting, and apps are not considered trustworthy.
- Barriers focused on personal limitations: lack of knowledge related to the programs and their use and lack of skills to use them.

The average ratings for each cluster were calculated to compare the ratings obtained and the differences among countries and stakeholders. A repeated-measure analysis of variance (ANOVA) was carried out. The results show significant differences among clusters (P<.001) with large effect size: 44%. Cluster 1 (barriers focused on resource constraints) scored significantly higher than cluster 2 (barriers focused on user limitations).

Therefore, to promote the use of emerging technologies for suicide prevention, emphasis should be placed on the shortcomings of the resource itself, meaning that difficulties are attached to resource constraints rather than to users experiencing difficulties.

Differences among countries and stakeholders were calculated using MANOVA. No differences among countries were observed (Pillai Trace Test: P=.86); barriers focused on resources were those that most hindered implementation in all of them. Neither were there differences among stakeholders (Pillai Trace Test: P=.08); all of them also attached the most relevance to barriers related to resources. Nevertheless, stakeholders-countries interaction effect (Pillai Trace Test: P=.01) was observed in cluster 1; barriers focused on resource constraints (P=.02) with an effect size of 13%. This interaction effect indicates that the valuations of resource constraints made by the different stakeholders do not follow a standard pattern in the different countries, but they are different depending on the country, as shown in Figure 5.

As shown in the graph, in Germany, for example, MHPs are the stakeholders that attach the greatest importance to resource constraints, whereas in Romania, it is DPMs, and in Slovenia, it is NGOs. In Spain, for example, the valuations of the different stakeholders are very similar. Each country has different profiles with regard to resource constraints, which should be taken into account according to the target stakeholders at whom promotion of the use of emerging technology for suicide prevention is aimed.

Figure 4. Clusters of barriers to the use of emerging technologies.

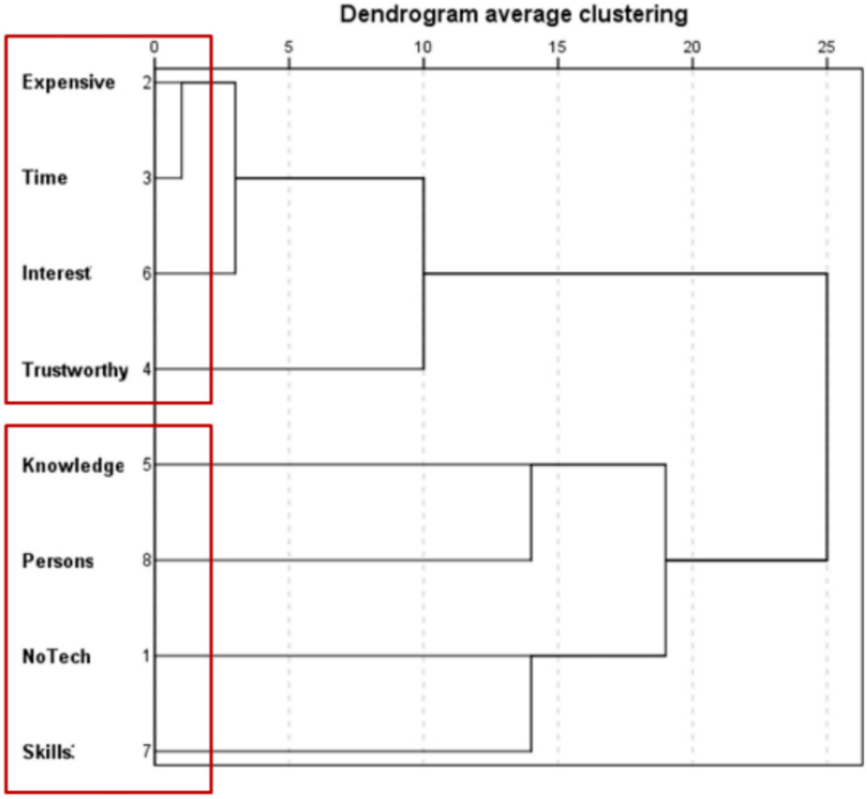
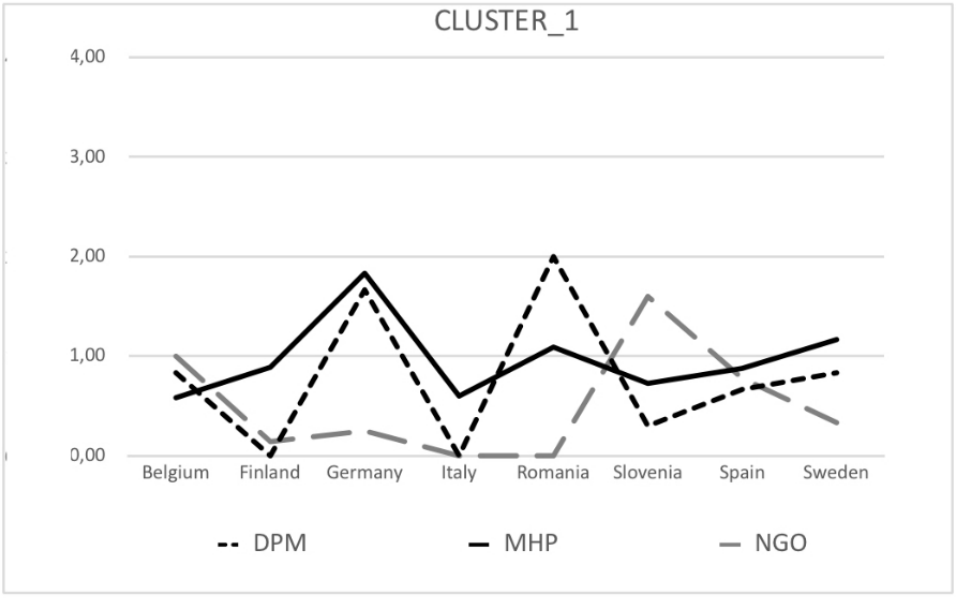


Figure 5. Cluster 1: barriers focused on resource constraints.



Discussion

Principal Findings

The use of emerging technologies for suicide prevention could prove an opportunity to ameliorate its results and the accessibility to intervention programs, especially by young people. Emerging technologies can be a means to address situations involving people at suicide risk who are otherwise difficult to engage in traditional intervention models. A recent study by Sueki supports the efficacy of the use of Internet for early detection of suicide risk. The study involved posting offers of psychological treatment on webpages that people at risk for suicide might visit. The psychological treatment was provided via email, and the presence of suicide ideation was detected in 74% of the consultations held [43]. Therefore, it improves accessibility to a population that does not usually turn to health services, and when they do so, they have already made a suicide attempt [57].

If we consider the factors facilitating the usability of emerging technologies according to the different countries, it is interesting to observe how northern European countries, except for Belgium, attach greater importance to the facilitating factors that optimize implementation and to those than maximize the benefits (Dimension 2) than to those focused on professionals and users (Dimension 1). To some extent, this result could be explained by the differences between northern and southern European countries in the use of emerging technologies, considering that the implementation of emerging technologies in northern Europe is more widespread than in the south. On this subject, when defining the type of intervention, northern European countries seem to attach more importance to ensuring efficacy than to it being different or more or less innovative. On the other hand, southern European countries seem more concerned with the development of the intervention than with its degree of efficiency. In this regard, the importance attached in Spain to barriers and difficulties hindering professionals' use of this type of technologies can be observed. This basically expresses that the use of emerging technologies involves changes in traditional welfare processes based mainly on routine clinical visits and scheduled appointments. It is also significant that in countries where psychiatric care is essentially community-based and health care has a solid social component, as is the case in Sweden, emphasis on barriers and facilitating factors centered on users and professionals is not as strong as that placed on the implementation and efficacy of the tool. This leads to the hypothesis that the use of emerging technologies to contact users or potential patients requires a more community-based health system, which is less constrained by clinical visits, and where the measuring of health care activities goes beyond a mere count of the number of medical consultations performed following conventional methods. How could the activity conducted by MHPs communicating with patients via social networks be calculated and measured? Or, could the Spanish system for the provision of posts envisage establishing a profile for MHPs with expertise in the use of emerging technologies to allow potential patients to access their services? Hence, the answers to the questionnaire provided by the different countries also reveal their care patterns and their capacity to integrate the use of new models, such as the use of emerging technologies, into the dynamics of their activity.

Likewise, although the stakeholders participating in the study are aware of the advantageous uses of emerging technologies for users, they stress the difficulties associated with their use by professionals and the costs in time, training, and activity involved in their implementation. This is the main barrier to their use, as there is an agreement (Dimension 2) on valuing the positive aspects related to accessibility and anonymity so that the user does not feel exposed to stigmatization.

On the other hand, the distribution of the 3 different stakeholder groups across the two dimensions draws attention to the fact that professionals in the social area (NGO) stand apart from the other 2 groups (DMP and MHP). The former (NGO) attach greater relevance to the facilitating factors that optimize implementation and to those that maximize the benefits

(Dimension 2), whereas the other groups (DPM and MHP) believe that the most relevant facilitating factors are the professionally oriented and user-centered ones (Dimension 1). These results could answer to the usual need for professionals in the social area to obtain positive outcomes in their health interventions, because negative results or absence of results have a very strong impact on this group. It should be noted that when the health system fails in its interventions, this has a strong impact on the subject's social environment, which is often poor or lacking adequate supporting structures, thus requiring the intervention of social services. MHPs believe that the most important facilitating factors are those that are professionally oriented and user-centered (Dimension 1), although to a lesser degree than DMPs. This confirms what is stated above, that is, public-sector providers whose health care processes are more constrained and move away from the community-based ones are those who find the greatest difficulties in using emerging technologies. So, they do not take enough account to use the technologies as a tool for improving access to better care. It is significant that the further stakeholders from the community (political decision makers and policy makers) give a higher value to the barriers to their work, while the closer to the community underlie the greatest flexibility for organizing the delivery of care (NGOs), and increasing the efficacy that technology could make, while the difficulties encountered by professionals are given less relevance.

In general, although emerging technologies are a tool that can be used to address problems related to suicidal behavior, the knowledge required to design their use and obtain satisfactory results belongs to the MHPs. This explains why MHPs are more concerned with the elements that may facilitate implementation of the intervention than with its costs, even though they are aware of the limitations of the system of which they are part. Finally, the fact that political decision makers and policy makers (DPM) attach greater relevance to facilitating factors targeted at professionals and users (Dimension 1), leaving aside the economic aspect, is highly significant, because it illustrates the extent of the problem of suicide in the Western society and the increasing involvement of this group of stakeholders in addressing suicidal behavior. Nevertheless, they should be aware that, beyond the application of such technologies, it is essential to foster working on the community and directing (mental) health services toward (mental) health outcomes in the population of the area where they are located, rather than just measuring health care–oriented activity in a rigid fashion where there is no room for these new tools.

The use of technology applied to the health care area does not always yield expected or desirable results, but limitations or barriers may appear. However, in the area of suicide prevention, this type of communication technologies could provide major advantages, because limitations to intervention in these cases are frequently linked to the stigma attached to the issue of suicide in our society. Good examples of clinical uses of technology for the suicidal behavior are as follows: Mewton et al's work, which implemented a Web-based program of cognitive behavioral therapy to reduce suicidal ideation in people suffering from depression, obtaining statistically significant results in the reduction of self-harming ideation and symptoms of depression in general terms [18]; and Guille et al's work, which refers to an ease of implementation of Web-based cognitive behavioral therapy, emphasizing that it is cost free and user-friendly and very useful for suicide prevention [41].

Consequently, the growing deployment of Internet in our environment and its development as a way of communication offers an excellent chance to use it as a means for the detection and treatment of suicidal behavior and ideation. The possibility of distance intervention that does not require contact in a physical space is an advantage for the high number of individuals who perceive the issue of suicide as a taboo. In a recent study, Biddle analyzed the changes in accessibility to suicide-related information on the Internet between 2007 and 2014, obtaining as a result that the number of blogs and Internet forums on suicide grew considerably over this 7-year period [46]. This is why it is important to assess the results obtained and take them into account to be able to overcome the barriers to the implementation of emerging technologies in the health system.

A key aspect to be considered in the application of the emerging technologies to health care is the anonymity. This anonymity can be appreciated clearly in the Internet use by persons who look for information about issues relating to health. It should be pointed out that the use of Internet browsers such as Google is currently widespread in our environment, and the trend analysis of search for research purposes have grown in recent years. For its capacity to ensure anonymity, these Internet browsers can be used by persons with thoughts or ideas of suicide to search for help online. On the other hand, Internet browsers might also constitute a useful tool for the study and detection of behaviors related to suicide [58,59]. There are several studies that have used the potential of the Google Trends tool in the field of suicide and self-harm behaviors. One study by Bragazzi shows the usefulness of Google Trends to detect nonsuicidal self-injuries [60]. Another recent study by Parker could verify that the use of Google Trends can predict the suicide rate associated with the consumption of alcohol and drugs better than the conventional methods associated with the level of unemployment and economic incomes [61]. Solano detected that the search volume of the term "suicide" is significantly related with the suicide valuations in Italy [62], and Arora observed a cyclical tendency in the search activity of suicide and in the searches related to the depression, with peaks in autumn and winter months and a decrease in summer months [63].

Equally, attention should be drawn to the fact that the analysis of the results of this study on the barriers to the use of emerging technologies shows that barriers focused on resource constraints (cluster 1) are more relevant, both by countries and stakeholders, than those focused on personal limitations (cluster 2). Once again, this points out the difficulties in organization and in obtaining resources for the implementation of these new tools. The use of new technologies in the health sector requires appropriate organization and a care delivery model to facilitate their implementation, economic resources to acquire the material needed to build the tool's structure (hardware), and the availability of skilled technicians to update and develop the

functioning of the structure (software). For this reason, it should be noted that, despite the fact that, in the mid and long term, intervention based on emerging technologies could prove more efficient than traditional methods, these resources are not always available, sometimes not at all. This would also justify the limitations observed for emerging technologies to become integrated into the health system, an example of this being telemedicine, the implementation of which is taking place at a much slower pace than expected [64].

In this regard, Donker's recent systematic review to assess the cost of Internet-based mental health interventions proved their greater cost-effectiveness [13]. Van Spijker conducted a randomized controlled clinical trial to analyze the cost-effectiveness of Web-based interventions for the reduction of suicidal ideation, and it was found that they were indeed more cost-effective than traditional interventions [14]. This means that there are advantages in terms of effectiveness and costs and that it is a relevant public health issue, which leads to the question of why their use is not more widespread.

Finally, solely considering the barriers focused on resource constraints (cluster 1), it can be observed that there are differences among countries and stakeholders. The most remarkable cases are Germany and Romania, where the differences among the different stakeholder groups are stronger, as opposed to the rest of countries, where there is greater consistency among the 3 stakeholder groups. Nevertheless, these differences are mainly associated with barriers observed by health professionals rather than managers, and it is necessary to study such differences in depth to assess the reason for their existence, which could perhaps be attributed to shortcomings related to the sample and should be confirmed in future studies.

Attention should also be drawn to limitations in our sample, which, though randomly selected from each country based on the subjects' experience in the area of suicide, is not representative of the entire group it is part of. Nevertheless, it is adequate for a first approach to the study of limitations to the use of technologies in the health care area, assessing contrasts among countries and differences in health care models. On the other hand, the heterogeneous distribution of the different professional categories taking the survey makes it difficult to ensure a representative sample for each of them. Still, the data gathered contribute an interesting approximation to the potential and facilitating factors and barriers involved in the use of emerging technologies for the prevention and treatment of suicidal behavior.

Limitations and Strengths

The stakeholders involved in the study were not selected in a randomized way; therefore, they are not representatives of the stakeholders as a whole. The number of stakeholders involved in the study is different in every country, and probably, the motivation for answering is different too. Besides, the sociodemographic data collected in the questionnaire (gender, age, and professional category) could have an impact on the findings, but it has not been possible to control these variables because of the small size of this study sample. It should be considered that the principal objective of the project was to analyze the knowledge of relevant professionals in suicide field to improve and create prevention programs of suicide in different regions of Europe. The questionnaire used to collect the data was elaborated internally by the members of the project, and this questionnaire was not validated regarding the psychometric criteria. It should be highlighted that the questionnaire was not designed like a useful tool in the prevention of the suicide and was elaborated just for the compilation of the data. The different translations of the questionnaire into each language of the country were not made in a homogenous way; every project partner made the translation from English using different translation resources.

Taking into account these limitations, the differences between countries can be associated to different perspective of the specific stakeholders selected instead of proper general differences between countries. However, the data are interesting for knowing the possibilities and potential benefits of technologies for being used in suicide prevention. In this sense, it is the first study in Europe comparing different countries (south-north/east-west) regarding this topic.

Conclusion and Clinical Implications

There is evidence that new communication technologies may help toward improving suicide prevention although their implementation and use in the health system is still quite limited. Barriers to their use are different from one country to another and also depend on the organizational models. Equally, assessments vary depending on professionals consulted. Southern European countries, such as Spain, where health care models are more traditional and not community-based, instead of focusing on the effectiveness and advantages that this new type of health care model could contribute, believe the main barriers are related to the organizational system, the characteristics of the health professionals, and the difficulties they experience when using emerging technologies for this purpose. In contrast, countries such as Sweden, with community-based health care models and, therefore, a more flexible organization that facilitates the implementation and use of these technologies, consider that the main difficulties lie in proving their effectiveness in the delivery of services and ensuring that they actually facilitate accessibility.

On the basis of the results of this study, we consider that a broader use of communication technologies in suicide prevention would facilitate accessibility and care of people at risk for suicide. However, to apply these tools it is necessary to change organizational models, taking into account both the investment required and the changes in health care provision, which should be more flexible and targeted at results rather than at specific activities (eg, medical consultations). This is probably one of the main obstacles that has so far limited the implementation of emerging technologies.

Acknowledgments

The authors thank all those who participated in this study and all the members of the Euregenas Project. The authors would also like to thank Salud de Castilla y León (SACYL) and Junta de Castilla y León. The Euregenas Project has been financed by the Executive Agency for Health and Consumers (EAHC) of the European Commission.

Conflicts of Interest

None declared.

References

1. Patriarca A, Di Giuseppe G, Albano L, Marinelli P, Angelillo IF. Use of television, videogames, and computer among children and adolescents in Italy. BMC Public Health 2009 May 13;9:139 [FREE Full text] [doi: 10.1186/1471-2458-9-139] [Medline: 19439070]
2. de la Torre-Díez I, López-Coronado M, Vaca C, Aguado JS, de Castro C. Cost-utility and cost-effectiveness studies of telemedicine, electronic, and mobile health systems in the literature: a systematic review. Telemed J E Health 2015;21(2):81-85. [doi: 10.1089/tmj.2014.0053] [Medline: 25474190]
3. Sousa VE, Dunn Lopez K. Towards usable e-health. a systematic review of usability questionnaires. Appl Clin Inform 2017;8(2):470-490. [doi: 10.4338/ACI-2016-10-R-0170] [Medline: 28487932]
4. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. Am J Prev Med 2009 Feb;36(2):165-173. [doi: 10.1016/j.amepre.2008.09.040] [Medline: 19135907]
5. Hyden C, Cohall A. Innovative approaches to using new media and technology in health promotion for adolescents and young adults. Adolesc Med State Art Rev 2011 Dec;22(3):498-520, xi. [Medline: 22423462]
6. Muench F, Weiss RA, Kuerbis A, Morgenstern J. Developing a theory driven text messaging intervention for addiction care with user driven content. Psychol Addict Behav 2013 Mar;27(1):315-321 [FREE Full text] [doi: 10.1037/a0029963] [Medline: 22963375]
7. Glick G, Druss B, Pina J, Lally C, Conde M. Use of mobile technology in a community mental health setting. J Telemed Telecare 2016 Oct;22(7):430-435. [doi: 10.1177/1357633X15613236] [Medline: 26519378]
8. Wilson LS, Maeder AJ. Recent directions in telemedicine: review of trends in research and practice. Healthc Inform Res 2015 Oct;21(4):213-222 [FREE Full text] [doi: 10.4258/hir.2015.21.4.213] [Medline: 26618026]
9. Todd NJ, Jones SH, Hart A, Lobban FA. A web-based self-management intervention for bipolar disorder 'living with bipolar': a feasibility randomised controlled trial. J Affect Disord 2014;169:21-29. [doi: 10.1016/j.jad.2014.07.027] [Medline: 25129531]
10. Berrouiguet S, Baca-García E, Brandt S, Walter M, Courtet P. Fundamentals for future mobile-health (mhealth): a systematic review of mobile phone and web-based text messaging in mental health. J Med Internet Res 2016;18(6):e135. [doi: 10.2196/jmir.5066] [Medline: PMC4920962]
11. Gerhards SA, de Graaf LE, Jacobs LE, Severens JL, Huibers MJ, Arntz A, et al. Economic evaluation of online computerised cognitive-behavioural therapy without support for depression in primary care: randomised trial. Br J Psychiatry 2010 Apr;196(4):310-318 [FREE Full text] [doi: 10.1192/bjp.bp.109.065748] [Medline: 20357309]
12. Griffiths KM, Farrer L, Christensen H. The efficacy of internet interventions for depression and anxiety disorders: a review of randomised controlled trials. Med J Aust 2010 Jun 07;192(11 Suppl):S4-11. [Medline: 20528707]
13. Donker T, Blankers M, Hedman E, Ljótsson B, Petrie K, Christensen H. Economic evaluations of internet interventions for mental health: a systematic review. Psychol Med 2015 Dec;45(16):3357-3376. [doi: 10.1017/S0033291715001427] [Medline: 26235445]
14. van Spijker BA, Majo MC, Smit F, van Straten A, Kerkhof AJ. Reducing suicidal ideation: cost-effectiveness analysis of a randomized controlled trial of unguided web-based self-help. J Med Internet Res 2012 Oct 26;14(5):e141 [FREE Full text] [doi: 10.2196/jmir.1966] [Medline: 23103835]
15. Ebert DD, Berking M, Cuijpers P, Lehr D, Pörtner M, Baumeister H. Increasing the acceptance of internet-based mental health interventions in primary care patients with depressive symptoms. A randomized controlled trial. J Affect Disord 2015 May 01;176:9-17. [doi: 10.1016/j.jad.2015.01.056] [Medline: 25682378]
16. Wykes T, Brown M. Over promised, over-sold and underperforming? - e-health in mental health. J Ment Health 2016;25(1):1-4 [FREE Full text] [doi: 10.3109/09638237.2015.1124406] [Medline: 26732733]
17. Wynn SD, Sherrod RA. Providing mental health care to veterans in rural areas: using telehealth in mobile clinics. J Psychosoc Nurs Ment Health Serv 2012 Jun;50(6):22-28. [doi: 10.3928/02793695-20120508-01] [Medline: 22589227]
18. Mewton L, Andrews G. Cognitive behaviour therapy via the internet for depression: a useful strategy to reduce suicidal ideation. J Affect Disord 2015 Jan 01;170:78-84. [doi: 10.1016/j.jad.2014.08.038] [Medline: 25233243]
19. Lobban F, Dodd AL, Sawczuk AP, Asar O, Dagnan D, Diggle PJ, et al. Assessing feasibility and acceptability of web-based enhanced relapse prevention for bipolar disorder (ERPonline): a randomized controlled trial. J Med Internet Res 2017 Mar 24;19(3):e85 [FREE Full text] [doi: 10.2196/jmir.7008] [Medline: 28341619]

20. Dyregrov K. What do we know about needs for help after suicide in different parts of the world? a phenomenological perspective. Crisis 2011;32(6):310-318. [doi: 10.1027/0227-5910/a000098] [Medline: 21940240]
21. World Health Organization. Preventing suicide: a global imperative. Geneva, Switzerland: WHO; 2014.
22. Kovess-Masfety V, Boyd A, Haro JM, Bruffaerts R, Villagut G, Lépine JP, ESEMeD/MHEDEA investigators. High and low suicidality in Europe: a fine-grained comparison of France and Spain within the ESEMeD surveys. J Affect Disord 2011 Sep;133(1-2):247-256 [FREE Full text] [doi: 10.1016/j.jad.2011.04.014] [Medline: 21621264]
23. Spallek J, Reeske A, Norredam M, Nielsen SS, Lehnhardt J, Razum O. Suicide among immigrants in Europe--a systematic literature review. Eur J Public Health 2015 Feb;25(1):63-71. [doi: 10.1093/eurpub/cku121] [Medline: 25096258]
24. Neeleman J, de Graaf R, Vollebergh W. The suicidal process; prospective comparison between early and later stages. J Affect Disord 2004 Oct 01;82(1):43-52. [doi: 10.1016/j.jad.2003.09.005] [Medline: 15465575]
25. Choi S, Lee W, Yoon JH, Won JU, Kim DW. Risk factors of suicide attempt among people with suicidal ideation in South Korea: a cross-sectional study. BMC Public Health 2017 Jun 15;17(1):579 [FREE Full text] [doi: 10.1186/s12889-017-4491-5] [Medline: 28619107]
26. Costanza A, D'Orta I, Perroud N, Burkhardt S, Malafosse A, Mangin P, et al. Neurobiology of suicide: do biomarkers exist? Int J Legal Med 2014 Jan;128(1):73-82. [doi: 10.1007/s00414-013-0835-6] [Medline: 23430141]
27. Oyesanya M, Lopez-Morinigo J, Dutta R. Systematic review of suicide in economic recession. World J Psychiatry 2015 Jun 22;5(2):243-254 [FREE Full text] [doi: 10.5498/wjp.v5.i2.243] [Medline: 26110126]
28. Tanji F, Kakizaki M, Sugawara Y, Watanabe I, Nakaya N, Minami Y, et al. Personality and suicide risk: the impact of economic crisis in Japan. Psychol Med 2015 Feb;45(3):559-573 [FREE Full text] [doi: 10.1017/S0033291714001688] [Medline: 25036366]
29. Borges G, Nock MK, Haro Abad JM, Hwang I, Sampson NA, Alonso J, et al. Twelve-month prevalence of and risk factors for suicide attempts in the World Health Organization World Mental Health Surveys. J Clin Psychiatry 2010 Dec;71(12):1617-1628 [FREE Full text] [doi: 10.4088/JCP.08m04967blu] [Medline: 20816034]
30. Onishi K. Risk factors and social background associated with suicide in Japan: a review. Jpn Hosp 2015 Jul(34):35-50. [Medline: 26373186]
31. Sareen J, Isaak C, Katz LY, Bolton J, Enns MW, Stein MB. Promising strategies for advancement in knowledge of suicide risk factors and prevention. Am J Prev Med 2014 Sep;47(3 Suppl 2):S257-S263. [doi: 10.1016/j.amepre.2014.05.041] [Medline: 25145748]
32. Qin P. The impact of psychiatric illness on suicide: differences by diagnosis of disorders and by sex and age of subjects. J Psychiatr Res 2011 Nov;45(11):1445-1452. [doi: 10.1016/j.jpsychires.2011.06.002] [Medline: 21722920]
33. Yoshimasu K, Kiyohara C, Miyashita K, Stress Research Group of the Japanese Society for Hygiene. Suicidal risk factors and completed suicide: meta-analyses based on psychological autopsy studies. Environ Health Prev Med 2008 Sep;13(5):243-256 [FREE Full text] [doi: 10.1007/s12199-008-0037-x] [Medline: 19568911]
34. Fleischmann A, de Leo D. The World Health Organization's report on suicide: a fundamental step in worldwide suicide prevention. Crisis 2014;35(5):289-291. [doi: 10.1027/0227-5910/a000293] [Medline: 25297514]
35. Arensman E, Coffey C, Griffin E, Van Audenhove C, Scheerder G, Gusmao R, et al. Effectiveness of depression-suicidal behaviour gatekeeper training among police officers in three European regions: outcomes of the optimising suicide prevention programmes and their implementation in Europe (OSPI-Europe) study. Int J Soc Psychiatry 2016 Sep 19 Epub ahead of print. [doi: 10.1177/0020764016668907] [Medline: 27647606]
36. Farré A, Portella MJ, De AL, Díaz A, de Diego-Adeliño J, Vegué J, et al. Benefits of a secondary prevention program in suicide. Crisis 2016 Jul;37(4):281-289. [doi: 10.1027/0227-5910/a000388] [Medline: 27245810]
37. Ftanou M, Cox G, Nicholas A, Spittal MJ, Machlin A, Robinson J, et al. Suicide prevention public service announcements (PSAs): examples from around the world. Health Commun 2017 Apr;32(4):493-501. [doi: 10.1080/10410236.2016.1140269] [Medline: 27308843]
38. King C, Eisenberg D, Zheng K, Czyz E, Kramer A, Horwitz A, et al. Online suicide risk screening and intervention with college students: a pilot randomized controlled trial. J Consult Clin Psychol 2015 Jun;83(3):630-636 [FREE Full text] [doi: 10.1037/a0038805] [Medline: 25688811]
39. Iorfino F, Davenport TA, Ospina-Pinillos L, Hermens DF, Cross S, Burns J, et al. Using new and emerging technologies to identify and respond to suicidality among help-seeking young people: a cross-sectional study. J Med Internet Res 2017 Jul 12;19(7):e247 [FREE Full text] [doi: 10.2196/jmir.7897] [Medline: 28701290]
40. Ghoncheh R, Gould MS, Twisk JW, Kerkhof AJ, Koot HM. Efficacy of adolescent suicide prevention e-learning modules for gatekeepers: a randomized controlled trial. JMIR Ment Health 2016 Jan 29;3(1):e8 [FREE Full text] [doi: 10.2196/mental.4614] [Medline: 26825006]
41. Guille C, Zhao Z, Krystal J, Nichols B, Brady K, Sen S. Web-based cognitive behavioral therapy intervention for the prevention of suicidal ideation in medical interns: a randomized clinical trial. JAMA Psychiatry 2015 Dec;72(12):1192-1198 [FREE Full text] [doi: 10.1001/jamapsychiatry.2015.1880] [Medline: 26535958]
42. Robinson J, Hetrick S, Cox G, Bendall S, Yung A, Pirkis J. The safety and acceptability of delivering an online intervention to secondary students at risk of suicide: findings from a pilot study. Early Interv Psychiatry 2015 Dec;9(6):498-506. [doi: 10.1111/eip.12136] [Medline: 24684927]

43. Sueki H, Ito J. Suicide prevention through online gatekeeping using search advertising techniques: a feasibility study. Crisis 2015;36(4):267-273. [doi: 10.1027/0227-5910/a000322] [Medline: 26440623]
44. Eylem O, van Straten A, Bhui K, Kerkhof AJ. Protocol: Reducing suicidal ideation among Turkish migrants in the Netherlands and in the UK: effectiveness of an online intervention. Int Rev Psychiatry 2015 Feb;27(1):72-81. [doi: 10.3109/09540261.2014.996121] [Medline: 25747026]
45. Robinson J, Hetrick S, Cox G, Bendall S, Yuen HP, Yung A, et al. Can an Internet-based intervention reduce suicidal ideation, depression and hopelessness among secondary school students: results from a pilot study. Early Interv Psychiatry 2016 Feb;10(1):28-35. [doi: 10.1111/eip.12137] [Medline: 24684946]
46. Biddle L, Derges J, Mars B, Heron J, Donovan JL, Potokar J, et al. Suicide and the Internet: Changes in the accessibility of suicide-related information between 2007 and 2014. J Affect Disord 2016 Jan 15;190:370-375. [doi: 10.1016/j.jad.2015.10.028] [Medline: 26546772]
47. Gilat I, Shahar G. Suicide prevention by online support groups: an action theory-based model of emotional first aid. Arch Suicide Res 2009;13(1):52-63. [doi: 10.1080/13811110802572148] [Medline: 19123109]
48. Shand FL, Ridani R, Tighe J, Christensen H. The effectiveness of a suicide prevention app for indigenous Australian youths: study protocol for a randomized controlled trial. Trials 2013 Nov 20;14:396 [FREE Full text] [doi: 10.1186/1745-6215-14-396] [Medline: 24257410]
49. Ahuja AK, Biesaga K, Sudak DM, Draper J, Womble A. Suicide on facebook. J Psychiatr Pract 2014 Mar;20(2):141-146. [doi: 10.1097/01.pra.0000445249.38801.d1] [Medline: 24638049]
50. Berrouiguet S, Alavi Z, Vaiva G, Courtet P, Baca-García E, Vidailhet P, et al. SIAM (Suicide intervention assisted by messages): the development of a post-acute crisis text messaging outreach for suicide prevention. BMC Psychiatry 2014 Nov 18;14:294 [FREE Full text] [doi: 10.1186/s12888-014-0294-8] [Medline: 25404215]
51. Berrouiguet S, Gravey M, Le Galudec M, Alavi Z, Walter M. Post-acute crisis text messaging outreach for suicide prevention: a pilot study. Psychiatry Res 2014 Jul 30;217(3):154-157. [doi: 10.1016/j.psychres.2014.02.034] [Medline: 24736112]
52. Jashinsky J, Burton SH, Hanson CL, West J, Giraud-Carrier C, Barnes MD, et al. Tracking suicide risk factors through Twitter in the US. Crisis 2014;35(1):51-59. [doi: 10.1027/0227-5910/a000234] [Medline: 24121153]
53. Larsen ME, Nicholas J, Christensen H. A systematic assessment of smartphone tools for suicide prevention. PLoS One 2016;11(4):e0152285 [FREE Full text] [doi: 10.1371/journal.pone.0152285] [Medline: 27073900]
54. Bailey E, Krysinska K, O'Dea B, Robinson J. Internet forums for suicide bereavement. Crisis 2017;38(6):393-402. [doi: 10.1027/0227-5910/a000471] [Medline: 28793818]
55. McManama OK, LeCloux M, Ross A, Gironda C, Wharff EA. A pilot study of the acceptability and usability of a smartphone application intervention for suicidal adolescents and their parents. Arch Suicide Res 2017;21(2):254-264. [doi: 10.1080/13811118.2016.1182094] [Medline: 27136115]
56. Pauwels K, Aerts S, Muijzers E, De Jaegere E, van Heeringen K, Portzky G. BackUp: development and evaluation of a smart-phone application for coping with suicidal crises. PLoS One 2017;12(6):e0178144 [FREE Full text] [doi: 10.1371/journal.pone.0178144] [Medline: 28636617]
57. Wasserman D, Hoven CW, Wasserman C, Wall M, Eisenberg R, Hadlaczky G, et al. School-based suicide prevention programmes: the SEYLE cluster-randomised, controlled trial. Lancet 2015 Apr 18;385(9977):1536-1544. [doi: 10.1016/S0140-6736(14)61213-7] [Medline: 25579833]
58. Bruckner TA, McClure C, Kim Y. Google searches for suicide and risk of suicide. Psychiatr Serv 2014 Feb 01;65(2):271-272 [FREE Full text] [doi: 10.1176/appi.ps.201300211] [Medline: 24492910]
59. Thornton L, Handley T, Kay-Lambkin F, Baker A. Is a person thinking about suicide likely to find help on the internet? an evaluation of google search results. Suicide Life Threat Behav 2017 Feb;47(1):48-53. [doi: 10.1111/sltb.12261] [Medline: 27111845]
60. Bragazzi NL. A google trends-based approach for monitoring NSSI. Psychol Res Behav Manag 2013;7:1-8 [FREE Full text] [doi: 10.2147/PRBM.S44084] [Medline: 24376364]
61. Parker J, Cuthbertson C, Loveridge S, Skidmore M, Dyar W. Forecasting state-level premature deaths from alcohol, drugs, and suicides using Google Trends data. J Affect Disord 2017 Apr 15;213:9-15. [doi: 10.1016/j.jad.2016.10.038] [Medline: 28171770]
62. Solano P, Ustulin M, Pizzorno E, Vichi M, Pompili M, Serafini G, et al. A Google-based approach for monitoring suicide risk. Psychiatry Res 2016 Dec 30;246:581-586. [doi: 10.1016/j.psychres.2016.10.030] [Medline: 27837725]
63. Arora VS, Stuckler D, McKee M. Tracking search engine queries for suicide in the United Kingdom, 2004-2013. Public Health 2016 Aug;137:147-153. [doi: 10.1016/j.puhe.2015.10.015] [Medline: 26976489]
64. Khanal S, Burgon J, Leonard S, Griffiths M, Eddowes LA. Recommendations for the improved effectiveness and reporting of telemedicine programs in developing countries: results of a systematic literature review. Telemed J E Health 2015 Nov;21(11):903-915. [doi: 10.1089/tmj.2014.0194] [Medline: 26103465]

Abbreviations

ANOVA: analysis of variance

DPM: decision and policy makers
EUREGENAS: European Regions Enforcing Actions against Suicide
IDS: individual differences scaling
MANOVA: multivariate analysis of variance
MDS: multidimensional scaling
MHP: mental health professionals
NGOs: nongovernmental organizations
PROXSCAL: PROXimity SCALing

Edited by G Eysenbach; submitted 30.03.17; peer-reviewed by N Bragazzi, S Berrouiguet, AE Aladağ; comments to author 10.08.17; revised version received 05.10.17; accepted 29.10.17; published 24.01.18.

Please cite as:
Muñoz-Sánchez JL, Delgado C, Sánchez-Prada A, Parra-Vidales E, de Leo D, Franco-Martín M
Facilitating Factors and Barriers to the Use of Emerging Technologies for Suicide Prevention in Europe: Multicountry Exploratory Study
JMIR Ment Health 2018;5(1):e7
URL: http://mental.jmir.org/2018/1/e7/
doi:10.2196/mental.7784
PMID:

Original Paper

A Web-Based Psychoeducational Intervention for Adolescent Depression: Design and Development of MoodHwb

Rhys Bevan Jones[1,2], PhD, MRCPsych; Anita Thapar[1,2], PhD, FRCPsych; Frances Rice[1,2], PhD; Harriet Beeching[1], MBBCh; Rachel Cichosz[1], MBBCh; Becky Mars[3], PhD; Daniel J Smith[4], MD, FRCPsych; Sally Merry[5], MD, FRANZP; Paul Stallard[6], PhD; Ian Jones[1,2], PhD, MRCPsych; Ajay K Thapar[1,2], PhD, MRCGP; Sharon A Simpson[7], PhD

[1]Division of Psychological Medicine and Clinical Neurosciences, Medical Research Council Centre for Neuropsychiatric Genetics and Genomics, Cardiff University, Cardiff, Wales, United Kingdom

[2]National Centre for Mental Health, Cardiff University, Cardiff, Wales, United Kingdom

[3]Population Health Sciences, University of Bristol, Bristol, England, United Kingdom

[4]Institute of Health and Wellbeing, University of Glasgow, Glasgow, Scotland, United Kingdom

[5]Faculty of Medical and Health Sciences, School of Medicine, University of Auckland, Auckland, New Zealand

[6]Department for Health, University of Bath, Bath, England, United Kingdom

[7]Medical Research Council/Chief Scientist Office Social and Public Health Sciences Unit, Institute of Health and Wellbeing, University of Glasgow, Glasgow, Scotland, United Kingdom

Corresponding Author:
Rhys Bevan Jones, PhD, MRCPsych
Division of Psychological Medicine and Clinical Neurosciences
Medical Research Council Centre for Neuropsychiatric Genetics and Genomics
Cardiff University
Hadyn Ellis Building
Maindy Rd
Cardiff, Wales, CF24 4HQ
United Kingdom
Phone: 44 02920688451
Fax: 44 02920687068
Email: bevanjonesr1@cardiff.ac.uk

Abstract

Background: Depression is common in adolescence and leads to distress and impairment in individuals, families and carers. Treatment and prevention guidelines highlight the key role of information and evidence-based psychosocial interventions not only for individuals but also for their families and carers. Engaging young people in prevention and early intervention programs is a challenge, and early treatment and prevention of adolescent depression is a major public health concern. There has been growing interest in psychoeducational interventions to provide accurate information about health issues and to enhance and develop self-management skills. However, for adolescents with, or at high risk of depression, there is a lack of engaging Web-based psychoeducation programs that have been developed with user input and in line with research guidelines and targeted at both the individual and their family or carer. There are also few studies published on the process of development of Web-based psychoeducational interventions.

Objective: The aim of this study was to describe the process underlying the design and development of *MoodHwb* (*HwbHwyliau* in Welsh): a Web-based psychoeducation multimedia program for young people with, or at high risk of, depression and their families, carers, friends, and professionals.

Methods: The initial prototype was informed by (1) a systematic review of psychoeducational interventions for adolescent depression; (2) findings from semistructured interviews and focus groups conducted with adolescents (with depressive symptoms or at high risk), parents or carers, and professionals working with young people; and (3) workshops and discussions with a multimedia company and experts (in clinical, research, and multimedia work). Twelve interviews were completed (four each with young people, parents or carers, and professionals) and six focus groups (three with young people, one with parents and carers, one with professionals, and one with academics).

Results: Key themes from the interviews and focus groups were: aims of the program, design and content issues, and integration and context of the program. The prototype was designed to be person-centered, multiplatform, engaging, interactive, and bilingual. It included mood-monitoring and goal-setting components and was available as a Web-based program and an app for mobile technologies.

Conclusions: MoodHwb is a Web-based psychoeducational intervention developed for young people with, or at high risk of, depression and their families and carers. It was developed with user input using qualitative methods as well as user-centered design and educational and psychological theory. Further research is needed to evaluate the effectiveness of the program in a randomized controlled trial. If found to be effective, it could be implemented in health, education, youth and social services, and charities, to not only help young people but also families, carers, friends, and professionals involved in their care.

(JMIR Ment Health 2018;5(1):e13) doi:10.2196/mental.8894

KEYWORDS

adolescent; depression; internet; education; preventive psychiatry; early medical intervention

Introduction

Prevention and Management of Adolescent Depression

Depression is common in adolescence and is associated with distress, social and educational impairments, and poor physical health. It also predicts suicide and deliberate self-harm and can mark the beginning of long-term mental health difficulties [1]. Early treatment and prevention of adolescent depression is therefore a major public health concern [2]. However, engaging young people in prevention and early intervention programs is a challenge for health and other services. This is in part because of the anxiety and stigma related to mental health issues and services, the symptoms of depression (eg, motivation and social withdrawal), and the potential difficulties in identifying depression in adolescence [1,3,4].

Guidelines for the prevention and management of depression in young people (eg, National Institute for Health and Care Excellence [5] and American Academy of Child and Adolescent Psychiatry [6]) stress the need for good information and evidence-based psychosocial interventions for the young person, family, and carer. Psychosocial interventions are likely to be important in young people for promoting resilience and preventing relapse [1,7].

Psychoeducation

There has been growing interest in psychoeducational interventions (PIs), which deliver accurate information to individuals, families, and carers about mental health or a specific diagnosis, management and prognosis, and relapse prevention strategies [6,8-10] (Textbox 1). Although the risk factors and possible causes of adolescent depression are complex, a family history of depression, psychosocial stress, and a previous history of depression increase individual risk, and these groups could be targeted for such strategies [1].

Much of the existing literature on PIs has been in relation to individuals (mainly adults) with schizophrenia or bipolar disorder and their families [6,8,11], although there has been increasing interest in depression. Findings from a recent systematic review concluded that PIs are effective in improving the clinical course, treatment adherence, and psychosocial functioning of adults with depression [12]. We conducted a systematic review of PIs for adolescent depression [13] that showed that there were few existing programs that have been developed and evaluated using rigorous methods according to research frameworks.

eHealth Approaches

Electronic health (eHealth) and electronic multimedia have been identified as a key area of future clinical practice and research in depression in adolescents [10,14]. There is evidence to support the use of some cognitive behavioral therapy (CBT)–based and other Web-based programs for adolescent depression [15-17]. Although it is difficult to evaluate how much psychoeducation within the programs contributed to the outcomes, Web-based PIs for depression in adults has been shown to reduce symptoms of depression and improve understanding of treatments [18].

However, to our knowledge, there is no Web-based PI that has been specifically developed for adolescent depression (or those at high risk) and developed and evaluated in line with key guidance on the development and evaluation of complex interventions [19]. This is an important gap; depression is common in young people, and its presentation and management is different to that of adults (eg, the prominence of irritability and fluctuating symptoms and emphasis on educational and psychological approaches) [1]. Studies detailing the process of development of Web-based PIs are rare. In this paper, we describe the design and development of *MoodHwb*: a Web-based psychoeducation multimedia program for young people with, or at high risk of, depression and their families and carers. The program was designed so that it could be used regularly within everyday health, social, education, youth services, and charities. This method of development provides an example and framework that could help inform the development of future Web-based programs, to ensure that they are codesigned with potential users to maximize the chances of user engagement and therefore impact.

Textbox 1. Psychoeducation in childhood and adolescent depression.

The American Academy of Child and Adolescent Psychiatry (2007): "Practice parameter for the assessment and treatment of children and adolescents with depressive disorders" describe psychoeducation as "education of family members and the patient about the causes, symptoms, course, and different treatments of depression and the risks associated with these treatments as well as no treatment at all. Education should make the treatment and decision-making process transparent and should enlist parent and patient as collaborators in their own care." (Birmaher and Brent, 2007 [6]).

Methods

Research Plan

The research adhered to the *preclinical or theory* and *phase I or modeling phases* of the Medical Research Council (MRC) framework for complex interventions and the *development phase* of the new guidance on developing and evaluating complex interventions [19]. The project brought together audiovisual, interactive, and Web-based media, informed by research and practice from the areas of adolescent depression (particularly prevention and management strategies), psychoeducation (and learning), e-mental health, and design.

The developmental approach was *person-centered* or *person-based*, as described in guidelines for digital health-related interventions [20-22]. This focuses on understanding and accommodating the perspectives of the users and identifying "guiding principles." The approach embraces qualitative research, with a wide range of individuals from the target user population at every stage of the intervention development. This iterative approach helps to assess acceptability, usability, and satisfaction, as well as appreciating the context, anticipating usage and outcomes, and modifying the intervention to make it persuasive, feasible, and relevant.

Following a literature review of PIs in adolescent depression [13], a qualitative study was completed consisting of a series of semistructured interviews and focus groups with potential users of the program (adolescents, families, carers, and professionals working with young people). Interviews were used to generate initial detailed views and ideas from a range of users, to carry forward to the focus groups. The groups enabled a greater breadth of discussion and refinement of these ideas, to help inform the development of the program with the research team and multimedia company. The interviewing was iterative; where new themes emerged, they were incorporated into the subsequent interviews and focus groups. Figure 1 demonstrates how the design and content of the program was developed based on the literature review, interviews, focus groups, and other consultations.

Ethical and Health Board Approval

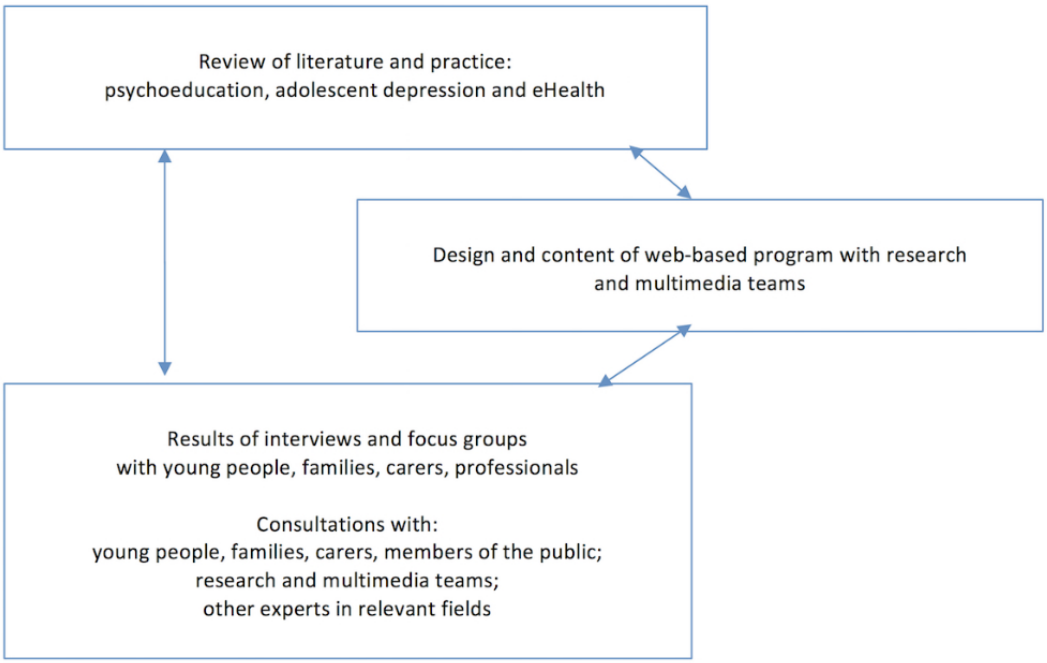
The Dyfed-Powys, Wales, United Kingdom (UK) REC, gave a favorable opinion for the research project. Research and development (R&D) approval was granted by Cwm Tâf, Cardiff and Vale, Abertawe Bro Morgannwg, Aneurin Bevan, and Hywel Dda University Health Boards (UHBs), five of the seven UHBs in Wales.

Recruitment for Interviews and Focus Groups

Inclusion and Exclusion Criteria

Young people were recruited from Child and Adolescent Mental Health Services (CAMHS) and from the Cardiff Early Prediction of Adolescent Depression (EPAD) study [23]. They were required to be at least 13 years of age and to have either current or past history of depression (recruited from CAMHS), or be at high risk of depression because of a family history (at least one parent with recurrent depression, recruited from the EPAD study).

Figure 1. Influences on the design and content of the Web-based program.



Parents, guardians and carers of these young people were also recruited for interviews and focus groups. Professionals (from health, education, social, and youth services and charities) were approached if they worked with young people who present with mental health difficulties. Participants were not eligible if they had severe health difficulties that would make it difficult for them to contribute, or make it more likely they would become distressed, or if they were unable to understand the intervention or questions or discussions (eg, because of insufficient understanding of English).

Sampling Frame

Participants were recruited from south and west Wales and included areas of high deprivation, as well as more affluent areas. Within the interviews and focus groups, we aimed to have a balance of participants with regard to age, gender, primary language (Welsh or English), severity of depressive symptoms, and service involvement.

Recruitment Documents

Participants from CAMHS and the EPAD study were sent invitation letters and information sheets (Figure 2) and asked to reply if interested in participating. Young people were consulted during the design of information sheets and consent and assent forms. These were developed with reference to a readability test [24] and with the help of an experienced graphic designer so that they could be engaging for young people. The documents and the program were developed in Welsh and English in line with depression guidelines [5] and to ensure inclusivity for the population of Wales [25]. Participants were offered gift vouchers for their participation, time, and travel.

Interviews (Discovery Phase)

A series of 12 semistructured interviews were conducted: four each with adolescents, parents or carers, and professionals. They were held either at Cardiff University or a location convenient for the participant (eg, home or school) and lasted up to 90 min. All interviews were completed by RBJ. A topic guide was used (Multimedia Appendix 1), although the interviews were informal, so that the interviewee perceived them more as a discussion. Where possible, the interviews were conducted in front of a computer screen so that initial ideas and imagery and existing resources could be discussed. All interviews were audio-recorded digitally, and a third-party company transcribed the recordings.

Focus Groups (Codesign Phase)

Following the completion and analysis of the interviews, focus groups were conducted, which allowed new ideas to be generated in a safe forum, where participants could build on each other's perspectives. In the earlier groups, general ideas were discussed, and in the latter groups, draft designs were shown, and participants could interact with preliminary components using tablets or laptops.

Six focus groups were held (Figure 3), three with young people, one with parents and carers, one with professionals working with young people, and one with clinical and other academics in child and adolescent psychiatry. The focus groups lasted approximately 90 to 120 min and were facilitated by RBJ, accompanied by a colleague (HB or RC). As well as engaging in a verbal discussion, participants were asked to draw or write ideas and to reflect on images and ideas presented on a screen. Each group was audio-recorded and transcribed.

The focus group discussion outline (moderator guide) evolved from the interview topic guide. Most of the questions and images discussed were projected on a screen with multimedia content (Multimedia Appendix 2). Between groups, the research team developed ideas for the presentation or content, and this shaped the multimedia slides shown to the next group. In this way, the program was developed in a staged, iterative manner.

Other Consultations

In addition to the interviews and focus groups, there were other discussions with potential users, researchers, multimedia groups, schools, and charities from around the United Kingdom and overseas (including in national and international conferences). A workshop was held with the National Youth Assembly of Wales, Funky Dragon, a peer-led organization of young people aged 11 to 25 years elected from around Wales (n=22). There were also public engagement events where groups were consulted on their ideas for the program, such as the public engagement exhibition, How the Light Gets In [26].

Figure 2. Information sheet for young people (in English).

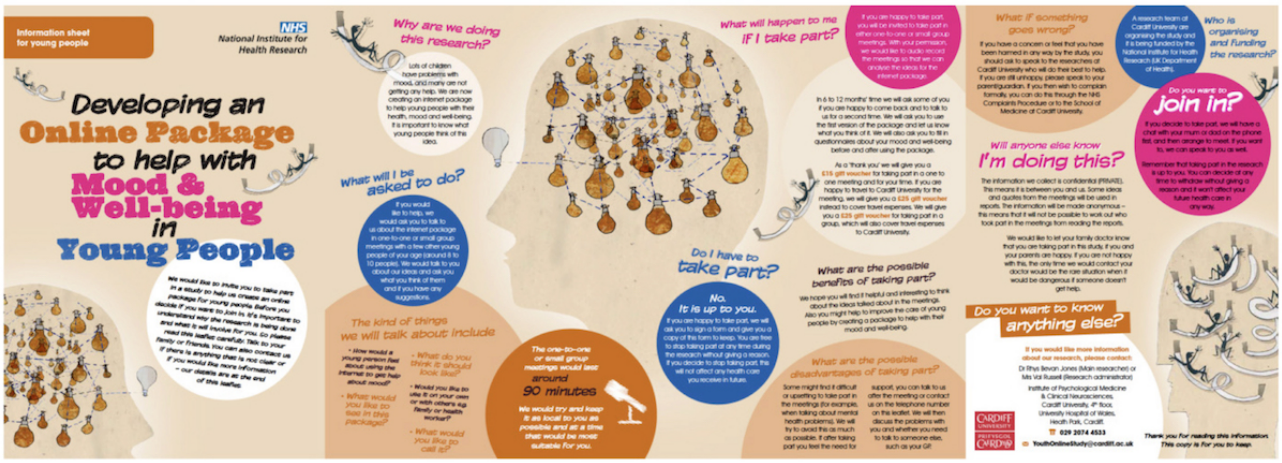
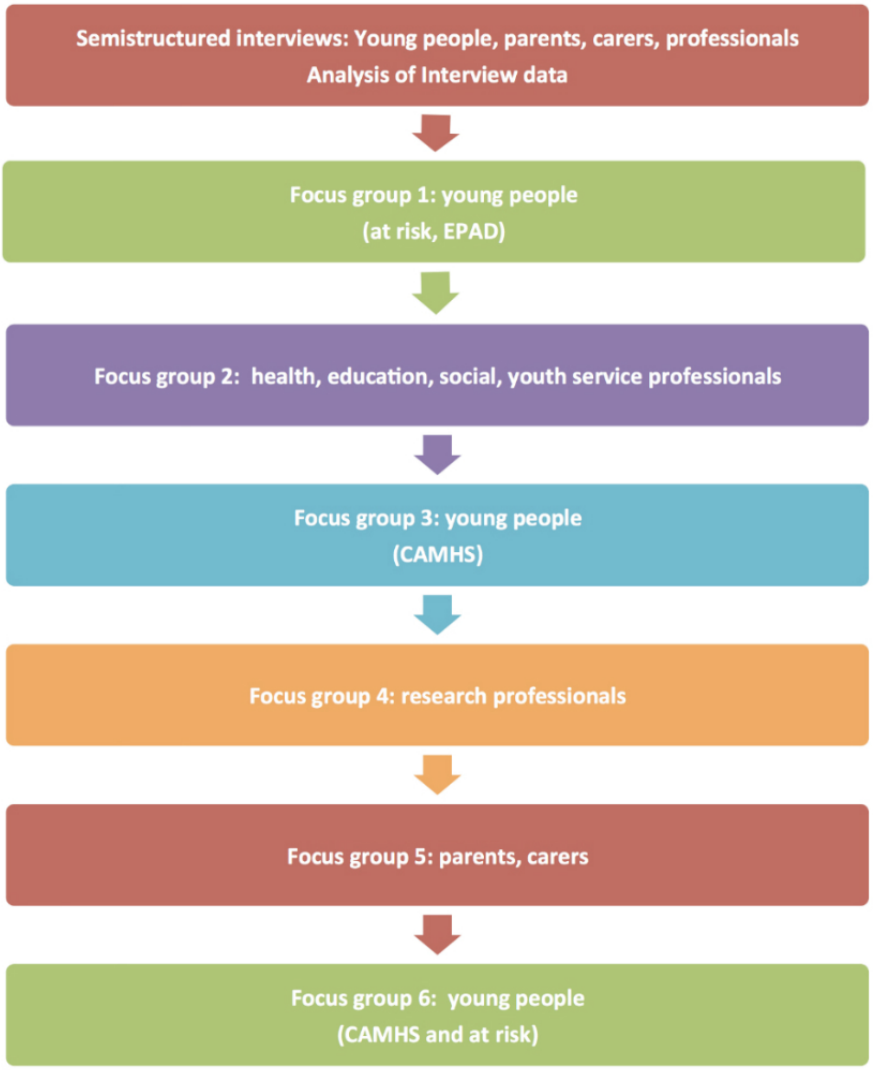


Figure 3. Flowchart—sequence of interviews and focus groups.



RBJ also visited and consulted experts in youth health and eHealth at the Werry Institute (Auckland) and Health Promotion Agency (Wellington) in New Zealand, and the Black Dog Institute (Sydney), National Institute for Mental Health (Canberra), and Orygen, The National Centre of Excellence in Youth Mental Health (Melbourne) in Australia.

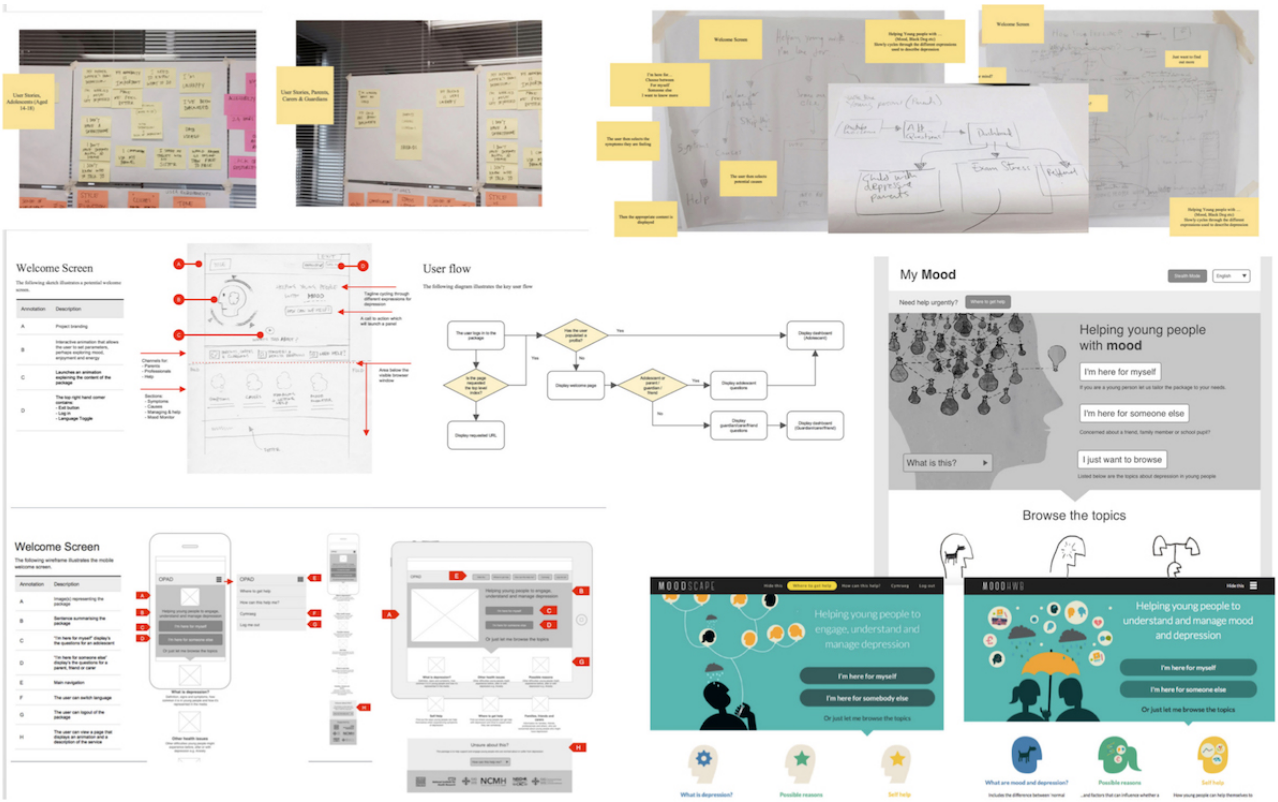
Data Analysis

The interview and focus group transcripts were analyzed using an inductive (or "bottom up") thematic analysis approach [27]. All transcripts were coded by RBJ and double coded independently by other authors (HB coded half of the transcripts and RC coded the other half). Initial ideas on the coding framework were discussed among the team members; the draft framework was applied to some of the data and refined as coding proceeded. Agreement on concepts and coding was then sought to ensure reliability. Where there was disagreement, the researchers reviewed the coding together. Other authors (SS, DJ, and AT) were consulted where there was uncertainty or disagreement. Codes were applied to broad themes, which were then broken down further into subcodes. Transcripts were closely examined to identify the key themes and associated subthemes. Thematic analysis was supported by the computer-assisted qualitative analysis software NVivo (QSR International) for Mac (version 10).

Development of Prototype

Workshops were held with a multimedia company to develop the prototype alongside the latter focus groups. The specifications for the different aspects of the content and design of the program were refined according to the level of importance given to them by the participants and the potential effect on the acceptability, feasibility, and ease of use of the program. Other considerations were the technical difficulty, time required, and development costs.

Figure 4. Development of welcome screen and user flow: notes or sketches (above, center left), wireframes (below left), black and white, and color designs (center and below right).



In early meetings with the multimedia company, note boards and sketches were created based on user and project requirements, and some initial designs were shown in the focus groups. Wireframes (skeletal framework or blueprints) were then constructed showing the layout and functionality of each proposed screen within the program. These wireframes further evolved into the digital prototype. The process of development from initial notes to prototype is shown in Figure 4.

RBJ wrote the script for the content and developed the initial designs and illustrations (alongside the interviews and groups), and these were reviewed by FR and discussed with other authors. During the final stages of development, components of the prototype (eg, animation scripts and storyboards) were reviewed by some of the participants who had taken part in the focus groups to ensure the material was clearly presented and age-appropriate.

Results

Interview and Focus Group Participants

Twelve people were interviewed in total (Table 1)—four young people aged 13 to 18 years (three females and one male), four parents (three mothers and one father), and four professionals (two child and adolescent psychiatrists, a general practitioner, and an educational psychologist).

Six focus groups were conducted (Table 2); three with young people (total N=29), one with parents and carers (N=7), and two with professionals (N=22, including one group of researchers with a special interest in child and adolescent mental health). The mean age of the participants in the young people focus groups was 16 years (range 13-19 years). The majority (69%, 20/29) were female.

Summary of Findings to Inform the Prototype

The key themes in the interviews and later in the focus groups were (1) the need for and aims of the Web-based program, (2) design issues, (3) content issues, and (4) its integration into the young person's life. The key themes were influenced by the topic guide and the main issues the research team wished to explore to help develop the content and design of the program. These key themes and the subthemes that emerged from interviews and groups are presented in Table 3.

Key Theme 1: Needs and Aims

All interview and group participants described how there was a need for this program, especially given the lack of specialist CAMHS and Web-based resources. Parents, carers and professionals also felt there was not enough time during CAMHS clinic sessions, and the waiting lists were long, as illustrated in the following quotes:

> *There's a huge gap as to what else that we can offer, beyond the four life hygienes...You've certainly hit an area where we've got a big, black hole, definitely...huge, huge.* [Professional 3: female: general practitioner]
>
> *My daughter didn't know where to turn.* [Parent 2: male: daughter under CAMHS]
>
> *It's important that people know about mental health information...There's not much out there...it would be pretty revolutionary if it works.* [Young person focus group 3]

Table 1. Participants—semistructured interviews.

Participant group	Background	Other demographics (nationality; language)
Young person 1	18-year-old female with a history of depression (previously under CAMHS[a])	Welsh, British; English, Welsh
Young person 2	13-year-old female with depression (under CAMHS at time of interview)	Welsh, British; English, Welsh
Young person 3	17-year-old male with depression (under CAMHS at time of interview)	Welsh, British; English, Welsh
Young person 4	16-year-old female at high risk of depression (mother has a history of recurrent depression)	Welsh, Lebanese; English, Arabic, Welsh, Spanish
Parent 1	Mother with a history of depression (14-year-old daughter is at risk)	Welsh, British; English
Parent 2	Father of a 13-year-old daughter who has a history of depression (under CAMHS)	Welsh, British; English, Welsh
Parent 3	Mother of a 13-year-old daughter who has a history of depression (under CAMHS)	Welsh, British; English, Welsh
Parent 4	Mother with a history of recurrent depression (16-year-old daughter is at risk)	Welsh, Lebanese; Arabic, English
Professional 1	Consultant child and adolescent psychiatrist (male) (advisor-National Assembly for Wales)	Welsh, British; English, Welsh
Professional 2	Consultant child and adolescent psychiatrist (male)	English, British; English
Professional 3	General practitioner (female)	Welsh, British; English
Professional 4	Educational psychologist (female)	Welsh, British; English, Welsh

[a]CAMHS: Child and Adolescent Mental Health Services.

Table 2. Characteristics of participants in all focus groups.

Focus group (FG)	Participants (n)	Gender (n), female:male	Age in years, mean (range)	Source of recruitment (n) EPAD[a]:CAMHS[b]	Profession
FG: young people 1 (at risk)	15	11:4	16.5 (13-19)	15:0	-
FG: young people 2 (current or history of depression)	8	5:3	15.8 (14-17)	0:8	-
FG: young people 3	6	4:2	16.8 (15-19)	2:3 (and 1 volunteer)	-
FG: parents and carers	7	7:0	-	5:2	-
FG: clinical professionals	12	8:4	-	-	2 psychiatrists, 2 psychiatric nurses, 3 educational psychologists, 2 school nurses, 1 teacher, and 2 youth workers
FG: academic professionals	10	6:4	-	-	4 psychiatrists (2 consultants and 2 trainees or fellows), 1 general practitioner, 4 research psychologists (1 senior lecturer, 2 postdoctoral, and 1 doctoral), and 1 medical student

[a]EPAD: Early Prediction of Adolescent Depression study.

[b]CAMHS: Child and Adolescent Mental Health Services.

Table 3. Themes from interviews and focus groups.

Key themes	Subthemes from interviews	Subthemes from focus groups
1: Needs and aims	Accessibility and target group	Increasing awareness and tackling stigma
	Increase awareness and tackle stigma	A lack of resources for young people
	Lack of resources for young people	Embrace digital technology as a medium that's relevant for young people
	Need to engage young people	Diversity
	Embrace a medium that's relevant for young people	Need to target parents, carers and families
	Promote self-management or autonomy	
	Accessible for a diverse range of users	
	Young people find it difficult to talk to adults	
	Help for parents, carers, and professionals working with young people	
2: Design issues	Harnessing multimedia to *engage* the user	Harnessing multimedia to engage the user
	Harnessing multimedia to *communicate* information	Multiplatform use and app
	Multiplatform approach and app	Clear structure, navigation, and distribution of information
	Clear structure and navigation	Language
	Language issues	Characters and avatars
	Characters and avatars	Imagery and metaphors
	Using metaphors to develop a relationship with the problem	Moodboards
	Color	Gaming element
	Images of heads and brains	Personalizing the space
	Gamification	Monitoring tool
	Personalizing the space	Technical aspects—security and confidentiality and use of forums or social media
	Monitoring tool	
	Forums, security, and confidentiality	
3: Content issues	General approach	General approach
	What are mood, well-being, and depression?	What are mood, well-being, and depression?
	Possible reasons for low mood and depression	Other difficulties related to low mood and depression
	Prevention and self-management	Causes, reasons and risk factors
	Where to get help	Prevention and self-management strategies
	Section for parents, carers, friends, and professionals	Where to get help
		Information for parents, carers, and professionals
4: Integration and context	Use of the program with others (eg, parent, friend, professional)	Use with parent, carer, friend, and professional
	School and education services	Use within education and health services
	Health and other services	Name, branding, and promotion
	Name, branding, and promotion	

Participants across the interviews and groups noted that using digital technologies was a valid approach to engagement, as young people use these in everyday life, although there were concerns about those without internet access:

> *My generation uses technologies.* [Young person 4: female:at risk]

> *It's tapping into something they're comfortable and familiar with.* [Professional 4: female: educational psychologist]

Participants in the interviews and groups stated the program could increase awareness and understanding of depression in young people, promote self-management, address the diversity

in the target group, and help those who find it difficult to talk to others:

> *Young people struggle to benefit from sitting in a room with an adult called a psychiatrist or psychologist.* [Professional 1: male: psychiatrist]
>
> *It's easier than plucking up the courage to talk to someone.* [Young person focus group 2]
>
> *Would rather go on internet, rather than face to face...anonymity is important.* [Young person focus group 2]

It was clear that there was a need to cater for parents, carers, and others concerned about a young person:

> *I think I would've liked...as we were going through it...in the beginning, I did feel that there was nobody there.* [Parent 2: male: daughter under CAMHS]

Key Theme 2: Design Issues

The overall design was discussed the most in the interviews and groups, especially by young people. This included discussions on how multimedia should *engage* users and *communicate* information:

> *Design is very important to teenagers…I think the visuals are everything where teenagers are concerned…Take advantage of the flexibility and complexity of multimedia.* [Parent 1: female: daughter at risk]

Participants suggested that the tone, language, and terminology should be at the level of the young person and discussed how much text would be appropriate. They also advised there should be clear structure and navigation:

> *Treating you as a mature person—not talking down.* [Young person focus group 2]
>
> *It should be clear what's going on—clear where to go, what to do, clear that what you answered leads to this.* [Parent and carer focus group]

Most recommended tailoring or personalizing the program, for example, by using a log-in, tailoring or modifying the content according to the needs of the user, allowing the user to save or upload information, and to set goals:

> *It's important that they have a say in the way they learn...You need options on how they learn that day e.g. read, do, listen etc.* [Professional 1: male: psychiatrist]
>
> *Everything out there's too generalised...nothing is personal to you...one tone fits all...doesn't feel like something you're confident in.* [Young person focus group 2]

Interview participants suggested that the program should be multiplatform, and there should be a mood monitor and an app. Group participants agreed and recommended developing other interactive elements (eg, to set goals and to save links to helpful resources). The introduction of designs for the program, including elements such as illustrations, characters, metaphors, moving images, and audio, helped to guide group discussions:

> *If you can identify triggers—you can do something about it earlier, before letting it get to the bad points.* [Young person focus group 2]
>
> *What I really liked was the app, an up-to-date, modern idea.* [Parent and carer focus group]
>
> *It would be good to be able to give something more interactive, rather than a bunch of leaflets.* [Clinical professionals focus group]

Security and confidentiality were key issues in the interviews and groups, especially for young people. There were also concerns about including a forum or links with social media:

> *I don't think it should be on social media—it can be so toxic.* [Young person focus group 2]

Key Theme 3: Content Issues

Participants in the interviews stated there should be different levels of information and a clear explanation of the program and its aims. There should be information on mood, the signs, symptoms and effects of depression, the difference with "normal sadness," and related issues such as anxiety and accounts of personal experiences. Many young people and parents wished to highlight to adolescents that they are "not alone" in their experiences of depression:

> *When I was diagnosed and they were like you've got depression, I was really confused and I didn't know what it was or what that meant for me or how that would affect my life.* [Young Person 1: female: under CAMHS]

Possible reasons for depression were discussed, including environmental and biological factors and also how there are sometimes no clear reasons for feeling low. Participants felt that self-management approaches should build on existing strengths and attributes:

> *You need to build on the positive, not magnify the downside...the depressed are quick to do this.* [Professional 1: male: psychiatrist]

A personalized tool kit was suggested to include short-term measures dealing with stress and healthy living:

> *Lots of simple solutions are usually good, these are better than complicated ones.* [Professional 1: male: psychiatrist]

Professionals suggested that the young person should take control and think about issues from an outsider's perspective:

> *Ask them, so what are we going to do about this? Put them in charge...do you want to do something about this?* [Professional 3: female: general practitioner]

Participants discussed where to get help for depression, including from trusted friends and family, from school and health services, and the different possible treatments:

> *It's good to talk—you don't have to internalise everything, there are people there to approach.* [Young person focus group 1]

> *Simply—what they [the treatments] are, how they work—make it more likely that they're used.* [Young person focus group 3]

They felt that there should also be information for parents or carers and others, and professionals suggested there was a need for reframing:

> *There's a risk—a child wants to concentrate on positives, parent wants to say why it's not perfect yet—child is then more depressed.* [Professional 1: male: psychiatrist]

Focus group participants agreed there should be levels of information, with a hierarchy of sections and subsections. The overall structure and content evolved with each group and the program prototype included sections on mood and depression, possible reasons, self-help, and where to get help. Although there were differing views, overall, it was felt there should be a separate section on "other health issues" such as anxiety, bipolar disorder, and physical illness, although there was caution:

> *It's easy for the programme to become an 'all mental health problems' programme'*. [Research professional focus group]

Key Theme 4: Integration and Context

To help with adherence and encourage support, participants in the interviews and groups suggested it would be helpful for the young person to be able to use the program with others, including family, carers, friends, or professionals, as well as independently. The creation of a separate user pathway and section for parents, carers, friends, and professionals was supported by all focus groups—with information on signs, symptoms, and triggers; supporting the young person; and dealing with difficulties.

With regard to implementation, schools were considered an important setting for the intervention, particularly personal, social, and health education sessions. It was also felt that the program could be integrated into health and other services:

> *This is essential...teachers see you every day for five years!* [Young person 2: female: under CAMHS]

The name and promotion of the program was discussed, and the use of the term "mood" was considered more acceptable than "well-being" to young people.

Comparison of Data From Young People, Parents, Carers and Professionals

Across the interviews and groups, young people were as interested, if not more so, in the design as they were in the content. Although parents, carers and professionals also stressed the importance of design, they were especially interested in the content. Health and research professionals stressed the underlying evidence base and guidelines for assessment and management and suggested that young people should decide on the design.

Some differences emerged in how "adults" perceived adolescent depression compared with the actual adolescent experience. Possible reasons included the adults "normalizing" of depressive symptoms and episodes, how some might not consider this to be a "real illness," and the changing experience of young people with each generation, for example, in relation to stressors such as exam pressure, expectations, social media, cyberbullying, and parental separation.

Young people were generally positive about early versions of the program presented in the groups, and one young person stated, *It felt like it could actually do something.* Parents and carers tended to be more cautious, for example, some noted that mood monitoring might encourage a preoccupation and rumination (although monitoring can be a component of CBT for depression). To address these concerns, they suggested including alerts when the mood was low and links to sources of help. With regard to the mood boards presented in the focus groups, young people preferred the graphic and illustrative imagery, whereas parents and carers felt that the photographs would be more appealing:

> *They should be real, not posed or pretending to be sad, cheesy...type of thing you'd see in a school slideshow.* [Young person focus group 3]
>
> *Young people want real people...they can relate, connect with them...everyone wants faces.* [Parent and carer focus group]

Similar issues were raised in other consultations, for example, with the Funky Dragon youth group. Everyone highlighted the advantages of multimedia, given its role in the lives of young people and that the program should also target those concerned about a young person.

Development of the Initial Prototype

Design and Content of Prototype

Structure and Functionality

Findings from the qualitative work were used to inform the development of the initial prototype. The program MoodHwb (*hwb* is the Welsh translation for *hub* and also means a *lift* or *boost*) was designed so that it could be delivered across platforms using a range of multimedia and an app. As recommended by participants, the information was developed to be clear, factual, comprehensive, age-appropriate, avoiding jargon, but not patronizing. The bilingual approach meant that the program was more inclusive and that it was designed so that it could be translated into other languages in future. Security and confidentiality were also key considerations, and this was reflected, for example, in the password-protected log-in and encryption of data. In conjunction with the multimedia company, information architecture documents were created (Figure 5) that provided an overall framework for the program.

The program was designed so that it could be used independently by the young person, together with another person, or used by others to obtain information and advice. The user could personalize the content shown by choosing the relevant user pathway from the welcome screen ("I'm here for myself" or "I'm here for someone else": Figure 6, above left).

Figure 5. Primary level user flow diagram from the information architecture document.

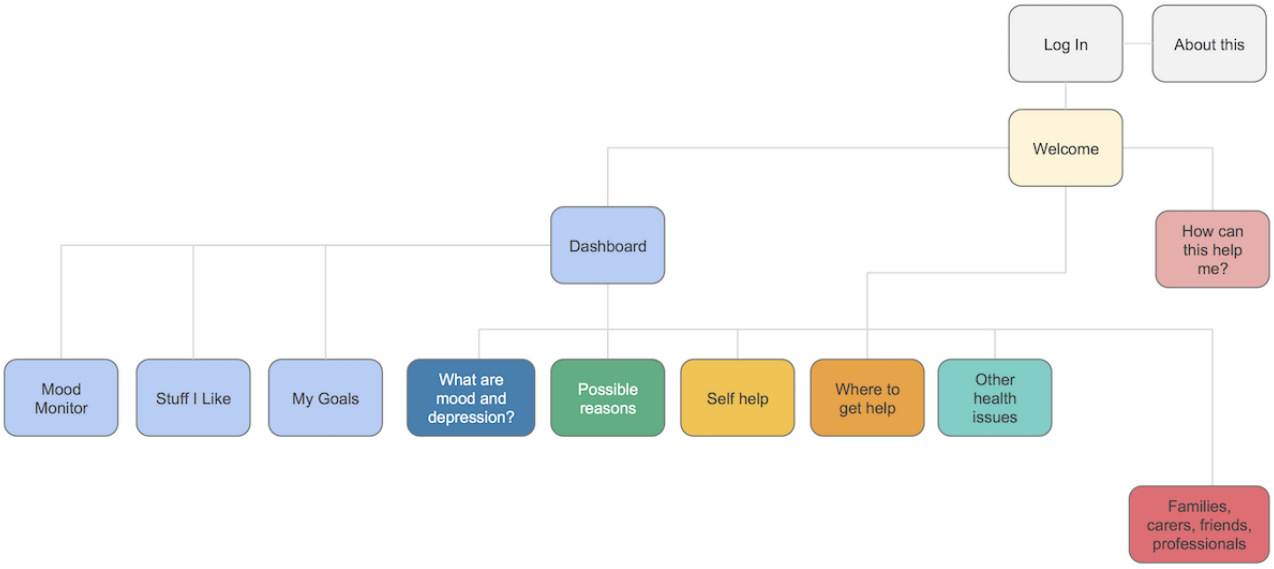
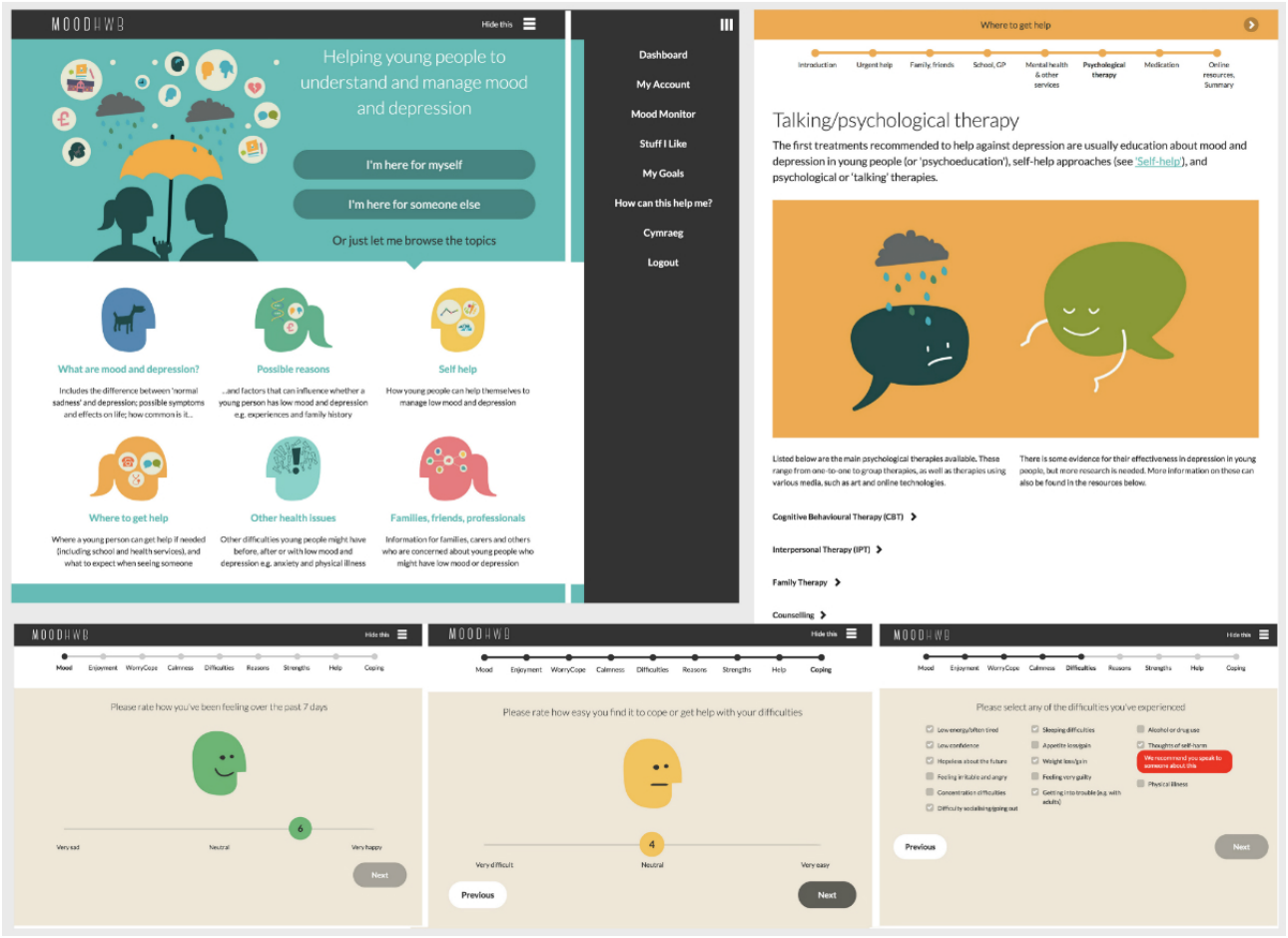


Figure 6. Welcome screen or menu (above left); questions when entering program or monitoring mood (below); subsection on psychological therapies (above right).



The user would then be asked nine questions on their mood, anxiety, and other issues (Figure 6, below), and the answers helped to determine which subsections were relevant to them and were highlighted on the dashboard. If the user indicated they had thoughts of self-harm, a message would appear to advise them to seek help. These questions also enabled the user to monitor their mood or other issues over time, as the data were stored in a profile section. Along with this mood monitor, there were two other interactive elements: users could save links to helpful resources (Stuff I Like) and set goals (My Goals) by using the main site or the app.

The six main sections ("What are mood and depression?" "Possible reasons," "Self help," "Where to get help," "Other

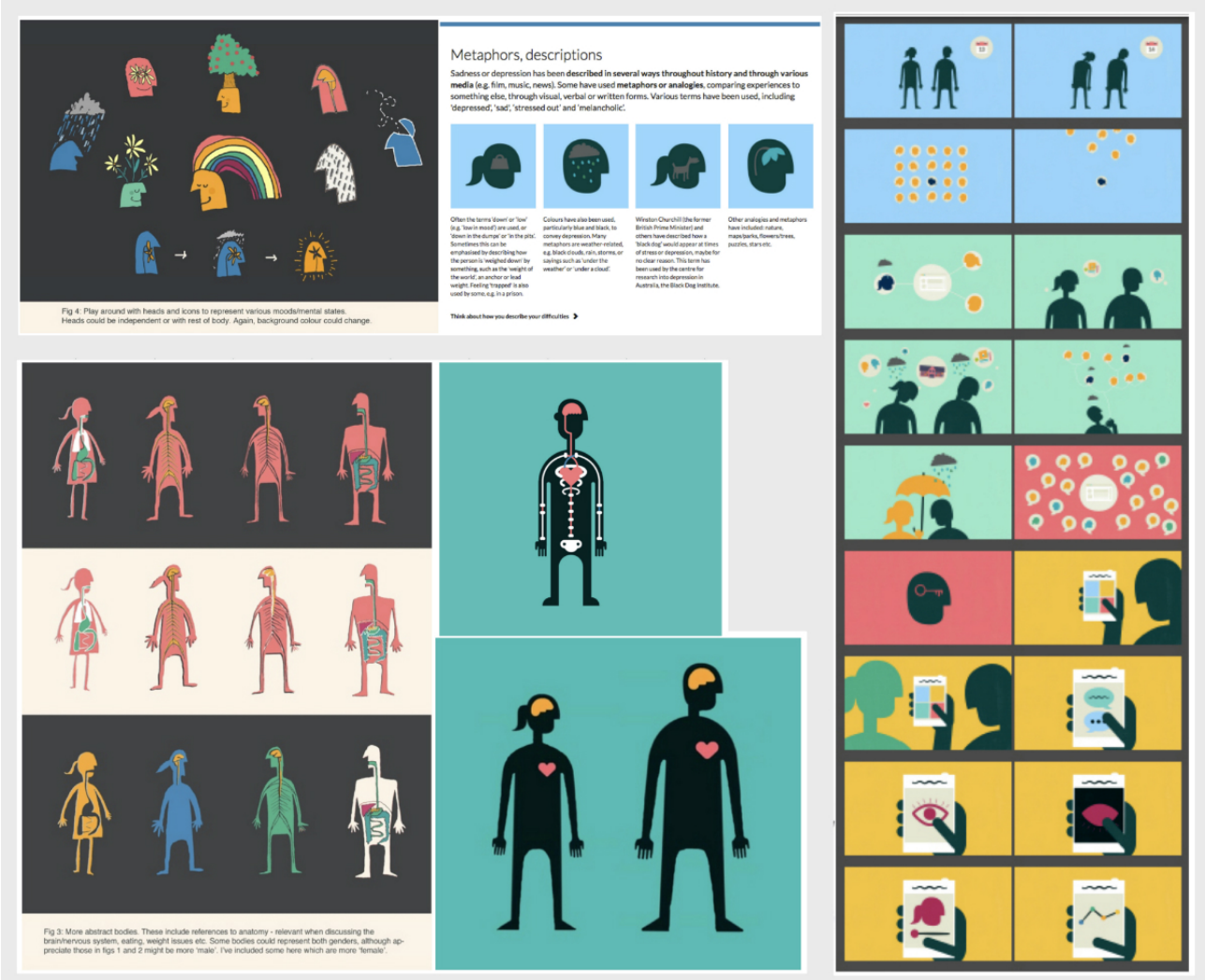
health issues," and "Families, carers, friends, professionals") were all structured in a similar manner, so that the user could scroll through the subsections and use menus and progress bars to navigate (Figure 6, above right). This helped ensure the program looked cohesive and enabled the user to become familiar with and easily navigate it. Information was presented in levels with (1) animations and introductory or summary subsections to deliver the key messages, (2) text and illustrations in each subsection, and (3) collapsible blocks of text and links to resources for further detail. Feature blocks were used to illustrate the key information and engage the user further; these included quizzes, personal stories, questions to relate the content to the user, and links to other sites or resources. The sections were built so that the information and format could be updated and changed in response to feedback.

Graphics, Color, and Moving Image

A graphic, illustrative, and colorful approach was taken for the overall design. Color was used as a tool to aid navigation—for example, blue represented the section "What are mood and depression?" and warm colors (yellow and orange) represented the help sections. The typography chosen was clear and had a distinctive character. Metaphors for depression were used to help engage the user and communicate ideas. These included "being weighed down," "a black dog," nature, and weather (Figure 7, above left).

The characters in the program were developed to be acceptable for a diverse range of users. A silhouette approach was deemed most appropriate, and this also allowed for graphic representations of the interior of the body, for example, when describing symptoms (Figure 7, below left). In addition, the characters needed to be clear when reducing the screen size (ie, when viewing the program on a mobile phone or tablet). An animation was developed to introduce the program and to engage the user from the start (Figure 7, right). A separate animation was also developed for each of the six main sections to communicate the key messages. The voiceovers for the animations were chosen to be warm, approachable, and bilingual, and the accompanying background music was mellow but uplifting.

Figure 7. Design elements—metaphors (above left), experimental character design (below left), animation storyboards (right).



Theories and Approaches Underpinning the Program

Many theories and approaches were suggested in the interviews and groups with professionals. Some theories and approaches were also mapped onto the suggestions for the design and content made by young people, parents and carers, with reference to relevant literature (Multimedia Appendix 3).

Design and Educational Theories and Approaches

A key issue relating to the program was that it should be person-centered and follow guidelines for the development of digital health-related interventions [20-22]. The framework by Mohr et al [21] describes considerations for the theoretical approaches (aims ["why"] and conceptual or behavior change strategies ["how"]), as well as the instantiation and technical approaches (elements ["why"], characteristics ["how"], and workflow ["when"]). Another approach followed was the Persuasive System Design [22] that identifies four general design features: (1) primary task support, including tailoring or personalization and self-monitoring; (2) dialogue support, including positive reinforcement and suggestions; (3) credibility, by conveying trustworthiness and expertise, in the general tone and references to evidence and guidelines, supporting institutions, and user input in the development process; and (4) social support, by encouraging use and discussions with a trusted person and providing links to other sources of help.

The program was personalized where possible, so that engagement was a two-way process, whereby the participants could take ownership of the program rather than be a passive recipient of information [28,29]. Diversity and learning preferences are key considerations in education, and the program was developed to be accessible and inclusive. A range of media helped to engage and adapt to the user's learning style or preference, and key themes and messages were repeated in various ways [30]. This linked in with the VARK approach, which states that individuals prefer to learn through different sensory modalities: visual, auditory, read or write, and kinaesthetic.

Other theories and approaches that informed the development of the program included a blended learning approach, Bloom's taxonomy, Kolb's experiential learning theory, the constructivist approach, and approaches to help with concentration, such as segmenting sections and interactive elements [31-34].

Psychological Theories and Approaches

Information on talking or psychological therapies for depression was presented in the help sections. Elements of CBT were suggested by professionals, possibly because many practiced this and because this approach is recommended in guidelines for treating depression [5]. CBT theory was referred to in the program when discussing possible symptoms, effects, reasons, negative thoughts, and metaphors related to mood, depression, and other issues. The goal-setting component and self-help subsections used elements of behavioral activation theory [35].

Aspects of positive psychology were incorporated in the general tone of the program, particularly where the user was encouraged to think of their "strengths and positives," and how these can help them to overcome difficulties. Interpersonal and family systems theories were referenced in help sections, encouraging the user to consider their relationship or roles with friends and family and those advising others to support the young person.

The development and content of the intervention was influenced by several behavior change theories including information, motivation, behavior theory, self-regulation theory, self-determination theory, and social cognitive theory [36-38].

Logic Model

A logic model (Multimedia Appendix 4) was developed based on the initial qualitative work, a literature review, and relevant theory. There were a range of possible areas of change that could be targeted by the program and a range of possible outcomes. The model described the inputs in terms of intervention components, the mediators of change or mechanisms, and the intermediate and long-term outcomes, as well as contextual factors that might influence the effectiveness (or otherwise) of the intervention. The model gave a reference point while developing the various elements of the program and not only informed the content of the program (especially the information in the six main sections) but also the way in which it was designed (eg, the different user pathways). The logic model was critical in the development of the program as it demonstrated mechanisms by which the intervention would be expected to work to support young people and gave a framework which could be tested with mixed methods approaches in the evaluation phase.

Discussion

Summary, Integration, and Context

The Web-Based Program MoodHwb

This manuscript describes the collaborative design and development of a Web-based psychoeducation program for adolescent depression (MoodHwb, or HwbHwyliau in Welsh). This program could help young people with (or at risk of) depression, as well as their families, carers, friends, and professionals. It has the potential to be integrated into a range of services including health, education, social, and youth services and charities.

MoodHwb meets the need outlined in the guidelines for depression in young people [5,6] for good information and evidence-based psychosocial interventions for the young person and family or carer. The review conducted as part of this work on PIs for adolescent depression [13] concluded that there were few existing programs, particularly Web-based, that have been developed and evaluated using rigorous methods. This program will help to fill this important gap.

The program also fits with the UK government's push to provide access to Web-based therapies to young people through information and communication technology [39-42]. Over 90% of young people aged 16 to 24 years have internet access in their homes [43], and the use of technological devices (such as computers and smartphones) is similar in individuals with mental health disorders compared with the general population [44]. eHealth approaches offer a valuable opportunity to provide a novel intervention widely and at low cost compared with

face-to-face therapies. Web-based interventions also address issues of accessibility, waiting lists, and treatment flexibility.

The findings from the development work suggested the program might be particularly helpful in the early stages of depression when a young person starts to experience difficulties. This could be when they first present to professionals in education, health, or other sectors. MoodHwb could be integrated into each of these services at the lower levels of the stepped care approach for depression in young people [5]. It could also complement (and be an adjunct to) other approaches, for example, in the management of more severe or chronic difficulties.

MoodHwb fits with the guided self-help approach as it has been designed so that it can be used either independently or with another person. PIs could be delivered by a range of professionals, and Colom [9], a pioneer in psychoeducation for mood disorders, states that facilitators need to be "an expert on the disorder not the technique," avoiding the "complex training" and associated funding required, for example, for CBT. Web-based PIs could therefore help in areas where there is a lack of skilled alternative approaches, including in low and middle-income countries [45].

The Development Process

Historically, pressure to identify effective interventions in public health has led to many interventions being tested for effectiveness in randomized controlled trials (RCTs), with little rigorous development work being completed [46]. This has led to large amounts of resources being invested in interventions that are unlikely to be effective. However, frameworks for the development and evaluation of complex interventions [19] stress the importance of the development phase, which is at least as important as the effectiveness evaluation stage. Proper development involving users, relevant theory, and research evidence is more likely to produce an intervention that is acceptable and feasible to deliver and also potentially effective. This process also facilitates identification of potential problems that may be preventable at a later stage (eg, in a large trial).

In the world of digital health, this development phase is also crucial, and user-centered design is a common approach used [20-22]. As more digital health apps and interventions are being developed, one issue that is important to consider is whether these interventions should be tested in RCTs or whether other evaluation methods should be used. Given the pace of development of digital health, evaluation methods are needed that are more agile and more user-centered than the standard RCT methodology, which may take too long to produce the results needed. However, when feasible, RCTs represent the most internally valid means of establishing the effectiveness of complex public health interventions [47]. In the MRC guidance, emphasis is placed on conducting randomized trials of such interventions [19]. The staged, user-centered approach to development taken here is recommended regardless of whether the effectiveness is evaluated in an RCT or using other methods of evaluation.

There is a lack of literature not only on the overall development process of Web-based (PI) programs but also specific elements such as the approach to graphic design or illustration in the context of youth mental health. This paper gives a detailed account of the process of development and a practical example of how to follow existing guidelines and could help inform other studies and programs in this field. The paper stresses the importance of involving all potential users (young people and their families, carers and professionals) in the development of all aspects of the program—not only the content but also the design and technical elements and why this is crucial especially when attempting to engage young people with mental health issues. The underlying theories associated with all these aspects were considered (not only the psychological theories), and this influenced the development of the logic model. The researchers were also involved in all stages and in regular discussion with the multimedia company and other agencies.

Comparison With Other Web-Based Programs

There are few studies that describe the process of development of Web-based PIs to give context to this study. However, there was some overlap in the content of MoodHwb and existing Web-based or computerized PI programs. For example, the program The Journey by Stasiak et al [48] also covered depression, "mental health hygiene," and stress reduction. Furthermore, Demaso et al [49] found that personal stories were well-received in their feasibility trial of the Depression Experience Journal. This Web-based program, and the one described by Stjernswärd and Hansson [50], stressed the importance of supporting the families and carers of those with depression.

The graphic illustrative and animated approach favored by the participants in this study is different to the approach taken by many youth mental health sites (eg, YoungMinds, Childline (United Kingdom), Headspace (Australia), and The Lowdown (New Zealand) [51-54]) that are based largely on photographs of young people—although some have used illustrations and characters. When showing examples of other sites to the young person groups, they noted that the most attractive resources were those that were clear, colorful, graphic, and uplifting in their design and content, such as Headspace (United States); a mindfulness resource that also uses characters, imagery, and visual metaphors [55].

Web-based CBT and other therapeutic programs for adolescent depression incorporate a range of elements, from mainly text-based to image-based designs [16,17]. Some of the themes discussed by participants for this project (eg, characters, avatars, and gamification) also applies to the computer game CBT program, SPARX [15]. The researchers behind this intervention also consulted young people in its development.

Strengths and Limitations

Strengths

One of the main strengths of the project relates to the rigorous methodology, which followed the MRC guidance for complex interventions and the consultative and person-based approach [20]. Interviews and focus groups progressed in an iterative fashion so that participants could guide the development. The interview and group transcripts were all analyzed and double coded to ensure reliability of coding.

Another strength was the diverse range of participants, including young people from mental health services (primary and secondary care) and volunteers, many of their parents and carers, and a mix of professionals. Young people at high risk were also recruited from a previous study sample. There were a range of recruitment centers in urban and rural areas, including in areas with several ethnicities and areas of deprivation. Participants were also recruited from communities where Welsh was spoken widely.

The results from the review, interviews, and focus groups were complemented by other investigations, including advice from experts, visits to centers of excellence in youth mental health and eHealth in the United Kingdom and overseas, and workshops with multimedia professionals. The development was further strengthened by using user-centered design, educational and psychological approaches, and a logic model, as well as basing the content and design on current research evidence and guidelines. All these approaches helped to create a potentially accessible, engaging, and informative program that the user could personalize, which fits with the increasing interest in precision (personalized) medicine [56]. The detailed account of the development process could inform the development of other programs in the future.

Limitations

The research or multimedia teams were involved throughout the project, and it is possible that their personal views could have influenced the process of development. However, a range of different groups was consulted, which would help minimize bias. Certain decisions regarding development were made before the interviews and groups (eg, that this would be a Web-based resource targeting adolescent depression), and the key themes that emerged may have been influenced by the topic or discussion guide. However, it was necessary to have some focus to the discussions, and this was not intended as an open scoping exercise. All prior decisions were based on a literature review and expert clinical opinion.

As with all methods of data collection, there are limitations to the interview and focus group approach. Although efforts were made to recruit a diverse sample with different backgrounds and experiences of depression, the overall number of participants was small and may not be representative of the population of adolescents who are experiencing depression or who are at risk. In addition, it is possible there was self-selection, in that participants who volunteered were more likely to have an interest in the project. Although the number of initial interviewees (n=12) was small, many ideas and themes were repeated as the interviews progressed, indicating that saturation might have been reached. The participants were purposively chosen at this early stage of the project to offer a range of viewpoints or ideas to guide later focus groups.

Focus groups were balanced as far as possible with regard to age, gender, and experience of mental health difficulties. However, the number of those who attended the focus groups varied across the study. Recruitment for young person groups 2 and 3, where the majority had experience of mental health difficulties, was difficult. Some participants cancelled at short notice or did not attend, although this is not unusual for focus groups [57,58]. In addition, three fathers had stated they would attend the groups but did not, leading to an all-female parent and carer group. This is consistent with other depression studies involving families, where most participants were mothers [23].

Conclusions

A Web-based psychoeducation program was coproduced to help adolescents with or at high risk of depression and their families, carers, friends, and professionals. The program MoodHwb was developed following rigorous methods. This included a review of the literature, interviews and groups with potential users at all stages, and consultations with experts and with a multimedia company.

An early evaluation is planned to assess whether the program (and its assessment) is potentially acceptable, feasible, clear, and easy to use. Young people (and their parents or carers) will be recruited from CAMHS, the EPAD sample, primary mental health services, and school counselors and nurses. Participants will complete questionnaires before and after using MoodHwb, a subsample will be interviewed to collect feedback on the package and the study process, and there will be a focus group for professionals. Web usage will also be analyzed.

The results will inform the future development of the program. A feasibility trial would then be completed in line with the MRC guidance [19]. A key focus of future work would be to develop and test the logic model to examine the mechanism of action and active components of the intervention. The program would also be developed further in response to the feedback from each evaluation phase, and this is particularly important when considering the advances in technology and health research. If MoodHwb is proved to be effective, it could be rolled out in health, education, youth, and social services and charities.

Acknowledgments

The authors would like to thank all the young people, parents, carers, professionals, and researchers who participated in the study.

RBJ was supported by a National Institute for Health Research/Health and Care Research Wales program fellowship (NIHR-FS-2012). This project has been funded by the Welsh Government through Health and Care Research Wales, and the authors thank them for their support. SS was supported by a MRC Strategic Award (MC-PC-13027, MC_UU_12017_14, (MC_UU_12017 _ 11 and SPHSU11) and SPHSU14). BM is supported by a grant from the American Foundation for Suicide Prevention (PDF-0-091-14). IJ is Director of the National Centre for Mental Health (NCMH), and the authors thank the center for its support.

Will Richards and Andrew Price (Made by Moon digital media company), Mike Clague (Carbon Studio animation company), and Dyfan Williams (graphic designer) helped to develop the program and accompanying literature, and the authors thank them for their work.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Topic guide for the semistructured interviews.

[PDF File (Adobe PDF File), 26KB - mental_v5i1e13_app1.pdf]

Multimedia Appendix 2

Questions and selection of slides shown during a focus group.

[PDF File (Adobe PDF File), 382KB - mental_v5i1e13_app2.pdf]

Multimedia Appendix 3

How interview and group findings influenced the development of the program.

[PDF File (Adobe PDF File), 41KB - mental_v5i1e13_app3.pdf]

Multimedia Appendix 4

Logic model.

[PNG File, 647KB - mental_v5i1e13_app4.png]

References

1. Thapar A, Collishaw S, Pine D, Thapar A. Depression in adolescence. Lancet 2012 Mar;379(9820):1056-1067. [doi: 10.1016/S0140-6736(11)60871-4]
2. The National Archives. London: Department of Health; 2009. New Horizons: A Shared Vision for Mental Health URL: http://webarchive.nationalarchives.gov.uk/20130104235147/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_109705 [accessed 2018-02-01] [WebCite Cache ID 6wtumFVGL]
3. Thapar A, Collishaw S, Potter R, Thapar A. Managing and preventing depression in adolescents. Br Med J 2010 Jan 22;340:c209. [doi: 10.1136/bmj.c209]
4. World Health Organization. International Classification of Diseases 10. Geneva: World Health Organization; 1992.
5. National Institute for Health and Care Excellence (NICE). Depression In Children and Young People. London: NICE Clinical Guideline; 2005.
6. Birmaher B, Brent D, AACAP Work Group on Quality Issues, Bernet W, Bukstein O, Walter H, et al. Practice parameter for the assessment and treatment of children and adolescents with depressive disorders. J Am Acad Child Adolesc Psychiatry 2007 Nov;46(11):1503-1526. [doi: 10.1097/chi.0b013e318145ae1c] [Medline: 18049300]
7. Collishaw S, Hammerton G, Mahedy L, Sellers R, Owen M, Craddock N, et al. Mental health resilience in the adolescent offspring of parents with depression: a prospective longitudinal study. Lancet Psychiatry 2016 Jan;3(1):49-57. [doi: 10.1016/S2215-0366(15)00358-2]
8. Smith DJ, Jones I, Simpson S. Psychoeducation for bipolar disorder. Adv psychiatr treat 2018 Jan 2;16(02):147-154. [doi: 10.1192/apt.bp.108.006403]
9. Colom F. Keeping therapies simple: psychoeducation in the prevention of relapse in affective disorders. Br J Psychiatry 2011 May;198(5):338-340 [FREE Full text] [doi: 10.1192/bjp.bp.110.090209] [Medline: 21525516]
10. Brent D, Maalouf F. Depressive disorders in childhood and adolescence. In: Thapar A, Pine DS, Leckman JF, Scott S, Snowling MJ, Taylor E, editors. Rutter's Child and Adolescent Psychiatry (6th ed). New Jersey: Wiley-Blackwell; 2015:874-892.
11. Miklowitz D, Schneck C, Singh M, Taylor D, George E, Cosgrove VE, et al. Early intervention for symptomatic youth at risk for bipolar disorder: a randomized trial of family-focused therapy. J Am Acad Child Adolesc Psychiatry 2013 Feb;52(2):121-131 [FREE Full text] [doi: 10.1016/j.jaac.2012.10.007] [Medline: 23357439]
12. Tursi M, Baes C, Camacho F, Tofoli S, Juruena M. Effectiveness of psychoeducation for depression: a systematic review. Aust N Z J Psychiatry 2013 Nov;47(11):1019-1031. [doi: 10.1177/0004867413491154] [Medline: 23739312]

13. Bevan Jones R, Thapar A, Stone Z, Thapar A, Jones I, Smith D, et al. Psychoeducational interventions in adolescent depression: a systematic review. Patient Educ Couns 2017 Oct 24 Epub ahead of print (forthcoming) [FREE Full text] [doi: 10.1016/j.pec.2017.10.015] [Medline: 29103882]
14. Hollis C, Morriss R, Martin J, Amani S, Cotton R, Denis M, et al. Technological innovations in mental healthcare: harnessing the digital revolution. Br J Psychiatry 2015 Apr;206(4):263-265 [FREE Full text] [doi: 10.1192/bjp.bp.113.142612] [Medline: 25833865]
15. Merry SN, Stasiak K, Shepherd M, Frampton C, Fleming T, Lucassen MF. The effectiveness of SPARX, a computerised self help intervention for adolescents seeking help for depression: randomised controlled non-inferiority trial. Br Med J 2012 Apr 18;344:e2598 [FREE Full text] [Medline: 22517917]
16. Reyes-Portillo JA, Mufson L, Greenhill LL, Gould MS, Fisher PW, Tarlow N, et al. Web-based interventions for youth internalizing problems: a systematic review. J Am Acad Child Adolesc Psychiatry 2014 Dec;53(12):1254-1270.e5. [doi: 10.1016/j.jaac.2014.09.005] [Medline: 25457924]
17. Rice S, Goodall J, Hetrick S, Parker A, Gilbertson T, Amminger G, et al. Online and social networking interventions for the treatment of depression in young people: a systematic review. J Med Internet Res 2014 Sep 16;16(9):e206 [FREE Full text] [doi: 10.2196/jmir.3304] [Medline: 25226790]
18. Christensen H, Griffiths K, Jorm A. Delivering interventions for depression by using the internet: randomised controlled trial. Br Med J 2004 Jan 31;328(7434):265 [FREE Full text] [doi: 10.1136/bmj.37945.566632.EE] [Medline: 14742346]
19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J 2008 Sep 29;337:a1655. [doi: 10.1136/bmj.a1655]
20. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res 2015 Jan 30;17(1):e30 [FREE Full text] [doi: 10.2196/jmir.4055] [Medline: 25639757]
21. Mohr D, Schueller S, Montague E, Burns M, Rashidi P. The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. J Med Internet Res 2014 Jun 05;16(6):e146 [FREE Full text] [doi: 10.2196/jmir.3077] [Medline: 24905070]
22. Oinas-Kukkonen H, Harjumaa M. Persuasive systems design: key issues, process model, and system features. CAIS 2009;24(1):28 [FREE Full text] [doi: 10.1145/1541948.1541989]
23. Mars B, Collishaw S, Smith D, Thapar A, Potter R, Sellers R, et al. Offspring of parents with recurrent depression: which features of parent depression index risk for offspring psychopathology? J Affect Disord 2012 Jan;136(1-2):44-53. [doi: 10.1016/j.jad.2011.09.002] [Medline: 21962850]
24. Gunning R. The Fog Index after twenty years. JBC 2016 Sep 16;6(2):3-13. [doi: 10.1177/002194366900600202]
25. UK Government. London: UK Government; 1993. Welsh language act URL: https://www.legislation.gov.uk/ukpga/1993/38/contents [accessed 2018-02-01] [WebCite Cache ID 6wtvfKLJP]
26. Bevan Jones R, Thomas J, Lewis J, Read S, Jones I. Translation: from bench to brain – using the visual arts and metaphors to engage and educate. Research for All 2017 Jul 15;1(2):265-283. [doi: 10.18546/RFA.01.2.04]
27. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
28. Samuelowicz K, Bain J. Revisiting academics' beliefs about teaching and learning. High Educ 2001;41(3):299-325. [doi: 10.1023/A:1004130031247]
29. Beardslee W, Gladstone T, Wright E, Cooper A. A family-based approach to the prevention of depressive symptoms in children at risk: evidence of parental and child change. Pediatrics 2003 Aug 01;112(2):e119-e131 [FREE Full text] [Medline: 12897317]
30. Fleming N, Mills C. Not another inventory, rather a catalyst for reflection. To Improve the Academy 1992;11(1):137-155. [doi: 10.1002/j.2334-4822.1992.tb00213.x]
31. Singh H. Building effective blended learning programs. Educ Technol 2003;43(6):51-54.
32. Anderson LW, Krathwohl DR, Airasian PW, Cruikshank KA, Mayer RE, Pintrich PR, et al. A Taxonomy for Learning, Teaching, and Assessing: A Revision of Bloom's Taxonomy of Educational Objectives. London: Pearson Education; 2013.
33. Kolb A, Kolb D. 2005. The Kolb Learning Style Inventory - Version 3.1 2005 Technical Specifications URL: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.182.316&rep=rep1&type=pdf
34. Biggs J, Tang C. Teaching for quality learning at university (3rd ed.). Maidenhead: Open University Press; 2007.
35. Stott R, Mansell W, Salkovskis P, Lavender A, Cartwright-Hatton S. Oxford Guide to Metaphors in CBT. Oxford: Oxford University Press; 2010.
36. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008 May;27(3):379-387. [doi: 10.1037/0278-6133.27.3.379] [Medline: 18624603]
37. National Institute for Health and Care Excellence. Behaviour change: general approaches. London: NICE; Oct 2007. URL: https://www.nice.org.uk/guidance/ph6
38. National Institute for Health and Care Excellence. Behaviour change: individual approaches. London: NICE; 2014. URL: https://www.nice.org.uk/guidance/ph49

39. CMO. Annual Report of the Chief Medical Officer. London: Department of Health; 2014. URL: https://www.gov.uk/government/publications/chief-medical-officer-cmo-annual-report-public-mental-health
40. UK Government. No health without mental health. London: Department of Health and Social Care; 2011. URL: https://www.gov.uk/government/publications/no-health-without-mental-health-a-cross-government-outcomes-strategy
41. National Information Board (NIB). Annual Report. Leeds: NIB; Sep 2016. URL: https://www.gov.uk/government/publications/national-information-board-nib-annual-report-2016
42. Kelsey T, Cavendish W. 2014 Nov. Personalised health and care 2020: using data and Technology to Transform Outcomes for Patients and Citizens URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf [accessed 2018-02-01] [WebCite Cache ID 6wtwVQHny]
43. Office for National Statistics. 2016. Internet users in the UK URL: https://www.ons.gov.uk/businessindustryandtrade/itandinternetindustry/bulletins/internetusers/2016 [accessed 2018-02-01] [WebCite Cache ID 6wtwbQS2z]
44. Ennis L, Rose D, Denis M, Pandit N, Wykes T. Can't surf, won't surf: the digital divide in mental health. J Ment Health 2012 Aug;21(4):395-403 [FREE Full text] [doi: 10.3109/09638237.2012.689437] [Medline: 22712756]
45. World Health Organization. mHealth New Horizons for Health through mobile technologies. Geneva: WHO; 2011.
46. Sanson-Fisher RW, Bonevski B, Green LW, D'Este C. Limitations of the randomized controlled trial in evaluating population-based health interventions. Am J Prev Med 2007 Aug;33(2):155-161. [doi: 10.1016/j.amepre.2007.04.007] [Medline: 17673104]
47. Macintyre S. Good intentions and received wisdom are not good enough: the need for controlled trials in public health. J Epidemiol Community Health 2011 Jul;65(7):564-567. [doi: 10.1136/jech.2010.124198] [Medline: 21148137]
48. Stasiak K, Hatcher S, Frampton C, Merry S. A pilot double blind randomized placebo controlled trial of a prototype computer-based cognitive behavioural therapy program for adolescents with symptoms of depression. Behav Cogn Psychother 2014 Jul;42(4):385-401. [doi: 10.1017/S1352465812001087] [Medline: 23253641]
49. Demaso D, Marcus N, Kinnamon C, Gonzalez-Heydrich J. Depression experience journal: a computer-based intervention for families facing childhood depression. J Am Acad Child Adolesc Psychiatry 2006 Feb;45(2):158-165. [doi: 10.1097/01.chi.0000190353.98570.fe] [Medline: 16429086]
50. Stjernswärd S, Hansson L. A web-based supportive intervention for families living with depression: content analysis and formative evaluation. JMIR Res Protoc 2014 Feb 14;3(1):e8 [FREE Full text] [doi: 10.2196/resprot.3051] [Medline: 24550185]
51. YoungMinds. Youngminds. 2017. Championing the wellbeing and mental health of young people URL: https://youngminds.org.uk [accessed 2017-09-29] [WebCite Cache ID 6tpterU44]
52. Childline. 2017. Online, on the phone, anytime URL: https://www.childline.org.uk/ [accessed 2017-09-29] [WebCite Cache ID 6tptA5shD]
53. Headspace. 2017. National youth mental health foundation URL: https://www.headspace.org.au/ [accessed 2017-09-29] [WebCite Cache ID 6tq2mtvfR]
54. The LowDown. 2017. Straight up answers for when life sucks URL: https://thelowdown.co.nz/ [accessed 2017-09-29] [WebCite Cache ID 6tq16Lxu9]
55. Headspace. Headspace. 2017. Meditation made simple URL: https://www.headspace.com/ [accessed 2017-09-29] [WebCite Cache ID 6tpsfpvoF]
56. Bahcall O. Precision medicine. Nature 2015 Oct 15;526(7573):335. [doi: 10.1038/526335a] [Medline: 26469043]
57. Pope C, Mays N. Qualitative methods in health research. In: Pope C, Mays N, editors. Qualitative Research in Health Care (3rd Ed.). Oxford: Blackwell Publishing; 2006.
58. Greenbaum TL. The Handbook for Focus Group Research (2nd Ed.). Thousand Oaks: SAGE Publications; 1998.

Abbreviations

CAMHS: Child and Adolescent Mental Health Services
CBT: cognitive behavioral therapy
eHealth: electronic health
EPAD: Early Prediction of Adolescent Depression
MRC: Medical Research Council
PI: psychoeducational intervention
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 03.10.17; peer-reviewed by M Lennon, C Buntrock, G Cox; comments to author 26.10.17; revised version received 21.11.17; accepted 22.11.17; published 15.02.18.

Please cite as:
Bevan Jones R, Thapar A, Rice F, Beeching H, Cichosz R, Mars B, Smith DJ, Merry S, Stallard P, Jones I, Thapar AK, Simpson SA
A Web-Based Psychoeducational Intervention for Adolescent Depression: Design and Development of MoodHwb
JMIR Ment Health 2018;5(1):e13
URL: http://mental.jmir.org/2018/1/e13/
doi:10.2196/mental.8894
PMID:29449202

Original Paper

Influencing the Conversation About Masculinity and Suicide: Evaluation of the Man Up Multimedia Campaign Using Twitter Data

Marisa Schlichthorst[1], MA (SocSci), PhD; Kylie King[1], BSc, PGDip, DPsych; Jackie Turnure[2], BA, MFA; Suku Sukunesan[3], BSc (CompSci), MSc (CommTech), PhD; Andrea Phelps[4], MPsych (Clin), PhD; Jane Pirkis[1], BA (Hons), MPsych, MAppEpid, PhD

[1]Centre for Mental Health, Melbourne School of Population and Global Health, The University of Melbourne, Parkville, Australia

[2]Heiress Films, Sydney, Australia

[3]Department of Business, Technology and Entrepreneurship, Faculty of Business and Law, Swinburne University of Technology, Melbourne, Australia

[4]Phoenix Australia, Centre for Posttraumatic Mental Health, The University of Melbourne, Parkville, Australia

Corresponding Author:
Marisa Schlichthorst, MA (SocSci), PhD
Centre for Mental Health
Melbourne School of Population and Global Health
The University of Melbourne
207 Bouverie Street
Parkville, 3010
Australia
Phone: 61 390353508
Email: marisa.schlichthorst@unimelb.edu.au

Abstract

Background: It has been suggested that some dominant aspects of traditional masculinity are contributing to the high suicide rates among Australian men. We developed a three-episode documentary called *Man Up*, which explores the complex relationship between masculinity and suicide and encourages men to question socially imposed rules about what it means to be a man and asks them to open up, express difficult emotions, and seek help if and when needed. We ran a three-phase social media campaign alongside the documentary using 5 channels (Twitter, Facebook, Instagram, YouTube, and Tumblr).

Objective: This study aimed to examine the extent to which the *Man Up* Twitter campaign influenced the social media conversation about masculinity and suicide.

Methods: We used Twitter insights data to assess the reach of and engagement with the campaign (using metrics on followers, likes, retweets, and impressions) and to determine the highest and lowest performing tweets in the campaign (using an aggregated performance measure of *reactions*). We used original content tweets to determine whether the campaign increased the volume of relevant Twitter conversations (aggregating the number of tweets for selected campaign hashtags over time), and we used a subset of these data to gain insight into the main content themes with respect to audience engagement.

Results: The campaign generated a strong following that was engaged with the content of the campaign; over its whole duration, the campaign earned approximately 5000 likes and 2500 retweets and gained around 1,022,000 impressions. The highest performing tweets posted by the host included video footage and occurred during the most active period of the campaign (around the screening of the documentary). The volume of conversations in relation to commonly used hashtags (*#MANUP*, *#ABCMANUP*, *#LISTENUP*, and *#SPEAKUP*) grew in direct relation to the campaign activities, achieving strongest growth during the 3 weeks when the documentary was aired. Strongest engagement was found with content related to help-seeking, masculinity, and expressing emotions. A number of followers tweeted personal stories that revealed overwhelmingly positive perceptions of the content of the documentary and strongly endorsed its messages.

Conclusions: The *Man Up* Twitter campaign triggered conversations about masculinity and suicide that otherwise may not have happened. For some, this may have been game-changing in terms of shifting attitudes toward expressing emotions and reaching out to others for help. The campaign was particularly effective in disseminating information and promoting conversations

in real time, an advantage that it had over more traditional health promotion campaigns. This sort of approach could well be adapted to other areas of mental (and physical) health promotion campaigns to increase their reach and effectiveness.

(JMIR Ment Health 2018;5(1):e14) doi:10.2196/mental.9120

KEYWORDS

mental health; suicide; masculinity; men's health

Introduction

Background

In Australia, suicide is the leading cause of death in males aged 15 to 45 years [1]. Suicide rates of Australian men are three times higher than those of women [1], and this gender inequality is reflected internationally [2].

A number of factors have been found to contribute to higher suicide rates in men. Men are known to choose more lethal methods [3], show increased alcohol and substance use [4], and have less well-established coping strategies and social support networks [5-7]. In addition, men tend to avoid or delay help-seeking, particularly for emotional issues [8-10], have greater difficulties in recognizing negative emotions or distress [11], and are less aware of help services available to them [12,13]. Mostly, these factors are considered in isolation, with little regard to the mechanisms or driving forces that may underpin them [14].

It has been suggested that masculinity—or the rules prescribed by society about how men should live their lives [15]—help to explain gender disparities in suicide. Although gender roles have arguably changed and continue to vary with time and place, dominant masculine norms still exist in many western societies and influence how men navigate life. Independence, self-reliance, invulnerability, and the avoidance of negative emotions are some commonly expected behaviors [16], and these have been linked to men's lower likelihood of seeking help or dealing with emotional problems [8,17,18]. Men often see help-seeking as a measure of weakness or failure and prefer solving problems on their own [10]. This stoic behavior can be lethal; self-reliance has been found to reduce and delay help-seeking and increase the likelihood of suicidal thoughts [14,19-22].

Seeking to change the picture on male suicide may benefit from challenges to some of these widely accepted male stereotypes. Discussing dominant masculinity and creating opportunities for redefining help-seeking strategies for men and opening up options for negotiating difficult life events can potentially have significant impacts. However, changing social norms is no easy feat, and requires holistic population-based interventions that are able to reach and engage with the wider community of men from all walks of life, backgrounds, and geographic locations. Developing and testing such interventions have the potential to take the field of suicide prevention forward; at present, only a relatively small number of population-based interventions have been shown to be effective (eg, restricting access to means and school-based awareness campaigns) [8].

The Study

We developed one such intervention, with funding from the Movember Foundation. We collaborated with Heiress Films to create a three-episode television documentary called *Man Up*, seeking guidance from an advisory committee comprising representatives from various community organizations and other academic experts in men's health. *Man Up* follows Sydney Triple M Radio personality, Gus Worland, across Australia as he explores the complex relationship between masculinity and male suicide. Gus meets a multitude of men who have struggled with suicidal thoughts or attempted suicide, as well as many individuals and organizations that are addressing the problem of male suicide by encouraging men to reach out to others. Gus is so affected by this that he creates a community service announcement (CSA) with the tagline "Man Up. Speak Up," which serves as a call to action.

From the beginning, *Man Up* was conceived as something far greater than a television show. It was viewed as part of a multimedia intervention that also included components that took full advantage of the Web environment to kick-start a national conversation. Our collaborator, Heiress Films, created a website that acted as a hub for content and resources, housed the show's trailer, and ran a 14-week social media campaign around the show. The campaign and related assets were released via 5 Web-based platforms (Twitter, Facebook, Instagram, YouTube, and Tumblr) over three phases. Phase 1 ran from August 15 until October 10, 2016, stopping just before the documentary was screened by the Australian Broadcasting Corporation (ABC). This phase encouraged men (and women) to watch the show. Phase 2 ran from October 11 to 30, 2016, coinciding with the 3 weeks over which the show was aired. This phase encouraged viewers to talk and share. Phase 3 ran from October 31, 2016 (the end of the screening period) to November 20, 2016, and prompted the community to take action. These phases corresponded to the campaign goals of creating a social media audience, promoting a conversation about masculinity and male suicide, and generating and maintaining engagement with the documentary and its content throughout the campaign and beyond. The campaign capitalized on our relationships with partner organizations, including Movember, beyondblue, Lifeline, Mindframe, Triple M Radio, and the ABC network. It also linked to events and trending topics (eg, the month of Movember, Mental Health Week, Father's Day, and World Kindness Day).

The social media campaign was a crucial component of the overall intervention. There is increasing recognition that social media may have potential in suicide prevention, and may be particularly useful for otherwise hard-to-reach groups such as men [23,24]. Other social media interventions have been deployed in suicide prevention (eg, apps designed to support

individuals at imminent risk and machine learning algorithms that aim to detect suicidal content or sentiment in web conversations) [25,26]. To our knowledge, however, there are no precedents for the way in which we used the social media campaign in our intervention.

This study focuses on the Twitter activity that was generated by the *Man Up* Twitter account (*manuptvseries*), evaluating the extent to which the campaign influenced the social media conversation about masculinity and suicide. It forms part of a larger evaluation of *Man Up*, the findings of which have been [27] or will be reported elsewhere (personal communication with M Schlichthorst, unpublished data, 2017; and K King, unpublished data, 2017).

The study addresses the following evaluation questions:

- What was the overall reach of the campaign and how did the audience engage with it?
- What were the highest and lowest performing tweets and what assets were associated with them?
- Did the Man Up campaign increase the volume of relevant Twitter conversations and, if so, was the increase sustained after the show?
- What were the main content themes with regard to audience engagement?

Methods

Overarching Approach

We used Twitter data to answer our evaluation questions. These data are easy to access and represent a real-time response, making them ideal for monitoring responses to events, patterns of communication, and general attitudes [28]. Twitter data have been used in studies on the mental health and suicide prevention field to understand how users discuss mental health issues and why they use social media to do so, to monitor attitudes toward depression and schizophrenia, to gauge how Twitter is used in the provision of feedback and support by mental health services, and to track suicide risk factors [29-33]. In the general health arena, Twitter data have also been used to monitor the impact of campaigns and related interventions (eg, in cervical cancer screening and smoking cessation) [34-36].

Data Collection

We collected Twitter data from two sources, one via the social media tool *Twitter insights* and the other through harvesting original content tweets. In combination, these different sources provided us with the information we needed to address our 4 evaluation questions.

Twitter Insights Data

During the campaign, we downloaded weekly data reports from *Twitter insights* into an Excel file to monitor the growth and reach of the campaign, audience engagement with its content, and selected demographic variables such as age. These reports covered the full period of the campaign (August 15 to November 20, 2016) and enabled us to look at the campaign's performance across its three phases. Specifically, we looked at "reactions" (retweets, replies, likes, profile clicks, URL clicks, hashtag clicks, expanded click, follows, and views) to tweets posted by *manuptvseries* between August 15 and November 20, 2016.

Original Content Tweets

We harvested original content tweets from a broader period to capture activity in the 14 weeks before the campaign (May 9 to August 14, 2016), the 14 weeks during the campaign (August 15 to November 20, 2016), and the 14 weeks after the campaign (November 21, 2016 to February 26, 2017). Tweets were harvested using the free-of-charge Twitter application programming interface and were included in the dataset if they used the hashtag #MANUP, which was the main hashtag used in promoting the campaign. These data included the full text of each tweet and additional information on when (eg, time and date) and by whom (eg, host, organization, private person, and public person or forum) it was tweeted. Data were stored in an external holding database by a US company called Rackspace. We had access to the data and could download customized datasets throughout the entire observation period (pre, during, and post campaign). A final dataset was imported into Excel, and a subset of that dataset was then imported into the qualitative data analysis software NVIVO Pro V11 developed by QSR International.

Figure 1 summarizes the time periods covered by the two data sources and the evaluation questions each of them addressed.

Data Analysis

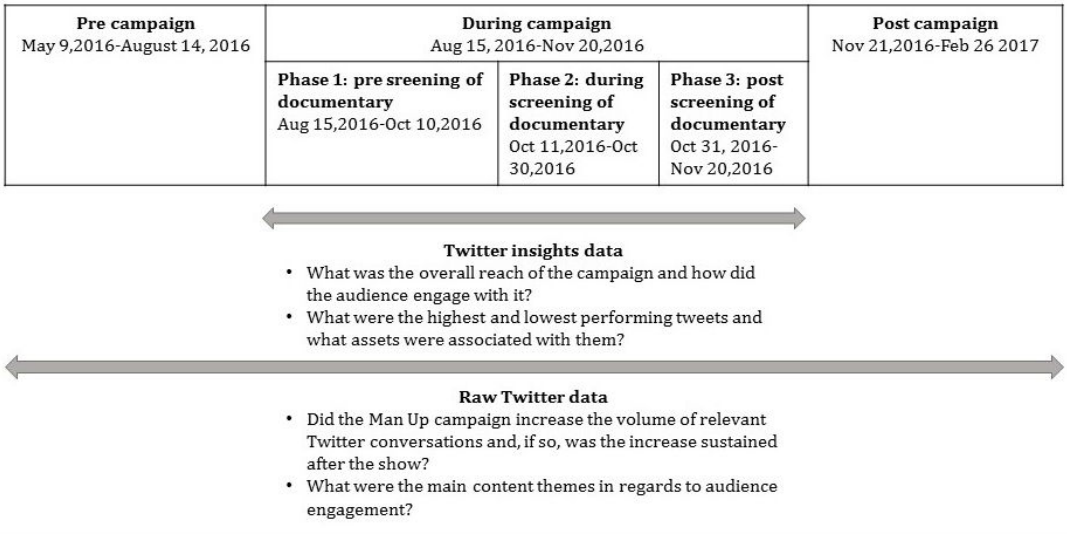
All quantitative analyses were undertaken in Excel, and all qualitative analyses were performed in NVIVO Pro V11.

For evaluation question 1, we assessed the reach of and engagement with the campaign by using metrics from the Twitter insights data on followers, new followers, likes, retweets, and impressions (the number of people who saw campaign tweets on their timeline). We calculated frequencies, averages, and percentages for each as relevant, doing so for each of the three phases of the campaign.

For evaluation question 2, we determined the highest and lowest performing tweets in the campaign by ordering all tweets posted by *manuptvseries* based on an overall performance measure calculated as the number of "reactions" to these tweets, using Twitter insights data to do so. As each standard engagement measure assesses a different objective, we felt that an aggregate measure was a more democratic approach for comparing performance of tweets rather than using any single measure on its own. We took the "top 20" and "bottom 20" tweets, analyzed their content, and compared them in terms of their use of different assets.

For evaluation question 3, we used the original content tweets to determine whether the campaign increased the volume of relevant Twitter conversations, aggregating the number of tweets for selected campaign hashtags (*#MANUP, #ABCMANUP, #LISTENUP,* and *#SPEAKUP*) by week and plotting these for the precampaign period, the period of the campaign, and the postcampaign period. Specifically, we looked at the performance of *#MANUP* (occurring with or without other hashtags) and *#ABCMANUP, #LISTENUP,* and *#SPEAKUP* (occurring in combination with *#MANUP*).

Figure 1. Data sources by time frames and evaluation questions covered.



We calculated the average number of tweets per period and used *t* tests to test for significant differences in tweet volumes between the campaign period and the pre- and postcampaign periods. For evaluation question 4, we created a subset of data from the original content tweets to gain insight into the main content themes with respect to audience engagement with the campaign. We took all tweets that included the hashtag *#MANUP* and at least one other hashtag that had been used at least 10 times during the campaign by the *manuptvseries*. We then concentrated on those tweets in this group that were campaign-related (ie, tweets by the host, retweets of tweets by the host, or tweets that featured *Man Up* campaign content). We performed a thematic analysis of these tweets; MS read through 50% of the selected tweets and developed a preliminary coding framework with a list of themes. MS and KK then tested this framework using 10% of the tweets, revised it, and then retested it on another 10% of the tweets. MS and KK then finalized the framework by consensus (consulting with one another or another member of the team to resolve any disagreement), and each coded 50% of the total set of tweets.

Results

What Was the Overall Reach of the Campaign and How Much Did the Audience Engage With It?

Table 1 shows the reach of and engagement with the campaign. During the campaign, the number of followers of *manuptvseries* rose from 0 on August 15, 2016 to 1453 by November 20, 2016. The strongest growth in followers occurred during the time the documentary was screened (October 11 to 30, 2016). During this time, the campaign was most active with an average of 5 tweets per day being posted from the *Man Up* account. The number of likes and retweets was highest during this period. Impressions were strong before the show went to air as well as during the screening period. Over its whole duration, the campaign earned approximately 5000 likes and 2500 retweets and gained around 1,022,000 impressions. The beginning of the campaign saw more males being attracted to the campaign, but as time went by, there was a shift toward a more even distribution of genders among followers.

Table 1. Reach of and engagement with the *Man Up* campaign. Data source: Twitter insights; downloaded by Jackie Turnure.

Indicator	Prescreening of documentary (Aug 15-Oct 10, 2016)	During screening of documentary (Oct 11-30, 2016)	Post screening of documentary (Oct 31-Nov 20, 2016)
Frequent followers, n	519	1355	1453
Frequent new followers, n	519	836	98
Frequent likes, n	1500	2500	851
Average likes,n	26	118	41
Frequent retweets, n	656	1300	417
Average retweets, n	12	64	20
Frequent impressions, n	423,000	436,000	163,000
Gender, n (%)			
Male	379 (73.0)	813 (60.0)	857 (59.0)
Female	140 (27.0)	542 (40.0)	596 (41.0)

What Were the Highest and Lowest Performing Tweets and What Assets Were Associated With Them?

Table 2 shows the type of assets associated with the highest and lowest performing tweets, as measured by "reactions." A total of 12 (60%) of the highest performing tweets included a video, whereas only a single tweet (5%) among the lowest performing tweets did so. Furthermore, 18 (90%) of the lowest performing tweets included a link to an external source. Overall, the most successful tweet based on "reactions" was one that heralded the final episode before it went to air and provided a preview of the CSA that Gus created. The next most successful tweet promoted a relaunch of the trailer for the complete series. These videos were some of the main promotional assets for the show and were not only released via tweets but also across other Web-based platforms. The 20 highest performing tweets were all posted between October 11 and November 17, 2016, whereas the majority of the 20 lowest performing tweets (60%) were tweeted in August and September 2016, the first phase of the campaign.

Did the Man Up Campaign Increase the Volume of Relevant Twitter Conversations and, if so, Was the Increase Sustained After the Show?

The original content tweets included 46,130 tweets that used the hashtag *#MANUP* (13,804 posted between May 9 and August 14 2016, pre campaign; 19,845 posted between August 15 and November 20, 2016, during the campaign; and 12,481 posted between November 21, 2016 and February 26, 2017, post campaign).

Figure 2 shows the aggregated number of times *#MANUP* was tweeted (with or without other hashtags) in the three periods: pre, during, and post campaign. *#MANUP* was used an average of 979 times per week pre campaign. This rose to 1338 times per week during the campaign, and then dropped to 844 times per week post campaign. There was no significant difference in the use of *#MANUP* between pre and post campaign ($t_{1.683}$, P=.052), but its use was significantly higher during the campaign period than either the pre ($t_{2.68}$, P=.004) or post ($t_{4.13}$, P<.001) campaign periods. Most of the increase was observed from week 22 (which corresponded with the airing of the documentary), and the use of *#MANUP* stayed at higher than average levels until week 27 (the end of the campaign).

Because *#MANUP* was commonly used in contexts that were unrelated to the campaign, we thought it would be useful to consider the performance of three other hashtags that were newly introduced by *manuptvseries* (*#ABCMANUP*, *#LISTENUP*, and *#SPEAKUP*), looking at them when they were used in combination with *#MANUP*. Figure 2 also shows these results. *#ABCMANUP* was used to promote the documentary on the ABC. This hashtag was introduced during the campaign and intensely used and shared in the period in which the documentary was aired (from week 22 to week 26), and then, its use was largely discontinued. *#LISTENUP* and *#SPEAKUP* were introduced by *manuptvseries* in the lead-up to the final episode in the context of the CSA. Again, their use peaked at this time but dropped as the campaign faded out.

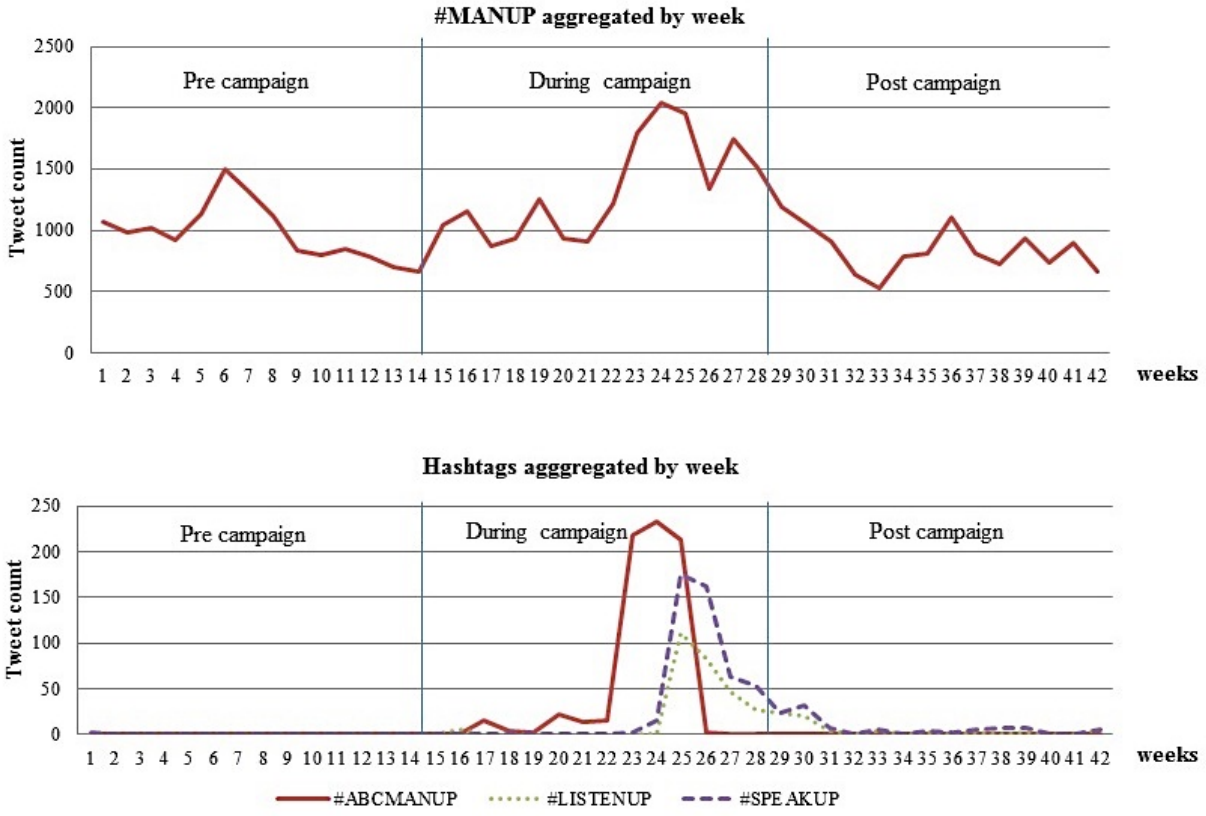
Table 2. Engagement with tweets by asset type for the 20 highest and lowest performing tweets. Data source: Twitter insights.

Asset type	Frequency, n (%)	Sum of reactions[a]	Sum of retweets	Sum of replies	Sum of likes	Sum of media views
Top 20 tweets						
Video	12 (60)	14,069	240	28	395	12,856
Graphic	5 (25)	1599	148	26	293	542
Link	2 (10)	2205	43	3	62	2014
GIF[b]	1 (5)	897	2	0	6	872
Total	20 (100)	18,770	433	57	756	16,284
Bottom 20 tweets						
Link	18 (90)	62	2	0	42	0
Graphic	1 (5)	3	0	0	2	1
Video	1 (5)	3	0	0	1	0
Total	20 (100)	68	2	0	45	1

[a]Aggregate of all engagement including video views.

[b]GIF: Graphics Interchange Format .

Figure 2. Hashtag frequencies on Twitter before, during, and after the campaign based on original content tweets.



What Were the Main Content Themes With Regard to Audience Engagement?

We identified a subset of 2093 tweets that included the hashtag *#MANUP* and at least one other hashtag that had been used at least 10 times during the campaign by *manuptvseries*. Of these, 1876 were campaign-related tweets, and we focus on these here. Of the campaign-related tweets, 229 were from *manuptvseries*. In total, 417 (22.2%) of the campaign-related tweets were original tweets and 1459 (77.77%) were retweets. The majority (1328 or 70.79%) were neutral in tone and did not show any specific expression of sentiment. In addition, 544 (29.0%) tweets provided positive feedback about the campaign or endorsed it, and 4 (<1%) took a negative stance or criticized the content of the campaign. The 3 tweets listed below provide examples of positive, neutral, and negative sentiment, respectively:

> *RT @ManUpTVSeries: Great to see the conversation getting started. #ManUp #SmashTheStigma #itsokaytotalk*
>
> *@newlz in @HuffPostAU Talking. Listening. Sharing. These are the tenets that now drive me. #ManUp #weneedtotalk*
>
> *@username Except if you're a male victim of #domesticviolence - then you get told to #ManUp and discriminated against #Reality #ABCManUp*

Several content themes were identified in the tweets: expressing emotions, mental health issues with the subthemes of mental health and suicide, men's issues with the subthemes of being a man and fathering and raising boys, help-seeking with the subthemes of providing options for help and other help-seeking, personal stories, and supporting others. Table 3 summarizes these content themes for the 1876 campaign-related tweets and indicates whether they were original tweets or retweets.

Expressing emotions was the theme identified most commonly, occurring in 710 tweets (37.8% of all campaign-related tweets). The strength of this theme is not surprising, as the CSA that was produced and released in the final episode of the show encouraged men to open up and express difficult emotions. The tweet that promoted the CSA achieved 125 retweets on its own and was the highest performing tweet of the entire campaign measured by the number of "reactions." The number of the tweets related to expressing emotions highlighted the difficulties men experience in opening up and asking for help in difficult times, and the stigma around mental health. Some tweeters acknowledged that *Man Up* made them cry, or that they had opened up to someone after watching the show. Examples are provided here:

> *RT @ManUpTVSeries: The need for men to be emotionally honest is greater than ever. Interesting #blog post from @3DMathW. #ManUp*
>
> *RT @username: Not ashamed to admit a few tears have been shed watching #ManUp over the last few weeks #ABCManUp*
>
> *RT @ManUpTVSeries: The strong silent type might be sexy in films, but it's unhealthy in real life. #ManUp #itsokaytotalk*

Table 3. Content themes of the 1876 campaign-related tweets. Data source: Original content tweets.

Theme	Description	Tweet count n (%)	Retweet n (%)	Original tweet n (%)
Expressing emotions	Tweets that include topics such as speaking up, opening up, talking about uncomfortable issues, breaking down stigma, and crying	710 (100.0)	550 (77.5)	160 (22.5)
Mental health issues				
Mental health	Tweets that indicate mental health, depression, or posttraumatic stress disorder, or include materials and links that discuss these topics, or use the hashtag mental health	410 (100.0)	300 (73.2)	110 (26.8)
Suicide	Tweets that indicate suicide or suicide prevention, or include materials and links to sites that discuss these topics, or use the hashtag suicide	182 (100.0)	140 (76.9)	42 (23.1)
Men's issues				
Being a man	Tweets that discuss the concept of masculinity or challenge the concept of masculinity	165 (100.0)	125 (75.8)	40 (24.2)
Fathering and raising boys	Tweets that encourage discussion about what it means to be a father and raising boys	82 (100)	63 (77)	19 (23)
Help-seeking				
Providing options for help	Tweets that provide information on help services and encourage their use	165 (100.0)	147 (89.1)	18 (10.9)
Help-seeking other	Tweets mentioning other content on help-seeking (ie, not about providing options for help)	96 (100)	79 (82)	17 (18)
Personal stories	Tweets relating personal stories, written in the individual's own voice, and revealing detail about the person (not commentaries or statements)	101 (100)	61 (60)	40 (40)
Supporting others	Tweets about providing support to others, support options and general advice	78 (100)	63 (81)	15 (19)

The theme of *mental health issues and suicide* occurred in 484 tweets (25.8% of all campaign-related tweets). Moreover, 410 of these tweets featured references to *mental health issues* and 182 made mention of *suicide* (with 108 covering both). Tweets that exemplified this theme provided information on mental health issues or suicide, aimed to raise awareness about them, and encouraged people to speak up about them. There was some overlap in the two subthemes as some tweets referred to mental health more broadly and suicide more specifically within the one tweet. Examples of tweets involving the theme of *mental health issues and suicide* are provided below:

> *Massive shout out to @GusWorland. As sufferer of PTSD for 8 years as Ex-Cop #ManUp really hit home hard. Congrats mate. #ManUp #SpeakUp*
>
> *RT @username: Depression is an illness people can help you recover from #ManUp on ABC at the moment is great. #mentalhealthweek*
>
> *Suicide has touched so many lives, I'm tearing up already #ABCManUp #manup #blackdoginstitute #lifeline #beyondblue*
>
> *RT @ManUpTVSeries: How suicide can become "contagious" to other at-risk young men. Important piece in @DailyMailAU. #ManUp #SpeakUp*

Men's issues were also a relatively common theme, accounting for 211 tweets (11.2% of all campaign-related tweets). In addition, 165 of these tweets related to *being a man* and 82 contained content about *fathering and raising boys* (with 36 making reference to both). Tweets that related to *being a man* encouraged discussions about the concept of masculinity, provoking and challenging stereotypical masculinity, and encouraging others to engage in a conversation about masculinity and what it means to be a man. Examples included:

> *Inspired by the #ManUp TV series, we have a chat about what it means to be a MAN https://t.co/0a6wqtimAP #Movember #mentalhealth #goodcause*
>
> *RT @ManUpTVSeries: "Our ideals of #masculinity have shifted." @MichaelGLFlood is one of our #RealAussieblokes. #ManUpâ€¦*
>
> *RT @OliShawyer: This ad made me cry. I'm covered in Tatts. I ride a Harley. And I'm crying. Try tell me that's weak. #manup #speakup thank you @gusworland*

Tweets on *fathering and raising boys* provided information on these topics. These were often linked to notions of being a man and raised issues around the expectations placed on boys as they grow up. Some prompted consideration of what could be done differently in raising boys today to avoid reinforcing traditional stereotypes. Examples included:

RT @ManUpTVSeries: We need to have a hard look at how we raise our boys. #ManUp #raisingboys #ChildHealthDay @harkin_tom

RT @username: #ABCManUp #ManUp Let's start helping boys from a young age. Dads need to give them cuddles, talk about feelings. #natural

RT @Top_Blokes: Providing boys with positive older male mentors is important to keep them safe and alive #ABCManUp #ManUp

The theme of *help-seeking* was evident in 202 tweets (10.8% of all campaign-related tweets). In addition, 165 of these tweets embodied the subtheme of *providing options for help* and 96 were classified as falling under the subtheme of *other help-seeking* (with 59 exemplifying both subthemes). Tweets that exemplified *providing options for help* promoted help-seeking in general and pointed to particular services more specifically (eg, Mindframe, Lifeline, headspace, SANE Australia, Kids Helpline, and MensLine). A tweet that typified this theme was:

RT @ManUpTVSeries: #RealTalk for a sec: if you or a mate are doing it tough please call @LifelineAust on 13 11 14 #ItsOkayToTalk #ManUp

The tweets in the theme *other help-seeking* mentioned two different aspects of help-seeking. They provided information on male help-seeking behavior and the issues that arise from it, thereby providing opportunity to create awareness and reflection on the issue. They also gave advice on taking action in help-seeking and motivating behavior change. Examples included:

RT @ManUpTVSeries: #ManUp survey: over 56% of men would rather manage themselves than seek professional help. #weneedtotalk #questmh

RT @ManUpTVSeries: Shame could be a big reason why…some men [don't] ask for help. Beautiful #blog from @drmwroberts #ManUp #NoShame

Another key theme— *personal stories* —was embodied in 101 tweets (5.4% of all campaign-related tweets) where people opened up to tell their story in their own voices. The stories included reflections on the experience these people had watching the documentary, and things that may have happened to them or someone they knew. Furthermore, they included responses to a collection of self-reflective portraits revealing personal struggles and hope that were released on the *Man Up* website in a segment called "Aussie Blokes." Examples included:

Absolutely opened my eyes to the daily struggles of both genders. #ManUp I gave my fiancÃ© a big hug after watching that tonight #ABCManUp

I've lost 3 mates to suicide. Wish I noticed what they were going through. Don't #Manup, seek help cuz there're many out there #ABCManUp.

When I was younger, everything I did was bulletproof #RealAussieBlokes #ManUp #exercise.

The final theme was *supporting others.* This was apparent in 78 tweets (4% of all campaign-related tweets). These tweets discussed the importance of supporting others and reaching out to those in need, and the skills of listening. Examples included:

Powerful stuff @ManUpTVSeries #ManUp #ABCManUp We have a way to go to support our young men on their journeys. It's a tough world we live in.

Sometimes the most important thing is just to listen. @BeardedGenius in @JOE_co_uk. #ManUp #SpeakUp #ListenUp

Across all themes and subthemes, the majority of tweets were retweets rather than original tweets, indicating high levels of engagement. Proportionally, the highest percentage of retweets was for *providing options for help* (90% retweets; 10% original tweets), and the lowest percentage was for *personal stories* (60% retweets; 40% original tweets).

Discussion

The Success of the Man Up Twitter Campaign

We evaluated the extent to which the *Man Up* Twitter campaign influenced the conversation about masculinity and suicide among Australian men. The campaign was very successful in reaching an audience that was engaged with its content, as evidenced by the number of "reactions." Not surprisingly, campaign performance was highest during the period in which the show was aired, but social media conversations continued and followers stayed engaged beyond this. In fact, social media channels are still active today.

Certain elements of the campaign were particularly successful. These included tweets relating to the CSA Gus created on screen that encouraged men and boys to reject the constraints of traditional masculinity and speak up if they were facing tough times, as well as tweets featuring the trailer and episode teaser videos. The conversations generated by the campaign aligned with its major themes of expressing emotions, mental health issues and suicide, being a man and fathering and raising boys, help-seeking, personal stories, and supporting others. Again, related to the CSA release, the most discussed theme was expressing emotions.

The large number of positive comments indicated great acceptance and endorsement of the documentary. Many tweets welcomed open discussion of masculinity and male suicide and embraced the call for men to open up and express their emotions. There was a sense that for some men, questions on male identity and masculine norms had been bubbling beneath the surface, and the campaign gave men permission to articulate these thoughts and emotions. For others, ideas around changing the way we look at masculinity and its link to suicide appeared to be new, thought-provoking, and even challenging. These differing perspectives added to the richness of the discussion.

The Man Up Twitter Campaign as Part of a Strategic Multimedia Intervention

The Twitter campaign occurred as part of a strategic multimedia campaign. It was rolled out around the documentary via three phases, each of which aligned with a specific goal, and it was one component of the broader campaign. A significant

proportion of the content released by *manuptvseries* was directly related to the documentary, as were many of the comments tweeted by the general public. We are confident that the Twitter campaign had an independent effect in terms of influencing the social media conversation about masculinity and suicide, but it is difficult to tease out its independent contribution to the overall success of the *Man Up* enterprise.

Contributing to the Broader Field of Suicide Prevention

As noted earlier, there is still much that is unknown about what works and what does not work in suicide prevention. There are relatively few interventions for which there is indisputable evidence of effectiveness [37], although improvements are being made. The jury is still out on suicide prevention media campaigns [38], although there is emerging evidence that they may work for some audiences. Most of the media campaigns that have been evaluated have tended to be fairly traditional, typically involving brief CSAs that may be delivered through different channels. Few have targeted men specifically, although some have targeted groups (eg, police) in which men may be well represented. Our intervention had the luxury of being more extensive, partly because it was underpinned by a three-episode documentary and partly because it capitalized on the digital environment to get its message out. Harnessing the media in suicide prevention in a nontraditional manner certainly seems to show promise.

Limitations

Both datasets that we used here had certain limitations, and these should be considered in interpreting our findings. In the case of the Twitter insights data, the key limitation relates to our measurement of success. We used the standard metrics of numbers of followers, likes, and retweets, and we created an aggregate measure, which we termed "reactions" (retweets, replies, likes, profile clicks, URL clicks, hashtag clicks, expanded click, follows, and views) to rank tweets in terms of their performance over the duration of the campaign. The way we aggregated "reactions" is open to challenge, although, as noted above, we felt that it was a democratic approach. In addition, the fact that we monitored tweets' performance over the duration of the campaign disadvantaged tweets from earlier in the promotion cycle as these had less exposure because of lower numbers of followers and generally lower engagement with the campaign. This comparison could be improved by monitoring the performance of each tweet over the same duration (eg, for the first 2 weeks after it was posted) and creating some sort of performance per follower weighting, but "leveling the playing field" in this way was beyond the scope of our current endeavors.

In the case of the original content tweets, the main limitation relates to the way in which we were able to capture tweets relating to the campaign. We monitored the use of the hashtag *#MANUP*, assuming that this would provide a window into the effectiveness of the social media campaign. The difficulty with this approach was that *#MANUP* was already commonly used worldwide in different contexts (eg, politics, sports, and entertainment), often with negative connotations (ie, promoting messages such as "harden up" and "tough it out"). The volume of tweets that were unrelated to our campaign created a challenge for identifying the relevant content that would tell the story of our campaign. For this reason, we also looked at a subset of *#MANUP* paired with other campaign-related hashtags for more in-depth qualitative analysis.

There are also limitations associated with using Twitter data in general. These data present something of a skewed picture because they can only represent those who are active on Twitter. In Australia, only about 19% of Internet users use Twitter, and a majority of these are relatively young [39]. This means that our Twitter evaluation data will be likely to have some inherent biases.

Conclusions

The *Man Up* Twitter campaign triggered conversations about masculinity and suicide that otherwise may not have happened. For some, this may have been game-changing in terms of shifting attitudes toward expressing emotions and reaching out to others for help. The campaign was particularly effective in disseminating information and promoting conversations in real time, an advantage that it had over more traditional health promotion campaigns. This sort of approach could well be adapted to other areas of mental (and physical) health promotion campaigns to increase their reach and effectiveness.

Acknowledgments

The authors would like to thank the Movember Foundation for supporting the development and evaluation of *Man Up*. They would also like to thank Heiress Films for producing the documentary and associated social media campaign, and the ABC for screening the documentary. The authors are grateful to the Advisory Group that provided guidance at various critical stages in the project. They would also like to acknowledge Gus Worland and everyone else who appeared in the documentary, and the men who took part in this study. Funding for *Man Up* was provided by the Movember Foundation. Funds supported the development of the documentary and associated social media campaign, as well as their evaluation. The Movember Foundation had no role in the design or conduct of this study; in the collection, management, and analysis of the data; or in preparation of this manuscript.

Conflicts of Interest

None declared.

References

1. ABS. 2017. Causes of Death, Australia 2016 URL: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/3303.0~2013~Main%20Features~Suicide%20by%20Age~10010 [accessed 2017-10-03] [WebCite Cache ID 6twrQxf43]
2. World Health Organization. 2015. Global Health Observatory (GHO) data: Suicide rates (per 100 000 population) URL: http://www.who.int/gho/mental_health/suicide_rates_male_female/en/ [accessed 2017-10-03] [WebCite Cache ID 6twtT8k9J]
3. Houle J, Mishara BL, Chagnon F. An empirical test of a mediation model of the impact of the traditional male gender role on suicidal behavior in men. J Affect Disord 2008;107(1):37-43. [doi: 10.1016/j.jad.2007.07.016] [Medline: 17707084]
4. Hawton K. Why has suicide increased in young males? Crisis 1998;19(3):119-124. [doi: 10.1027/0227-5910/a000369] [Medline: 26831210]
5. Kendler KS, Thornton LM, Prescott CA. Gender differences in the rates of exposure to stressful life events and sensitivity to their depressogenic effects. Am J Psychiatry 2001;158(4):587-593. [doi: 10.1176/appi.ajp.158.4.587] [Medline: 11282693]
6. Tomova L, von Dawans B, Heinrichs M, Silani G, Lamm C. Is stress affecting our ability to tune into others? Evidence for gender differences in the effects of stress on self-other distinction. Psychoneuroendocrinology 2014;43:95-104. [doi: 10.1016/j.psyneuen.2014.02.006] [Medline: 24703175]
7. Denney JT, Rogers RG, Krueger PM, Wadsworth T. Adult suicide mortality in the United States: marital status, family size, socioeconomic status, and differences by sex. Soc Sci Q 2009;90(5):1167-1185. [doi: 10.1111/j.1540-6237.2009.00652.x] [Medline: 20161640]
8. Galdas PM, Cheater F, Marshall P. Men and health help-seeking behaviour: literature review. J Adv Nurs 2005;49(6):616-623. [doi: 10.1111/j.1365-2648.2004.03331.x] [Medline: 15737222]
9. Möller-Leimkühler AM. Barriers to help-seeking by men: a review of sociocultural and clinical literature with particular reference to depression. J Affect Disord 2002;71(1-3):1-9. [Medline: 12167495]
10. Emslie C, Ridge D, Ziebland S, Hunt K. Men's accounts of depression: reconstructing or resisting hegemonic masculinity? Soc Sci Med 2006;62(9):2246-2257. [doi: 10.1016/j.socscimed.2005.10.017] [Medline: 16289741]
11. Goldney RD, Fisher LJ, Wilson DH, Cheok F. Mental health literacy of those with major depression and suicidal ideation: an impediment to help seeking. Suicide Life Threat Behav 2002;32(4):394-403. [Medline: 12501964]
12. Bruffaerts R, Demyttenaere K, Hwang I, Chiu WT, Sampson N, Kessler RC, et al. Treatment of suicidal people around the world. Br J Psychiatry 2011 Jul;199(1):64-70 [FREE Full text] [doi: 10.1192/bjp.bp.110.084129] [Medline: 21263012]
13. Wilson C, Deane F. Help-negation and suicidal ideation: the role of depression, anxiety and hopelessness. J Youth Adolesc 2010;39(3):291-305. [doi: 10.1007/s10964-009-9487-8] [Medline: 19957103]
14. Pirkis J, Spittal MJ, Keogh L, Mousaferiadis T, Currier D. Masculinity and suicidal thinking. Soc Psychiatry Psychiatr Epidemiol 2017;52(3):319-327. [doi: 10.1007/s00127-016-1324-2] [Medline: 28025691]
15. Thompson EH, Pleck JH. Masculinity ideologies: a review of research instrumentation on men and masculinities. In: Levant R, Pollack W, editors. A New Psychology of Men. New York, NY: Basic Books; 1995:129-163.
16. Rice S, Fallon B, Bambling M. Men and depression: the impact of masculine role norms throughout the lifespan. Aust Educ Dev Psychol 2012 Mar 27;28(2):133-144. [doi: 10.1375/aedp.28.2.133]
17. Boman EK, Walker GA. Predictors of men's health care utilization. Psychol Men Masc 2010;11(2):113-122. [doi: 10.1037/a0018461]
18. Nam SK, Chu HJ, Lee MK, Lee JH, Kim N, Lee S. A meta-analysis of gender differences in attitudes toward seeking professional psychological help. J Am Coll Health 2010;59(2):110-116. [doi: 10.1080/07448481.2010.483714] [Medline: 20864437]
19. Coleman D. Traditional masculinity as a risk factor for suicidal ideation: cross-sectional and prospective evidence from a study of young adults. Arch suicide res 2015;19(3):366-384. [doi: 10.1080/13811118.2014.957453] [Medline: 25383764]
20. Monk D, Ricciardelli LA. Three dimensions of the male gender role as correlates of alcohol and cannabis involvement in young Australian men. Psychol Men Masc 2003;4(1):57-69. [doi: 10.1037/1524-9220.4.1.57]
21. Levant RF, Wimer DJ, Williams CM, Smalley KB, Noronha D. The relationships between masculinity variables, health risk behaviors and attitudes toward seeking psychological help. Int J Men Health 2009;8(1):3-21. [doi: 10.3149/jmh.0801.3]
22. Wong YJ, Ho MR, Wang S, Miller IS. Meta-analyses of the relationship between conformity to masculine norms and mental health-related outcomes. J Couns Psychol 2017;64(1):80-93. [doi: 10.1037/cou0000176] [Medline: 27869454]
23. Clarke J, Van Amerom G. A comparison of blogs by depressed men and women. Issues Ment Health Nurs 2008;29(3):243-264. [doi: 10.1080/01612840701869403] [Medline: 18340611]
24. Luxton DD, June JD, Fairall JM. Social media and suicide: a public health perspective. Am J Public Health 2012;102(2):S195-S200. [doi: 10.2105/AJPH.2011.300608] [Medline: 22401525]
25. Aguirre RT, McCoy MK, Roan M. Development guidelines from a study of suicide prevention mobile applications (apps). J Technol Hum Serv 2013;31(3):269-293. [doi: 10.1080/15228835.2013.814750]
26. Cheng Q, Li TM, Kwok CL, Zhu T, Yip PS. Assessing suicide risk and emotional distress in Chinese social media: a text mining and machine learning study. J Med Internet Res 2017;19(7):e243. [doi: 10.2196/jmir.7276] [Medline: 28694239]
27. King KE, Schlichthorst M, Spittal MJ, Phelps A, Pirkis J. Can a documentary increase help-seeking intentions in men? A randomised controlled trial. J Epidemiol Community Health 2017;72(1):92-98. [doi: 10.1136/jech-2017-209502] [Medline: 29101215]

28. Sinnenberg L, Buttenheim A, Padrez K, Mancheno C, Ungar L, Merchant RM. Twitter as a tool for health research: a systematic review. Am J Public Health 2017;107(1):143. [doi: 10.2105/AJPH.2016.303512a] [Medline: 27925832]
29. Berry N, Lobban F, Belousov M, Emsley R, Nenadic G, Bucci S. #WhyWeTweetMH: understanding why people use Twitter to discuss mental health problems. J Med Internet Res 2017 Apr 05;19(4):e107 [FREE Full text] [doi: 10.2196/jmir.6173] [Medline: 28381392]
30. Jashinsky J, Burton SH, Hanson CL, West J, Giraud-Carrier C, Barnes MD, et al. Tracking suicide risk factors through Twitter in the US. Crisis 2014;35(1):51-59. [doi: 10.1027/0227-5910/a000234] [Medline: 24121153]
31. Lachmar EM, Wittenborn AK, Bogen KW, McCauley HL. # MyDepressionLooksLikexamining public discourse about depression on Twitter. JMIR Mental Health 2017;4(4):e43. [doi: 10.2196/mental.8141] [Medline: 29046270]
32. Reavley NJ, Pilkington PD. Use of Twitter to monitor attitudes toward depression and schizophrenia: an exploratory study. PeerJ 2014;2(e647). [doi: 10.7717/peerj.647] [Medline: 25374786]
33. Shepherd A, Sanders C, Doyle M, Shaw J. Using social media for support and feedback by mental health service users: thematic analysis of a twitter conversation. BMC Psychiatry 2015;15(1):29. [doi: 10.1186/s12888-015-0408-y] [Medline: 25881089]
34. Ayers JW, Westmaas JL, Leas EC, Benton A, Chen Y, Dredze M, et al. Leveraging big data to improve health awareness campaigns: a novel evaluation of the great American Smokeout. JMIR Public Health Surveill 2016;2(1):e16 [FREE Full text] [doi: 10.2196/publichealth.5304] [Medline: 27227151]
35. Chung JE. A smoking cessation campaign on Twitter: understanding the use of Twitter and identifying major players in a health campaign. J Health Commun 2016;21(5):517-526. [doi: 10.1080/10810730.2015.1103332] [Medline: 27115179]
36. Lenoir P, Moulahi B, Azé J, Bringay S, Mercier G, Carbonnel F. Raising awareness about cervical cancer using Twitter: content analysis of the 2015# SmearForSmear campaign. J Med Internet Res 2017;19(10):e344. [doi: 10.2196/jmir.8421] [Medline: 29038096]
37. Zalsman G, Hawton K, Wasserman D, van Heeringen K, Arensman E, Sarchiapone M, et al. Suicide prevention strategies revisited: 10-year systematic review. Lancet Psychiatry 2016 Jul;3(7):646-659. [doi: 10.1016/S2215-0366(16)30030-X] [Medline: 27289303]
38. Pirkis J, Rossetto A, Nicholas A, Ftanou M, Robinson J, Reavley N. Suicide prevention media campaigns: a systematic literature review. Health Commun 2017 Nov 30:1-13. [doi: 10.1080/10410236.2017.1405484] [Medline: 29190128]
39. Sensis. 2017. Sensis social media report 2017 URL: https://www.sensis.com.au/asset/PDFdirectory/Sensis-Social-Media-Report-2017.pdfArchived [accessed 2017-12-01] [WebCite Cache ID 6vS2paxDZ]

Abbreviations

ABC: Australian Broadcasting Corporation
CSA: community service announcement

Edited by G Eysenbach; submitted 09.10.17; peer-reviewed by N Bragazzi, S Berrouiguet, D Reidenberg; comments to author 03.11.17; revised version received 04.12.17; accepted 14.12.17; published 15.02.18.

Please cite as:
Schlichthorst M, King K, Turnure J, Sukunesan S, Phelps A, Pirkis J
Influencing the Conversation About Masculinity and Suicide: Evaluation of the Man Up Multimedia Campaign Using Twitter Data
JMIR Ment Health 2018;5(1):e14
URL: http://mental.jmir.org/2018/1/e14/
doi:10.2196/mental.9120
PMID:29449203

Original Paper

Targeted Secure Messages to Facilitate Access to Tobacco Treatment Counseling for Veterans: Feasibility Study

Shaun Shahani[1], DO, MPH; Pearl Korenblit[2], MD; Pauline Thomas[1], MD; Marian R Passannante[3], PhD; Richard Carr[2], PsyD; Lynn Davis[2], LCSW

[1]Rutgers New Jersey Medical School, Newark, NJ, United States

[2]Veterans Affairs New Jersey Health Care System, East Orange, NJ, United States

[3]Rutgers School of Public Health, Newark, NJ, United States

Corresponding Author:
Shaun Shahani, DO, MPH
Rutgers New Jersey Medical School
185 S Orange Ave
Newark, NJ, 07103
United States
Phone: 1 732 445 4636
Email: shaun.shahani@tu.edu

Abstract

Background: Studies show that combining nicotine replacement therapy (NRT) with tobacco treatment counseling is most effective for smoking cessation. However, tobacco treatment counseling has been underutilized across the nation. A secure email message sent to patients already taking NRT was hypothesized to increase the utilization of tobacco treatment counseling among Veterans in New Jersey. Secure messaging for communication between patients and providers was implemented through a web-based password-protected, secure messaging account, where Veterans get notified through their personal email when they have a message awaiting them.

Objective: The main objective of this project was to determine if there was a significant increase in adoption of tobacco treatment counseling among Veterans who received a secure message describing the options for tobacco treatment counseling available to them. Secondary objectives were to demographically characterize Veterans who were and were not enrolled in secure messaging, as well as those who opened or did not open a message. Finally, because the language and content of the messages were changed across project phases, this project also sought to determine (by analysis of response rates) the type of language that was most effective at eliciting a response.

Methods: Over two phases, messages were sent to two samples of Veterans prescribed NRT within the prior 90 days of each phase. In phase 1, one message was sent in December 2015 (message 1). In phase 2, one message was sent in July 2016 (message 2) and the same message (message 3) was resent in August 2016 to persons who did not open message 2. Messages 2 and 3 were more directive than message 1. Response rates to message 1 versus message 2 were compared. A logistic regression analysis determined effect of age and gender on enrollment in secure messaging across both phases. The effectiveness of each phase at increasing tobacco treatment counseling was analyzed using a McNemar test.

Results: Message 2, sent to 423 Veterans, had a significantly higher response rate than message 1, sent to 348 Veterans (18%, 17/93 vs 8%, 6/78, *P*=.04). Phase 2 (ie, messages 2 and 3) significantly increased utilization of tobacco treatment counseling (net increase of six tobacco treatment counseling adopters, *P*=.04), whereas phase 1 (ie, message 1) did not (net increase of two tobacco treatment counseling adopters, *P*=.48). Women (odds ratio [OR] 1.6, 95% CI 1.1-2.3) and those aged 30 to 49 years (compared to other age groups) were more likely to be enrolled in secure messaging. Gender and age were not significant predictors of opening or replying to either message.

Conclusions: Although the effect was small, secure messaging was a useful modality to increase tobacco treatment counseling. Directive content with a follow-up message appeared useful. Female Veterans and/or Veterans aged between 30 and 49 years are more likely to use secure messaging.

(JMIR Ment Health 2018;5(1):e18) doi:10.2196/mental.7957

KEYWORDS

secure messaging; tobacco use; smoking cessation

Introduction

The combination of medication, typically nicotine replacement therapy (NRT), and counseling (whether in person or by telephone) has been shown to be the optimal method for smoking cessation treatment [1-3]. In a counseling session, the smoker's motivation for cessation can be strengthened and he/she can learn about the mechanism and proper usage of the medicine [1]. However, in spite of the benefit of counseling in addition to medication, a majority of smokers attempt to quit without using counseling [1]. This lack of utilization of counseling was also apparent at the VA New Jersey Health Care System (VANJHCS), forming the basis for this project.

Generally, smoking rates are higher in Veterans than non-Veterans (29% vs 24%) in people aged 25 to 64 years [4]. One reason for the underutilization of tobacco treatment counseling at VANJHCS may be Veterans' lack of awareness of the counseling options being offered. At VANJHCS, these options, both of which are facilitated by a certified tobacco counselor, involve either attending weekly group classes or having a one-on-one session (in person or by telephone). In the past, efforts by VANJHCS to reach out to Veterans to inform them about available tobacco treatment counseling were mainly carried out by telephone, requiring excessive effort and time to call Veterans individually, often finding they were not available to be reached by telephone at the time of the call. The implementation of a mass secure email to Veterans already prescribed NRT or Chantix (a medication that helps people to quit smoking) was considered in this project as a more feasible and efficient way to increase awareness and utilization of tobacco treatment counseling in the Veteran population.

The VANJHCS, serving approximately 50,000 New Jersey Veterans, utilizes a system of secure messaging to facilitate communication between patients and providers. Approximately 14,000 Veterans, or 28% of the total Veterans in VANJHCS, are enrolled in secure messaging. Veterans are notified through their personal email when they have a message awaiting them on their password-protected, secure messaging account. One benefit of such a system is that one can, with a single mass email, reach a relatively large number of Veterans and identify how many actually opened the message (ie, clicked on the title of the message to read it).

Use of email communication to promote healthy behaviors has been studied at length [5,6], but not specifically to increase utilization of tobacco treatment counseling. Advantages of email usage in health care include convenience, rapidity of communication, enhanced access, and likely cost-effectiveness [7]. This project evaluated whether messages sent using the secure messaging modality would help to facilitate Veterans' access to behavioral tobacco treatment therapy sessions that are available at VANJHCS. The group of Veterans who were solicited were those already on NRT and other tobacco treatment medications, such as Chantix. The messages provided the Veterans with information on the times of existing tobacco treatment classes being offered at the VA and also gave the Veterans an opportunity to request a telephone call by a tobacco treatment counselor or to call the tobacco treatment counselor directly. In short, the messages were designed to give the Veterans information on how to access the necessary behavioral therapy component of tobacco treatment. Whether or not they were successful in doing so was determined by measuring the proportion of Veterans who utilized the VA-offered counseling after having received the message. Furthermore, because the language and number of messages sent changed across project phases, this project also sought to determine the optimal strategy in regards to increasing counseling adoption rates.

Another analysis performed in this project involved demographically characterizing Veterans who were and were not enrolled in secure messaging, as well as those who opened or did not open a message. Knowing the population being reached by secure messaging can be a vital piece of information because these findings can clue in administrators and providers on whom to target messages to and whom to target for interventions aimed at increasing secure message familiarity and usage.

Methods

Inclusion/Exclusion Criteria

All Veterans in VANJHCS who were currently taking NRT or Chantix were included in the study. "Currently" was defined as within 90 days before each phase because this time frame was expected to identify people who recently initiated or refilled their NRT or Chantix. Veterans taking the drug bupropion were excluded from this study because there are multiple indications for this drug, only one being tobacco treatment.

For the response rate analysis as well as the analysis of the effect of messages on counseling utilization, only those who had been prescribed NRT or Chantix and who were enrolled in secure messaging could be included in the analysis because only those enrolled in secure messaging were sent messages.

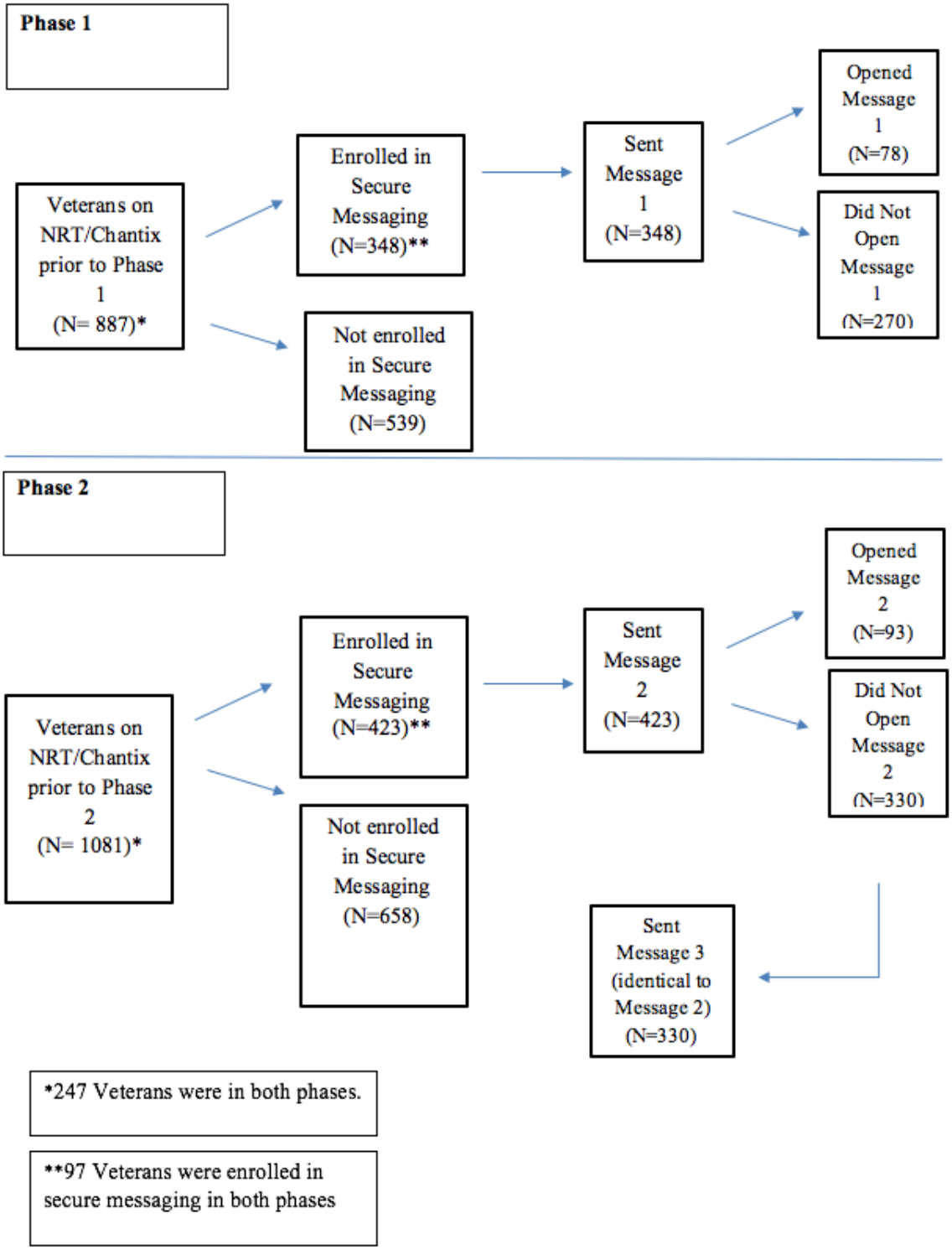
Description of Phases

A total of three secure messages were sent out in two phases. Phase 1 consisted of one message being sent in December 2015 (message 1). Phase 2 consisted of two identical messages being sent in July (message 2) and August (message 3) 2016. Message 3 was sent to every Veteran who was sent but did not open message 2. See Figure 1 for a flowchart illustrating the two project phases. Veterans who were on NRT/Chantix prior to both phases and enrolled in secure messaging in each phase were sent both message 1 and message 2 (with or without message 3 depending on if they opened message 2). The contents of both messages 1 and 2 are provided in Multimedia Appendix 1. The messages were an invitation to attend one of many group tobacco treatment classes offered in the VANJHCS. They also gave the Veteran an opportunity to express interest in receiving individualized phone or in-person counseling by a tobacco counselor.

Message 1 focused on providing information. Veterans were informed about the available tobacco counseling classes, and motivating and supportive language was used. Veterans were not specifically told to respond back with a specific counseling option preference, but they were advised to feel free to contact us so that we could assist them.

Message 2 was more directive. Veterans were given a multiple choice of counseling options and asked (both in the subject line and in the text) to select and then let us know which option they would like to pursue.

Figure 1. Flowchart illustrating both phases of project.



Data Collection

The list of Veterans who were currently on NRT or Chantix (ie, within 90 days prior to each phase) was provided by the pharmacy department at VANJHCS. As explained previously, there were two phases of sending out messages, one in December 2015 and the other in July and August 2016. Before

each of the two phases, a current list (ie, Veterans prescribed NRT or Chantix within the prior 90 days) was obtained. For the demographic analysis, the electronic medical record of each unique Veteran on NRT or Chantix was reviewed to abstract age and gender of the Veteran. Whether each Veteran on NRT or Chantix was enrolled in secure messaging and whether a message was opened or responded to (within 30 days after the message was sent) was identified on the VA internal secure messaging website. "Responding" to a message was defined as replying back to our message with another message within 30 days after our message was sent. Whether or not a Veteran was in counseling within the prior 90 days of each phase was determined from the electronic medical record at the outset of each phase by noting if there was a "smoking cessation note" in their electronic medical record. Whether counseling was adopted after each message was sent was reviewed 1 month following the message by a similar method. All these data were input into an Excel spreadsheet and then imported into SAS for analysis.

Data Analysis

Analysis was done using SAS at an alpha level of .05. The demographic analysis consisted of both bivariate and multivariate analyses. For the bivariate analysis, two-sample *t* tests determined (1) the difference in mean age of Veteran secure messaging enrollees versus nonenrollees and (2) the difference in mean age of enrollees who opened versus did not open each message. Chi-square (in the case of males) and Fisher exact tests (in the case of females due to small sample size) examined whether gender was associated with enrollment in secure messaging or opening a secure message.

For the multivariate analysis, a logistic regression analysis was performed with age and gender as the two covariates studied, and with three binary (yes/no) outcome variables: being enrolled in secure messaging, opening the message (among enrollees), or responding to the message (among message openers). For the latter two outcomes, because the language of messages 1 and 2 were different, the logistic regression was run separately for each message. When considering the outcomes of opening or responding to message 2, Veterans who had also been sent message 1 were excluded to account for any potential effect that receiving message 1 might have had on opening or responding to message 2. For all these outcomes, interaction effects were investigated between gender and age.

In the logistic regression analysis mentioned previously, age was measured first as a continuous variable; however, another logistic regression analysis was run coding age as a categorical variable. This was done because it was noted that secure message enrollment varied markedly by 10-year age group. The 10-year age groups with the highest percent enrollment in secure messaging were ages 30 to 39 (45.6%, 82/180) and 40 to 49 (46.1%, 76/165). Because of the similarity in percent enrollment between these two groups, one 20-year age group, namely 30 to 49 years, was created and used as the reference group to which other 10-year age groups were compared.

To analyze the message response, a two-proportion *z* test was performed to see if the response rate (among message openers) was significantly different between message 1 and message 2. To measure message effect on utilization of tobacco cessation counseling, 1 month after each phase (ie, analyzing message 1 versus both messages 2 and 3 in tandem), a McNemar test analyzed if there was a significant net increase in Veterans entering therapy as a result of opening the message(s). If a Veteran was already in counseling within the prior 90 days of the message, he or she was not counted as a "new" adopter of counseling, whether or not counseling continued after the message was received.

Results

Part 1: Demographic Analysis

Enrollment in Secure Messaging

There were 1721 unique Veterans who had been prescribed NRT: 640 in December only, 834 in July only, and 247 in both periods. Four were not enrolled in secure messaging prior to message 1 but enrolled prior to message 2 and were thus not included in the demographic analysis. The remaining 1717 had the same secure messaging enrollment status for both phases. Table 1 shows that approximately 39% (670/1717) of Veterans, who had been prescribed NRT or Chantix, were enrolled in secure messaging.

Of the 1717 Veterans, 92.02% (n=1580) were male. Age was available for 1586 Veterans and ranged from 22 to 92 years. The mean age was 56.4 (SD 13.5) years, and the median was 59 years. Of the 1586 Veterans, 63.68% (n=1010) were in the age group 50 to 69 years, (39.22%, 622/1586 aged 60-69 years and 24.46%, 388/1586 aged 50-59 years). Of the remaining 36.32% (576/1586), 21.75% (345/1586) were 30 to 49 (11.35%, 180/1586 aged 30-39 years and 10.40%, 165/1586 aged 40-49 years), and 14.56% (231/1586) were divided between 80 years and older (1.83%, 29/1586), 70 to 79 years (8.26%, 131/1586), and 20 to 29 years (4.48%, 71/1586). The mean age for women was 48.4 (SD 11.3) years compared with 57.0 (SD 13.5) years for men.

Mean age of secure message enrollees was 2 years younger than nonenrollees (mean 55.3, SD 13.0 years vs mean 57.0, SD 13.8 years, P=.01). In all, 53.2% (75/141) of women were enrolled in secure messaging versus 37.75% (595/1576) of men (P<.001).

Opening and Responding to Messages

As shown in Table 2, among those enrolled in secure messaging with available age data, the mean ages of those who opened and did not open message 1 was not significantly different (mean 54.0, SD 13.8 years for openers, mean 54.9, SD 12.9 years for nonopeners, P=.62). Similarly, the mean ages of those who opened and did not open message 2 was not significantly different (mean 56.3, SD 11.9 years for openers, mean 55.9, SD 12.7 years for nonopeners, P=.80). This nonsignificance was retained after excluding the 85 Veterans (with available age data) who were sent message 1.

Table 1. Secure messaging enrollment status of Veterans (total).

Enrollment status	n (%)
Enrolled in secure messaging	670 (39.02)
Not enrolled in secure messaging	1047 (60.98)
Total	1717

Table 2. Age of Veterans who opened and did not open messages 1 and 2.

Message	Opened the message		Did not open the message		*P* value
	n (%)	Age (years), mean (SD)	n (%)	Age (years), mean (SD)	
Message 1 (n=313)	68	54.0 (13.8)	245	54.9 (12.9)	.62
Message 2 total (n=375)	85	56.3 (11.9)	290	55.9 (12.7)	.80
Message 2 excluding 85 Veterans sent message 1 (n=290)	71	55.3 (12.1)	219	56.0 (13.0)	.69

Table 3. Gender of Veterans who opened and did not open messages 1 and 2.

Message and gender	Opened the message, n (%)	Did not open the message, n (%)	*P* value
Message 1 (n=348)			.41
Male	67 (21.8)	241 (78.2)	
Female	11 (28)	29 (72)	
Message 2 total (n=423)			.85
Male	84 (22.1)	296 (77.9)	
Female	9 (21)	34 (79)	
Message 2 excluding 97 Veterans sent message 1 (n=326)			.73
Male	68 (23.1)	223 (76.9)	
Female	9 (26)	26 (74)	

In all, 78 of the 348 Veterans sent message 1 opened it (22.4%). As shown in Table 3, men and women were equally likely to open message 1 (21.8%, 67/308 vs 28%, 11/40, *P*=.41). For message 2, 93 of the 423 Veterans who were sent the message opened it (22.0%). Men and women were equally likely to open this message (22.1%, 84/380 vs 21%, 9/43, *P*=.85). This nonsignificance was retained after excluding the 97 Veterans who were sent message 1.

The proportion of Veterans who responded to message 1 among those who opened message 1 (6/78, 8%) was significantly different from the proportion who responded to message 2 among those who opened message 2 (17/93, 18%, *P*=.04). The proportion of Veterans who opened message 1 (22.4%, 78/348) was not significantly different from the proportion that opened message 2 (22.0%, 93/423, *P*=.89).

Of the 19 responses to messages 2 and 3, when Veterans did choose an option for counseling, they favored receiving a phone call (5/19) or attending group in addition to receiving a phone call (1/19) more so than attending group alone (0/19). Of the remaining 13 Veterans not choosing a counseling option, five indicated that they had already quit, six indicated they would like to quit on their own without the aid of counseling, one Veteran indicated that he is already in group counseling, and one Veteran responded by asking if he could use his nicotine lozenges with his dentures. One of the Veterans who said he would like to quit on his own also used the opportunity of being sent a message to request a refill for his nicotine gum.

Logistic Regression Analyses

As shown in Table 4, when coding age as a continuous variable, female gender (OR 1.61, 95% CI 1.10-2.35), but not age (OR 0.99, 95% CI 0.99-1.00), was a significant predictor of being enrolled in secure messaging. However, once a Veteran was enrolled in secure messaging, neither gender nor age were significant predictors of opening either message 1 or message 2 (analysis conducted separately for both messages). Also, once a Veteran opened a message, whether he/she responded was independent of age and gender. There were also no significant interaction effects between age and gender for all outcomes mentioned previously (not shown).

Table 4. Logistic regression: odds ratios (with 95% confidence intervals) for the effect of age (as continuous variable) and female gender on different outcomes.

Variable	Outcomes, OR (95% CI)						
	Being enrolled in secure messaging (yes/no)	Opening message 1 (yes/no)	Opening message 2 (yes/no)	Opening any message[a] (yes/no)	Responding to message 1 (yes/no)	Responding to message 2 (yes/no)	Responding to any message[b] (yes/no)
Female gender	1.61 (1.10-2.35)	1.12 (0.47-2.68)	1.06 (0.43-2.65)	1.09 (0.58-2.04)	78.31 (0.75-999.99)	1.14 (0.11-11.34)	2.49 (0.41-15.08)
Age	0.99 (0.99-1.00)	0.99 (0.98-1.02)	1.00 (0.98-1.02)	1.00 (0.98-1.01)	1.18 (1.00-1.39)	1.03 (0.97-1.09)	1.05 (0.99-1.11)

[a]Among Veterans who received only message 1 or only message 2 (n=603).

[b]Among Veterans who opened only message 1 or only message 2 (n=139).

Table 5. Logistic regression: odds ratios (with 95% confidence intervals) for the effect of age category and female gender on enrollment in secure messaging.

Covariates	Enrolled in secure messaging (yes/no), OR (95% CI)
Female gender	1.57 (1.07-2.30)
Age group (years)[a]	
20-29	0.41 (0.23-0.73)
50-59	0.73 (0.54-0.98)
60-69	0.74 (0.57-0.97)
70-79	0.62 (0.40-0.94)
≥80	0.09 (0.02-0.40)

[a]Reference category: 30-49 years.

The preceding results pertain to age measured as a continuous variable. However, after coding age as a categorical variable with the age group 30 to 49 years as the reference category (Table 5), significance was also found for the effect of female gender on secure messaging enrollment (OR 1.57, 95% CI 1.07-2.30). Additionally, the following age groups were significantly less likely to be enrolled in secure messaging compared to those aged 30 to 49 years: 20 to 29 years (OR 0.41, 95% CI 0.23-0.73), 50 to 59 years (OR 0.73, 95% CI 0.54-0.98), 60 to 69 years (OR 0.74, 95% CI 0.57-0.97), 70 to 79 years (OR 0.62;, 95% CI 0.40-0.94), and 80 years or older (OR 0.09, 95% CI 0.02-0.40). After coding age as a categorical variable, odds ratios for opening and responding to either message did not change dramatically from before and are thus not included in this report.

Part 2: Analysis of Effect of Message on Increasing Counseling Utilization

McNemar tests were run after each phase of messaging to observe if the net increase in counseling adopters significantly increased. For message 1, although 78 Veterans opened the message, 10 charts were not accessible and were thus conservatively assumed to not have adopted counseling. Among the 68 (with accessible charts) who opened the message, only two additional Veterans adopted counseling (net increase from 4 to 6, P=.48).

Phase 2 (423 total Veterans sent message 2 or both messages 2 and 3) consisted of message 2 (93 message openers) and message 3 (21 additional message openers), for a total of 114 message openers for the entire phase. Of these, eight had charts that were not accessible and were thus conservatively assumed to not have adopted counseling. Among 106 Veterans with readily accessible charts, six new Veterans adopted counseling and this was statistically significant (net increase from 11 to 17, P=.04). Five of these six counseling adopters did so after having opened message 2, whereas one of the six adopted counseling after opening message 3. None of these six counseling adopters received message 1.

Discussion

This study examined use of secure messaging in VANJHCS to increase utilization of tobacco treatment counseling. A directive message (plus its identical follow-up message) resulted in a small but significantly greater number of new counseling enrollees. Female gender was found to be a significant predictor of enrollment in secure messaging even when controlling for age. Although not entirely comparable, this finding may be related to conclusions from previous literature that have found that women utilize health care more than men [8,9]. Messages directed toward females (eg, breast cancer screening reminders or osteoporosis screening reminders) might be more amenable to secure messaging.

Although age when measured as a continuous variable was not a significant predictor of enrollment in secure messaging, after combining age groups with similar enrollment percentages and adjusting for gender, those in the age group with the highest percentage of enrollment (30-49 years) were more likely to be enrolled in secure messaging than other age groups. Also, except

for the 20 to 29 age group, there does seem to be an association between increasing age (especially after age 50) and lack of enrollment in secure messaging. Secure messaging might not be as viable an option for those older than age 50. Future studies should attempt to identify specific barriers to using secure messaging in the older population. The association between increasing age and lack of enrollment was likely not noticed at first (when age was measured as a continuous variable) because of the 20 to 29 years age group having a disproportionate number of nonenrollees despite their young age. Determining reasons for lack of enrollment in this age group is a subject for further research. A notable limitation regarding the conclusions reached regarding demographic characteristics associated with secure messaging enrollment is that our sample only consisted of Veterans on NRT, which may or may not be representative of the population of Veterans who do not use NRT. Moreover, because of lack of access to data such as education level and socioeconomic status, we were unable to analyze the effect of these other factors on secure messaging enrollment.

The increase in tobacco counseling encounters was not significant after the first message was sent out (phase 1), but it was significant after the second and third messages (phase 2). Additionally, because none of the counseling adopters after the second and third messages had received message 1, this was a true measure of the effect of these messages. However, although being statistically significant, the net increase in counseling utilization was very small (only six Veterans). This is likely because of the low overall enrollment in secure messaging and the fact that the rate of opening the messages (for both the first and second phases) was low. We must look beyond demographic variables to explain this latter phenomenon because it was determined that age and gender were not statistically significant factors associated with opening a message. Future studies should explore other reasons why Veterans did not open the messages, such as uninteresting subject lines, lack of interest or motivation to click on a message having to do with tobacco (subject lines for both messages included the word “tobacco”), infrequent email checking, receiving too many emails, or lack of technical skill required to open a message in one’s inbox. Compared to message 1, the increase in response rate to message 2 (which was more directive in nature and contained a multiple-choice option that Veterans were requested to choose from) may have played a part in the significant increase in tobacco counseling utilization after phase 2. Another implication is that the sending of an identical follow-up message to those who did not open a preliminary message, as was done in phase 2, may be an effective approach. A limitation of our study was the seasonal difference in the timing of the phases (winter for phase 1, summer for phase 2), which may have led to the increased response rate to message 2 compared with message 1. Future studies should attempt to control for seasonal variation by comparing response rates to messages that were sent in the same season (of consecutive years).

In trying to determine which phase was associated with increased tobacco counseling enrollment, there were notable limitations in both the choice of our outcome measure and predictor variables. Regarding outcomes, an obvious limitation lies in what we used as our outcome measure, namely enrollment in tobacco cessation counseling, with “success” being defined as a net increase in enrollment. It would have been informative if we had an outcome measure on actual quit rates, which although not used in this study due to a lack of access to that data, would be advantageous to include in future studies. As far as addressing what drove Veterans to adopt tobacco cessation counseling, in our study we focused on the attributes of the messages themselves (ie, comparing differing content and number of messages sent in phase 1 vs phase 2). In future studies, among those who do adopt counseling, it would be helpful to also look at individualistic factors that may predispose one to adopt counseling, such as baseline intention of quitting and prior history of quitting.

When given several options for counseling (as was the case in messages 2 and 3), Veterans preferred telephone counseling (either alone or in addition to group), although the number of responses was too small to establish significance. No Veteran opted for attending group alone. Knowing that Veterans might be more inclined to utilize telephone counseling can clue in providers to offer this as an option to Veterans. An unexpected benefit from secure messaging was the facilitation of communication between patient and provider. Two Veterans utilized secure messaging as an opportunity to serve other related health interests, such as clarifying if dentures could be worn while using lozenges in the case of one Veteran or to ask for a refill on his nicotine gum in another. Although these Veterans may have had another opportunity to address these issues in the future, secure messaging provided them with a quick and convenient way to communicate these concerns with someone who was willing to listen.

The increases in tobacco counseling utilization in this study were achieved by using an economical and efficient approach (ie, secure messaging). An argument can be made that the cost-effectiveness and convenience of secure messaging make it a favorable action when compared with other alternatives of outreach, such as telephone calling each smoker who is on NRT or Chantix, which may not be practical given limited time and resources. However, the total number adopting counseling was quite small in this initial feasibility study and further research is needed to better understand both how to increase rates of enrollment in secure messaging and also to improve the effectiveness of messages.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Content of the messages.

[PDF File (Adobe PDF File), 32KB - mental_v5i1e18_app1.pdf]

References

1. Cummings KM, Hyland A. Impact of nicotine replacement therapy on smoking behavior. Annu Rev Public Health 2005;26:583-599. [doi: 10.1146/annurev.publhealth.26.021304.144501] [Medline: 15760302]
2. Zhu SH, Tedeschi G, Anderson CM, Rosbrook B, Byrd M, Johnson CE, et al. Telephone counseling as adjuvant treatment for nicotine replacement therapy in a "real-world" setting. Prev Med 2000 Oct;31(4):357-363. [doi: 10.1006/pmed.2000.0720] [Medline: 11006060]
3. Molyneux A, Lewis S, Leivers U, Anderton A, Antoniak M, Brackenridge A, et al. Clinical trial comparing nicotine replacement therapy (NRT) plus brief counselling, brief counselling alone, and minimal intervention on smoking cessation in hospital inpatients. Thorax 2003 Jun;58(6):484-488 [FREE Full text] [Medline: 12775857]
4. Centers for Disease Control and Prevention. 2016. Burden of tobacco use in the US URL: https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html [accessed 2018-02-25] [WebCite Cache ID 6xV0YvPtC]
5. Walters ST, Wright JA, Shegog R. A review of computer and Internet-based interventions for smoking behavior. Addict Behav 2006 Feb;31(2):264-277. [doi: 10.1016/j.addbeh.2005.05.002]
6. Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. J Med Internet Res 2009 May 14;11(2):e16. [doi: 10.2196/jmir.1138]
7. Car J, Sheikh A. Email consultations in health care: 1—scope and effectiveness. BMJ 2004 Aug 19;329(7463):435-438. [doi: 10.1136/bmj.329.7463.435]
8. Owens G. Gender differences in health care expenditures, resource utilization, and quality of care. J Manag Care Pharm 2008;14(3 Supp A):2-6.
9. Bertakis KD, Azari R, Helms LJ, Callahan EJ, Robbins JA. Gender differences in the utilization of health care services. J Fam Pract 2000 Feb;49(2):147-152. [Medline: 10718692]

Abbreviations

NRT: nicotine replacement therapy
VANJHCS: Veterans Affairs New Jersey Health Care System

Edited by G Eysenbach; submitted 21.09.17; peer-reviewed by D Cheung, K Bold, JC Chen; comments to author 19.10.17; revised version received 26.11.17; accepted 12.02.18; published 05.03.18.

Please cite as:
Shahani S, Korenblit P, Thomas P, Passannante MR, Carr R, Davis L
Targeted Secure Messages to Facilitate Access to Tobacco Treatment Counseling for Veterans: Feasibility Study
JMIR Ment Health 2018;5(1):e18
URL: http://mental.jmir.org/2018/1/e18/
doi:10.2196/mental.7957
PMID:29506969

Short Paper

Effect of a Gender-Tailored eHealth Weight Loss Program on the Depressive Symptoms of Overweight and Obese Men: Pre-Post Study

Myles D Young[1], PhD, BPsych; Philip J Morgan[1], PhD, BEd

Priority Research Centre in Physical Activity and Nutrition, University of Newcastle, Callaghan, Australia

Corresponding Author:
Myles D Young, PhD, BPsych
Priority Research Centre in Physical Activity and Nutrition
University of Newcastle
ATC301
University Drive
Callaghan, 2308
Australia
Phone: 61 249216096
Email: myles.young@newcastle.edu.au

Abstract

Background: Obesity and depression are of two of the largest contributors to the global burden of disease in men. Although lifestyle behavior change programs can improve participants' weight and depressive symptoms, the evidence is limited by a lack of male participants and a reliance on face-to-face treatment approaches, which are not accessible or appealing for many men.

Objective: This study examined the effect of a gender-tailored electronic health (eHealth) program on the depressive symptoms of a community sample of overweight and obese men with or without depression. A secondary aim was to determine whether the eHealth, self-directed format of the program was a feasible and acceptable treatment approach for the subgroup of men with depression at baseline.

Methods: In total, 209 overweight/obese men from the Hunter Region of Australia were assessed before and after completing a self-administered eHealth weight loss program over 3 months. To increase engagement, most program elements were socio-culturally targeted to appeal specifically to men and included printed materials, a DVD, motivational text messages, online- or app-based self-monitoring, and other weight loss tools (eg, pedometer). Depressive symptoms were measured with the validated 8-item Patient Health Questionnaire (PHQ-8). Program feasibility and acceptability were assessed with a process questionnaire plus recruitment and retention rates. Changes in depressive symptoms and weight were examined using intention-to-treat linear mixed models, adjusted for the centered baseline score and other covariates. Effect sizes were estimated with Cohen's d.

Results: At baseline, the mean weight and age of the sample was 105.7 kg (standard deviation [SD] 14.0) and 46.6 years (SD 11.3), respectively. Overall, 36 men (36/209, 17.2%) were experiencing depression (PHQ-8 score ≥10). Retention rates were comparable between men with and without depression (32/36, 88.9% vs 145/173, 83.8%; *P*=.44). At posttest, depressive symptoms had reduced by 1.8 units (95% CI 1.3 to 2.3; *P*<.001; d=0.5) for the whole sample. These improvements were particularly notable in the subgroup of men with depression (-5.5 units; *P*<.001; d=1.0) and 72.2% (26/36) of this subgroup no longer met the criterion for depression at posttest. A corresponding, albeit smaller, intervention effect on depressive symptoms was also observed in men without depression (-1.0 units; *P*<.001; d=0.4). The overall intervention effect on weight was -4.7 kg (d=1.3), which did not vary significantly by depression status. Program acceptability, feasibility, and online engagement metrics were also comparable between men with and without depression.

Conclusions: A gender-tailored eHealth lifestyle program generated short-term improvements in the mental health of overweight and obese men, particularly for men with depression at baseline. Despite receiving no personalized support, men with depression reported high levels of satisfaction and engagement with the program. As such, a longer-term controlled trial testing an adapted version of the program for this subgroup is warranted.

Trial Registration: Australian New Zealand Clinical Trials Registry: ACTRN12612000749808; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=362575 (Archived by WebCite at http://www.webcitation.org/6wJvbRsNW)

(JMIR Ment Health 2018;5(1):e1) doi:10.2196/mental.8920

KEYWORDS

male; weight loss; depression; behavior change; obesity; gender-sensitive

Introduction

Obesity and major depressive disorder, henceforth referred to as depression, are two of the largest global health concerns in men [1,2]. In addition, the two conditions are reciprocally associated [3], with the presence of obesity increasing the risk of depression, and vice versa. In Australia, 70.1% of men are overweight/obese [4] and up to 20% of these men may also be experiencing depression [5]. Although both conditions also affect women, men are much less likely to seek help [6,7], and men also experience unique health consequences. For example, men are more likely to store excess fat abdominally, which increases their risk of chronic disease [8], and are three times more likely to die by suicide [9]. As such, effective and scalable programs are urgently needed to reduce rates of obesity and depression in men.

Encouragingly, behavior change programs have shown initial efficacy to generate clinically meaningful improvements in participants' body weight [10] and depressive symptoms [11]. However, the evidence-base is undermined by a lack of men, who represent 27% of participants in behavioral weight loss trials [12] and 20% in trials where depression is a key outcome [11]. Many previous programs have also included multiple in-person consultations, which reduce program accessibility and appeal for many men [7,13].

The *Self-Help, Exercise and Diet using Information Technology* (SHED-IT) program is an electronic health (eHealth) weight loss intervention that is socio-culturally tailored to appeal specifically to men [14-16]. While substantially less intensive than previous programs [6,17], the program has assisted men to achieve clinically meaningful improvements in weight and multiple health behaviors [15]. However, the impact of the program on men's mental health has not been well established. Although the program has been tested in an efficacy trial (SHED-IT Weight Loss RCT [14]) and an effectiveness trial (SHED-IT Community RCT [15]), these studies did not assess men's depressive symptoms. In addition, while eHealth programs have been flagged as a promising treatment for men with depression [18], little research has examined men's perceptions of these programs; particularly those relating to lifestyle modification.

Thus, the primary aim of the current study was to examine the effect of the SHED-IT program on the depressive symptoms of a community sample of overweight and obese men with or without depression. A secondary aim was to determine whether program engagement and satisfaction metrics were comparable between men with and without depression.

Methods

Study Design

The data for this investigation were sourced from the SHED-IT weight loss maintenance trial, which has been published elsewhere [19,20]. Briefly, the study included 209 overweight/obese men from the Hunter Region of Australia who were recruited via a university media release [20]. Eligibility criteria were: (1) age 18-65 years old, (2) body mass index 25-40 kg/m^2, (3) Internet and mobile phone access, and (4) <5% weight loss in previous 6 months. The current study reports data from the initial weight loss phase of the trial (pre-post design), in which 209 men received the SHED-IT Weight Loss Program for 3 months before being randomized into one of two weight loss maintenance conditions. The study received ethics approval from the University of Newcastle's Human Research Ethics Committee and was prospectively registered (ACTRN12612000749808).

The SHED-IT Program

All men received the SHED-IT program, which was a self-administered eHealth program that included no personalized intervention components. The program consisted of: (1) the *SHED-IT Weight Loss Handbook* and *Weight Loss Log Book for Men*, (2) the *SHED-IT Weight Loss DVD for Men*, (3) self-monitoring tools (ie, tape measure, pedometer), and (4) weekly motivational text messages (standardized). During the program men were advised to self-monitor their physical activity and diet using the freely available CalorieKing Australia website [21] or MyFitnessPal app [22] to create a 2000 kilojoule energy deficit on most days. After receiving the resource pack and an instruction sheet, participants were not provided with additional support during the intervention period.

To increase engagement, most elements were socio-culturally targeted for men, with attention given to both surface-structure components (eg, male-specific pictures and research findings) and deep-structure, value-based components (eg, humor, frank and realistic communication). The program taught men how to lose weight sustainably, without eliminating valued discretionary choices (eg, beer). Extensive details on program development and components are provided elsewhere [20].

Measures

Depressive symptoms were measured with the validated 8-item Patient Health Questionnaire (PHQ-8) [23], with men indicating how often in the past two weeks they experienced a range of symptoms associated with major depression (range=0-24). Following established guidelines [24], PHQ-8 scores ≥10 were used to indicate the presence of depression. In a validation study, 88% of people with major depression reported a PHQ-8 score >10 and 88% of people without major depression reported a PHQ-8 score <10 [23]. Weight was measured without shoes on a digital scale to 0.01 kg. In addition to recruitment and retention

rates, program satisfaction metrics were collected using a revised process evaluation questionnaire, which was originally developed for use in a previous study [15]. In the current trial, the questionnaire also included new questions relating to engagement with online program components, which were developed specifically for this study.

Analyses

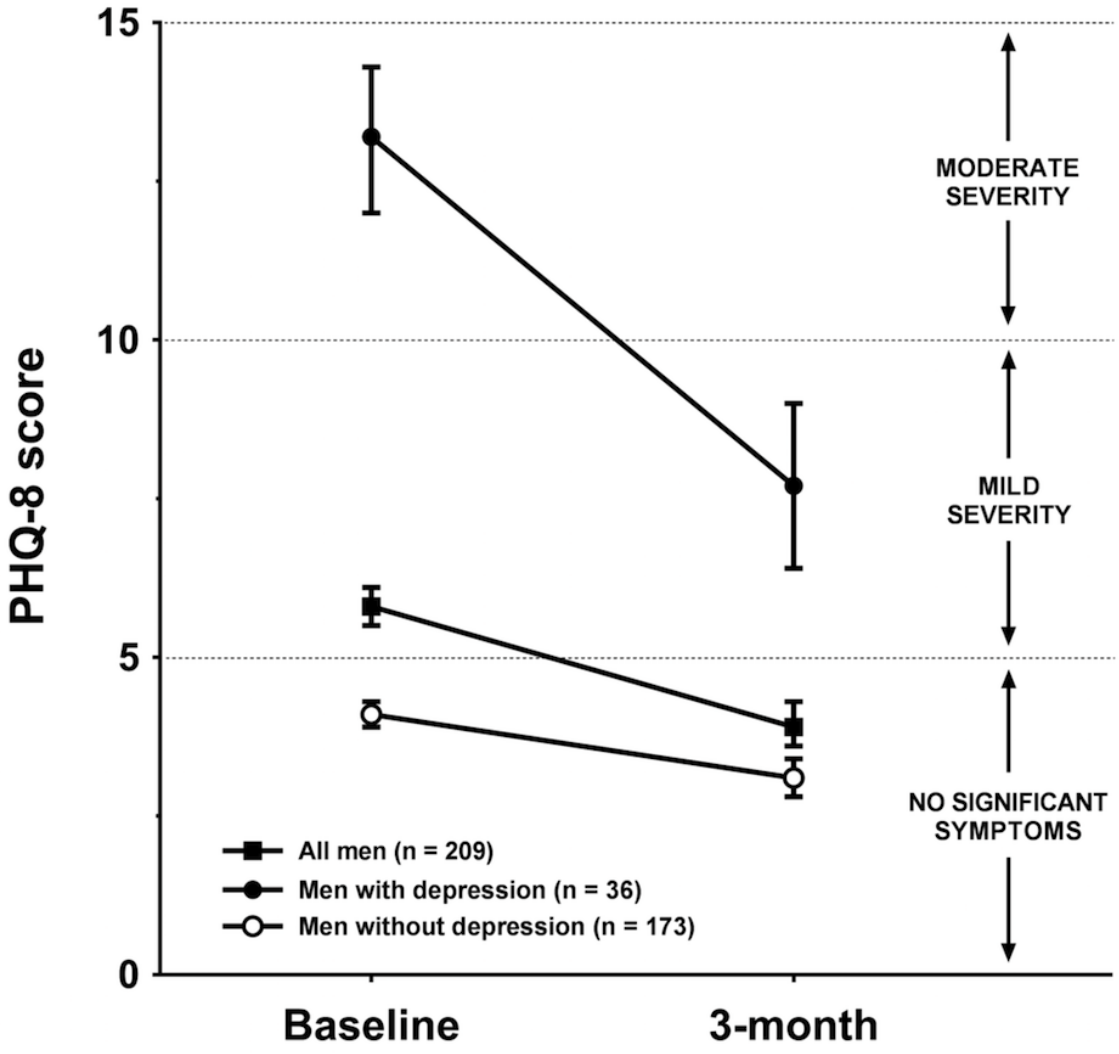
All analyses were conducted in IBM SPSS Statistics 22 (Armonk, NY; IBM Corp). Changes in depressive symptoms and weight were examined using linear mixed models, and adjusted for the centered baseline score and the following covariates: age, socio-economic status, physical activity (steps/day), energy intake (kilojoules/day), and risky alcohol consumption. Linear mixed models are consistent with an intention-to-treat approach as they model missing responses with a likelihood-based analysis that includes all available data. Effect sizes were represented with Cohen's d (mean change/standard deviation [SD] of change). Differences between men with and without depression for categorical outcomes were assessed with Chi-square tests.

Results

Baseline Characteristics and Participant Flow

As reported elsewhere [19], 209 of 236 men who met the study's eligibility criteria were enrolled after returning consent. The mean weight and age of the sample were 105.7 kg (SD 14.0) and 46.6 years (SD 11.3), respectively. Overall, 36 men (36/209, 17.2%) reported comorbid depression at baseline. Although no incentives/reimbursements were offered for attending assessments, the posttest retention rate was 84.7% (177/209). A greater proportion of men with depression attended the posttest assessment (32/36, 88.9%) compared to those without (145/173, 83.8%), but the difference was not significant (χ^2=0.6; degrees of freedom=1; *P*=.44).

Figure 1. Intention-to-treat analysis of changes in depression symptoms by baseline depression status for overweight and obese men in the SHED-IT trial.



Program Effect on Depressive Symptoms and Weight

As seen in Figure 1, men with depression reported a substantial decrease in depressive symptoms during the study (adjusted mean difference: -5.5 units, 95% CI -7.2 to -3.8; d=1.0). Consequently, 72.2% (26/36) of these men no longer met the criterion for depression at posttest. A corresponding, albeit smaller, intervention effect on depressive symptoms was also observed in men without depression at baseline (adjusted mean difference: -1.0 units, 95% CI -1.4 to -0.6; d=0.4). Overall, these changes represented a mean decrease in depressive symptoms of 1.8 units (95% CI 1.3 to 2.3; d=0.5) for the sample. The overall intervention effect on weight was -4.7 kg (95% CI -5.2 to -4.2; d=1.3), which did not vary significantly by depression status.

Program Acceptability and Online Engagement

No significant differences were detected between men with and without baseline depression for the program acceptability questions included in the posttest process evaluation (Table 1). Overall, 82.7% (24/29) of the men with depression who completed the process evaluation reported that the program provided them with sufficient support to lose weight, and 93.1% (27/29) indicated they would recommend the program to their friends. The men also reported high levels of agreement that the program resources were enjoyable to read (23/29, 79.3%) and watch (24/29, 82.7%).

Usage rates for the online program components were comparable between men with and without depression (Table 2). Of the 82.8% (24/29) of men with depression who accessed the online components, the median self-reported usage rates were 4 x 10-minute visits/week for the CalorieKing website and 3 x 5-minute visits/week for the MyFitnessPal app, which aligned with program recommendations.

Table 1. Program satisfaction indicators from men with and without depression at baseline.

Process evaluation questions	Agree/Strongly Agree, n (%)			*P* value
	Men with depression (n=29)	Men without depression (n=126)	Total[a] (N=155)	
SHED-IT program				
The SHED-IT program provided me with the support I needed to lose weight	24 (82.8)	114 (90.5)	138 (89.0)	.23
The SHED-IT program corrected some wrong beliefs I had about physical activity, nutrition, and weight loss	23 (79.3)	88 (69.8)	111 (71.6)	.31
I now have a much better understanding of energy balance and weight loss	27 (93.1)	110 (87.3)	137 (88.4)	.38
I would recommend SHED-IT to my friends	27 (93.1)	119 (94.4)	146 (94.2)	.78
CalorieKing website				
The website was easy to understand	20 (69.0)	81 (64.3)	101 (65.2)	.93
Recording my daily food and exercise on the website was time consuming	17 (58.6)	61 (48.4)	78 (50.3)	.50
The website was a valuable tool to help me understand how to lose weight	17 (58.6)	78 (61.9)	95 (61.3)	.45
Other resources				
The Weight Loss Handbook for Blokes was enjoyable to read	23 (79.3)	87 (69.0)	110 (71.0)	.41
The Weight Loss DVD for Blokes was enjoyable to watch	24 (82.8)	86 (68.3)	110 (71.0)	.22
The DVD helped me to understand the weight loss fundamentals	24 (82.8)	91 (72.2)	115 (74.2)	.43

[a]Total number of participants who attended the posttest assessment and completed the process evaluation (155/209, 74.2% of baseline sample).

Table 2. Men's engagement with the online components of the SHED-IT weight loss program.

Online engagement indicators	Men with depression (n=29)	Men without depression (n=126)	Total (N=155)
Online engagement, n (%)			
Accessed CalorieKing website	21 (72.4)	96 (76.2)	117 (75.5)
Accessed MyFitnessPal app	7 (24.1)	22 (17.5)	29 (18.7)
Accessed website or app	24 (82.8)	103 (81.7)	127 (81.9)
CalorieKing usage [a], median (inter-quartile range)			
Visits/week	4 (7)	3 (4)	3 (4)
Duration/visit (minutes)	10 (20)	10 (10)	10 (10)
MyFitnessPal usage [a], median (inter-quartile range)			
Visits/week	3 (6)	3 (14)	3 (10)
Duration/visit (minutes)	5 (12)	5 (5)	5 (6)

[a]Self-report estimate from participants who accessed each online component.

Discussion

This study revealed that an eHealth weight loss program designed specifically for men concurrently and significantly reduced men's weight and depressive symptoms. Although a recent review determined that lifestyle modification could effectively reduce depressive symptoms [11], 80% of participants in the review were female, 58% of included studies recruited females only, almost all programs were delivered in a face-to-face group format, and no programs were socio-culturally tailored for men [11]. Thus, the current findings represent an important contribution to the literature.

Despite the self-administered nature of SHED-IT, the intervention effect on men's depressive symptoms was comparable to those observed in more intensive interventions [11]. Furthermore, while depression is often characterized by feelings of worthlessness and apathy, men with depression in the current study reported comparable levels of program satisfaction and engagement to men without depression, despite receiving no personal support. Notably, the clinical improvements observed in this subgroup were similar to those achieved in other psychological treatments, including cognitive-behavioral therapy [25], in which participants can attend up to 16 sessions over 3-4 months. The current effect size for men with depression (d=1.0) was also comparable to effects observed in therapist-guided eHealth interventions for depression (d=0.6-1.9) and superior to previous self-guided eHealth interventions (d=0.3-0.7) [26]. In previous studies, SHED-IT participants reported medium-to-large improvements in key outcomes linked to depression in men [15], including physical activity [27] and risky alcohol consumption [28], which may partially explain these positive findings.

This study has some limitations to acknowledge. Although previous studies have established the effectiveness of the SHED-IT program over a control group [15], this pre-post evaluation was the first to assess depressive symptoms. As such, the unique impact of the program over other variables (eg, regression to the mean) could not be quantified. Furthermore, as depressive symptoms were a secondary outcome of the overall trial and the data were collected over a relatively short time frame, these results should be interpreted with caution and subject to examination in a fully-powered trial. Despite this, the study provided encouraging indicators for the potential of gender-tailored eHealth lifestyle programs to engage and improve the mental health of overweight and obese men in the short-term. Given the particular appeal and efficacy of the program for men with depression, a longer-term controlled trial testing a version of the program specifically tailored for this subgroup is warranted.

Acknowledgments

This study was funded by the Hunter Medical Research Institute's Thomson Family Healthy Lifestyles Grant and Greaves Family Early Career Support Grant. The funding agency did not have any input into the design or conduct of the study, the collection, management, analysis, or interpretation of data, the preparation, review, or approval of the manuscript, or the decision to submit the manuscript for publication.

Conflicts of Interest

None declared.

References

1. Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2014 Aug 30;384(9945):766-781. [doi: 10.1016/S0140-6736(14)60460-8] [Medline: 24880830]
2. GBD 2015 DALYs and HALE Collaborators. Global, regional, and national disability-adjusted life-years (DALYs) for 315 diseases and injuries and healthy life expectancy (HALE), 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016 Dec 08;388(10053):1603-1658 [FREE Full text] [doi: 10.1016/S0140-6736(16)31460-X] [Medline: 27733283]
3. Luppino FS, de Wit LM, Bouvy PF, Stijnen T, Cuijpers P, Penninx BWJH, et al. Overweight, obesity, and depression: a systematic review and meta-analysis of longitudinal studies. Arch Gen Psychiatry 2010 Mar;67(3):220-229. [doi: 10.1001/archgenpsychiatry.2010.2] [Medline: 20194822]
4. Australian Bureau of Statistics. 2015 Aug 12. 4364.0.55.001 - National Health Survey: First Results, 2014-2015 URL: http://www.abs.gov.au/ausstats/abs@.nsf/mf/4364.0.55.001 [WebCite Cache ID 6tIEUljYB]
5. Carey M, Small H, Yoong SL, Boyes A, Bisquera A, Sanson-Fisher R. Prevalence of comorbid depression and obesity in general practice: a cross-sectional survey. Br J Gen Pract 2014 Mar;64(620):e122-e127 [FREE Full text] [doi: 10.3399/bjgp14X677482] [Medline: 24567650]
6. Robertson C, Archibald D, Avenell A, Douglas F, Hoddinott P, van Teijlingen E, et al. Systematic reviews of and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men. Health Technol Assess 2014 May;18(35):v-vi, xxiii [FREE Full text] [doi: 10.3310/hta18350] [Medline: 24857516]
7. Möller-Leimkühler AM. Barriers to help-seeking by men: a review of sociocultural and clinical literature with particular reference to depression. J Affect Disord 2002 Sep;71(1-3):1-9. [Medline: 12167495]
8. Lovejoy JC, Sainsbury A, Stock Conference 2008 Working Group. Sex differences in obesity and the regulation of energy homeostasis. Obes Rev 2009 Mar;10(2):154-167. [doi: 10.1111/j.1467-789X.2008.00529.x] [Medline: 19021872]
9. Australian Bureau of Statistics. 3303.0 - Causes of death, Australia 2015. 2017 Sep 27. URL: http://www.abs.gov.au/ausstats/abs@.nsf/mf/3303.0 [WebCite Cache ID 6tIDOHmUJ]
10. Franz MJ, VanWormer JJ, Crain AL, Boucher JL, Histon T, Caplan W, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc 2007 Oct;107(10):1755-1767. [doi: 10.1016/j.jada.2007.07.017] [Medline: 17904936]
11. Fabricatore AN, Wadden TA, Higginbotham AJ, Faulconbridge LF, Nguyen AM, Heymsfield SB, et al. Intentional weight loss and changes in symptoms of depression: a systematic review and meta-analysis. Int J Obes (Lond) 2011 Nov;35(11):1363-1376 [FREE Full text] [doi: 10.1038/ijo.2011.2] [Medline: 21343903]
12. Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. Obesity (Silver Spring) 2012 Jun;20(6):1234-1239. [doi: 10.1038/oby.2011.140] [Medline: 21633403]
13. Morgan PJ, Warren JM, Lubans DR, Collins CE, Callister R. Engaging men in weight loss: experiences of men who participated in the male only SHED-IT pilot study. Obes Res Clin Pract 2011;5(3):e169-e266. [doi: 10.1016/j.orcp.2011.03.002] [Medline: 24331106]
14. Morgan PJ, Lubans DR, Collins CE, Warren JM, Callister R. The SHED-IT randomized controlled trial: evaluation of an Internet-based weight-loss program for men. Obesity (Silver Spring) 2009 Nov;17(11):2025-2032. [doi: 10.1038/oby.2009.85] [Medline: 19343018]
15. Morgan PJ, Callister R, Collins CE, Plotnikoff RC, Young MD, Berry N, et al. The SHED-IT community trial: a randomized controlled trial of Internet- and paper-based weight loss programs tailored for overweight and obese men. Ann Behav Med 2013 Apr;45(2):139-152. [doi: 10.1007/s12160-012-9424-z] [Medline: 23129021]
16. Morgan PJ, Young MD, Smith JJ, Lubans DR. Targeted health behavior interventions promoting physical activity: a conceptual model. Exerc Sport Sci Rev 2016 Apr;44(2):71-80. [doi: 10.1249/JES.0000000000000075] [Medline: 26829248]
17. Young MD, Morgan PJ, Plotnikoff RC, Callister R, Collins CE. Effectiveness of male-only weight loss and weight loss maintenance interventions: a systematic review with meta-analysis. Obes Rev 2012 May;13(5):393-408. [doi: 10.1111/j.1467-789X.2011.00967.x] [Medline: 22212529]
18. Robertson S, White A, Gough B, Robinson R, Seims A, Raine G. Promoting mental health and wellbeing in men and boys: what works?. Leeds, UK: Centre for Men's Health; 2015.
19. Young MD, Callister R, Collins CE, Plotnikoff RC, Aguiar EJ, Morgan PJ. Efficacy of a gender-tailored intervention to prevent weight regain in men over 3 years: a weight loss maintenance RCT. Obesity (Silver Spring) 2017 Jan;25(1):56-65. [doi: 10.1002/oby.21696] [Medline: 27925437]
20. Young MD, Collins CE, Callister R, Plotnikoff RC, Doran CM, Morgan PJ. The SHED-IT weight loss maintenance trial protocol: a randomised controlled trial of a weight loss maintenance program for overweight and obese men. Contemp Clin Trials 2014 Jan;37(1):84-97. [doi: 10.1016/j.cct.2013.11.004] [Medline: 24246820]
21. CalorieKing Australia. 2017. URL: http://www.calorieking.com.au [accessed 2017-12-21] [WebCite Cache ID 6vsy5hXQD]
22. MyFitnessPal. 2017. URL: https://www.myfitnesspal.com/ [accessed 2017-12-21] [WebCite Cache ID 6vsyHn2Rr]
23. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009 Apr;114(1-3):163-173. [doi: 10.1016/j.jad.2008.06.026] [Medline: 18752852]

24. Kroenke K, Spitzer R. The PHQ-9: a new depression diagnostic and severity measure. Psych Ann 2002 Sep 01;32(9):509-515. [doi: 10.3928/0048-5713-20020901-06]
25. Okumura Y, Ichikura K. Efficacy and acceptability of group cognitive behavioral therapy for depression: a systematic review and meta-analysis. J Affect Disord 2014 Aug;164:155-164. [doi: 10.1016/j.jad.2014.04.023] [Medline: 24856569]
26. Saddichha S, Al-Desouki M, Lamia A, Linden IA, Krausz M. Online interventions for depression and anxiety - a systematic review. Health Psychol Behav Med 2014 Jan 01;2(1):841-881 [FREE Full text] [doi: 10.1080/21642850.2014.945934] [Medline: 25750823]
27. Mammen G, Faulkner G. Physical activity and the prevention of depression: a systematic review of prospective studies. Am J Prev Med 2013 Nov;45(5):649-657. [doi: 10.1016/j.amepre.2013.08.001] [Medline: 24139780]
28. Cavanagh A, Wilson CJ, Kavanagh DJ, Caputi P. Differences in the expression of symptoms in men versus women with depression: a systematic review and meta-analysis. Harv Rev Psychiatry 2017;25(1):29-38. [doi: 10.1097/HRP.0000000000000128] [Medline: 28059934]

Abbreviations

eHealth: electronic health
PHQ-8: Patient Health Questionnaire (8-item)
SD: standard deviation
SHED-IT: Self-Help, Exercise and Diet using Information Technology

Edited by G Eysenbach; submitted 08.09.17; peer-reviewed by M allman-Farinelli, K Serrano; comments to author 29.09.17; revised version received 18.10.17; accepted 29.10.17; published 09.01.18.

Please cite as:
Young MD, Morgan PJ
Effect of a Gender-Tailored eHealth Weight Loss Program on the Depressive Symptoms of Overweight and Obese Men: Pre-Post Study
JMIR Ment Health 2018;5(1):e1
URL: http://mental.jmir.org/2018/1/e1/
doi:10.2196/mental.8920
PMID:29317379

Original Paper

Technology-Assisted Behavioral Intervention to Extend Sleep Duration: Development and Design of the Sleep Bunny Mobile App

Kelly Glazer Baron[1], MPH, PhD; Jennifer Duffecy[2], PhD; Kathryn Reid[3], PhD; Mark Begale[4], MS; Lauren Caccamo[4], BA

[1]Rush University Medical Center, Chicago, IL, United States

[2]Department of Psychiatry, University of Illinois at Chicago, Chicago, IL, United States

[3]Center for Circadian and Sleep Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

[4]Department of Preventive Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

Corresponding Author:
Kelly Glazer Baron, MPH, PhD
Rush University Medical Center
1653 W Congress Parkway
Chicago, IL, 60612
United States
Phone: 1 3129420566
Email: kgbaron@rush.edu

Abstract

Background: Despite the high prevalence of short sleep duration (29.2% of adults sleep <6 hours on weekdays), there are no existing theory-based behavioral interventions to extend sleep duration. The popularity of wearable sleep trackers provides an opportunity to engage users in interventions.

Objective: The objective of this study was to outline the theoretical foundation and iterative process of designing the "Sleep Bunny," a technology-assisted sleep extension intervention including a mobile phone app, wearable sleep tracker, and brief telephone coaching. We conducted a two-step process in the development of this intervention, which was as follows: (1) user testing of the app and (2) a field trial that was completed by 2 participants with short sleep duration and a cardiovascular disease risk factor linked to short sleep duration (body mass index [BMI] >25).

Methods: All participants had habitual sleep duration <6.5 hours verified by 7 days of actigraphy. A total of 6 individuals completed initial user testing in the development phase, and 2 participants completed field testing. Participants in the user testing and field testing responded to open-ended surveys about the design and utility of the app. Participants in the field testing completed the Epworth Sleepiness Scale and also wore an actigraph for a 1-week baseline period and during the 4-week intervention period.

Results: The feedback suggests that users enjoyed the wearable sleep tracker and found the app visually pleasing, but they suggested improvements to the notification and reminder features of the app. The 2 participants who completed the field test demonstrated significant improvements in sleep duration and daytime sleepiness.

Conclusions: Further testing is needed to determine effects of this intervention in populations at risk for the mental and physical consequences of sleep loss.

(JMIR Ment Health 2018;5(1):e3) doi:10.2196/mental.8634

KEYWORDS

sleep duration; wearable; obesity; technology; behavioral intervention

Introduction

According to data from the National Health Interview Survey, 70.1 million adults (29.2%) sleep <6 hours per a 24-hour period [1]. Short sleep duration is thought to contribute to the development of chronic illnesses, including hypertension, overweight, and diabetes, as well as increased risk for all-cause mortality [2-4]. A recent consensus panel determined that the evidence suggests that *at least 7 hours of sleep* is the recommended sleep duration for adults [5]. Increasing awareness

of short sleep duration as one of the US health priorities is noted in Healthy People 2020 [6].

A growing number of studies have demonstrated potential benefits of increasing sleep duration among individuals with short sleep duration. Studies conducted among small samples have demonstrated reductions in beat-by-beat blood pressure among individuals with hypertension and prehypertension [7], improvements in insulin resistance among prediabetics [8], reductions in appetite among overweight individuals [9], improvements in athletic performance among athletes [10], and improvement in some areas of cognitive functioning among adolescents [11,12]. These studies have focused on sleep extension under tightly controlled conditions for short periods of time. Typically, individuals with short sleep duration (<6 or <7 hours) were asked to increase time in bed by going to bed earlier and, if applicable, waking up later. Participants were tracked with sleep diaries, wrist actigraphy, and contact with study staff.

Building upon this research, our aim is to develop scalable behavioral interventions for reducing short sleep duration with the aim of improving health and well-being. The determinants of short sleep duration are multifactorial, with some but not all aspects amenable to intervention. For example, work schedules and caregiving responsibilities are often not modifiable. Epidemiologic research has demonstrated that short sleep duration is more prevalent in males than in females, more prevalent among blacks compared with whites, and more prevalent in middle-aged adults than in older adults [13-16]. Time use surveys indicate that sleep time is often exchanged for work and commute time [17]. A handful of studies have evaluated social/cognitive theories of sleep behavior. Attitudes, social norms, and perceived control were all areas that predicted behavioral intention to sleep 7 to 8 hours per night in college students [18]. In another study that used the health belief model, self-efficacy was the strongest predictor of sleep duration. Finally, Kroese and colleagues utilized principles of self-control theory to coin the term “bedtime procrastination” and reported associations between bedtime behavior with self-control and sleep duration [19]. These studies suggest that psychological and behavioral targets for interventions may be successful at extending sleep duration using behavioral interventions that target motivation and self-efficacy.

The rapidly expanding prevalence of wearable sleep-tracking devices provides the opportunity to engage a large number of individuals in sleep behavior change. It is estimated that 1 in 10 adults owns a wearable fitness device [20]. As of 2015, it is estimated that 33 million adults in the United States own a fitness device, many of which have sleep-tracking capabilities. However, there are currently no validated technology-assisted interventions to extend sleep duration. Existing technology interventions for sleep have been designed for insomnia [21,22] or treatment adherence in obstructive sleep apnea (eg, MyAir by ResMed Inc). Given the prevalence of short sleep duration and the popularity of sleep tracking, we designed a technology-assisted behavioral intervention to extend sleep duration: the “Sleep Bunny.” The goal of this paper was to describe the theoretical foundation, development, and present two case examples from field testing the Sleep Bunny intervention, a technology-assisted sleep extension intervention.

Methods

Participants

The general inclusion criteria for all participants included age between 18 and 65 years and self-reported sleep duration <7 hours per night. Exclusion criteria included the following: unstable or serious medical conditions (eg, neurological conditions, cancer); shift work; diagnosis of obstructive sleep apnea or high risk for apnea based on screening questionnaires; symptoms of other sleep disorders, including insomnia and restless legs syndrome; current series of unstable psychiatric disorders such as schizophrenia, bipolar, alcohol abuse, or drug abuse; and pregnancy or desire to become pregnant in the study period. We had separate recruitment strategies for each study phase, which were as follows: (1) user testing and (2) field testing.

For user testing, we recruited healthy volunteers from a list of participants who completed screening for a previous study [23] but were ineligible for the study because of sleep duration <7 hours. They were primarily medical students who were willing to evaluate our app, provide feedback, and identify potential problems in the tools. For the field test, we recruited participants with body mass index (BMI) >25, to test our fully functioning intervention in a population with at least one health risk factor linked to short sleep duration (overweight/obesity). The reason that participants with BMI>25 were selected was to have a specific health issue to focus the coaching sessions around (eg, links between sleep and weight). Participants for the field test were recruited from the community using online advertisements and flyers posted on campus. This study was approved by the Northwestern University Institutional Review Board, and enrolled participants provided written informed consent.

Procedure

User Testing

This phase of intervention development was used to elicit initial feedback from participants and identify and address any problems with the app. Eligible participants from our previous study were invited for a preintervention visit to the laboratory, which included questionnaires, setup and training of the Fitbit and mobile phone app, and actigraphy. Participants started with 1 baseline week at home where they entered sleep diaries but were asked not to alter their habitual sleep schedule. At the end of week 1, participants had the initial telephone coaching session (20 min) to review goals and motivation and troubleshoot any problems with the app or Fitbit. Participants had 4 weekly coaching sessions (10 min or less), with sessions 3 and 4 conducted via text or email if preferred. At the end of the 4-week intervention, participants returned to the laboratory to complete questionnaires and interviews about their experience. During this phase, participants received the coaching sessions as scheduled, but content from the intervention was in most cases delivered differently due to resolving initial problems in the app. For example, 3 participants were not able to view their Fitbit data in the app, and 4 participants’ mobile phone app did

not advance the didactic modules each week as planned. When possible, the study staff worked around these issues (eg, delivering content via email rather than the app, had participants view their Fitbit data in the Fitbit app if the Sleep Bunny app was not pulling in the data) to deliver the relevant intervention components. All issues with the technology were addressed before moving on to the next phase of the study (field testing).

Field Testing

We recruited participants from the community to complete a small field test to determine the feasibility and acceptability of the fully functioning intervention. The field test was conducted using the same procedure we described for user testing but was performed only after the app was fully functioning. Participants completed a pretreatment training session/questionnaires, 1 week of baseline monitoring, 4 weeks of intervention including weekly telephone or email/text coaching sessions, and a final follow-up visit at the end of the intervention to complete questionnaires and exit interviews. Participants received intervention components as intended, including content delivery and Fitbit integration.

Intervention Description

The Sleep Bunny program is a technology-assisted behavioral intervention aimed at increasing sleep duration by extending time in bed. The developers named the program the "Sleep Bunny" because it agrees with the graphics theme of sleeping animals and also follows the app-naming convention of nonsense- or silly-sounding words for technology products (eg, Grooveshark, Foursquare, Hulu). The intervention content and coaching techniques were based on elements of motivational interviewing, and cognitive behavioral therapy was based on a telephone coaching manual for an online depression intervention [24]. Participants in this intervention were provided with a mobile phone app and wearable sleep tracker (Fitbit), and they then participated in weekly brief telephone coaching sessions. Coaches were able to view participants' intervention engagement and data through a dashboard. The goal of the coaches' dashboard was to increase supportive accountability [25], a concept in technology-assisted behavioral interventions that suggests individuals are more likely to change their behavior if they are accountable to another person.

The app included the following components: (1) content, which is delivered in weekly "lessons," (2) interactive tools, (3) sleep tracking, (4) graphic feedback, and (5) reminders/notifications.

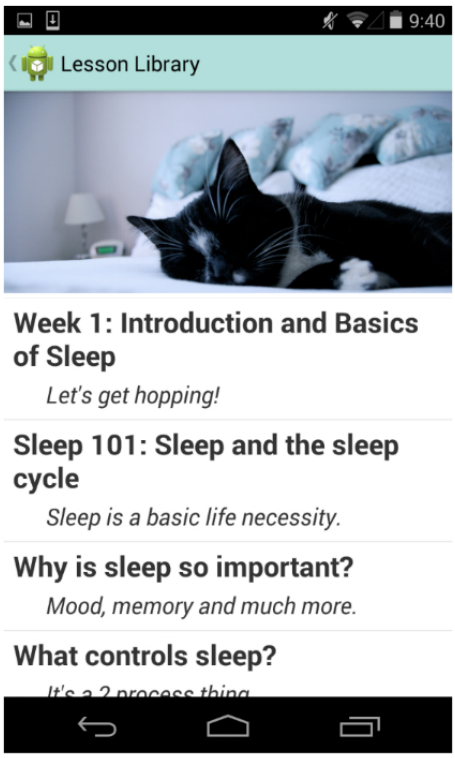
Intervention Content

An example of intervention content is listed in Figure 1. Participants received 4 weekly lessons, which included written didactic content via the mobile app. Lesson topics included the basics of sleep, beating bedtime procrastination, circadian rhythms, and relapse prevention. A new lesson was released each week, as new content can draw users back to an intervention. Participants also had access to past lessons.

Intervention Tools

Participants had access to a bedtime checklist, where they could organize and track activities they planned to complete before their scheduled bedtime; a daily sleep diary, which could be viewed on the dashboard by the telephone coach; and a "bedtime procrastination quiz" [19], where they could compare their scores with published values. Coaches could view all data entered in tools and were expected to discuss with participants.

Figure 1. Lesson, week 1, from the mobile phone app.



Sleep Tracking

Participants wore a Fitbit Flex sleep-tracking device for the 4-week intervention. The in-house development core at the Northwestern University Center for Behavioral Intervention Technology used the Fitbit open application programming interface to pull in the participant's data into the mobile app. Coaches were also able to see the participant's sleep tracker data on the coach's dashboard. Coaches were able to log in to a dashboard to view sleep diary, app use (eg, frequency of lessons and tools used), and Fitbit data including the bedtime, wake-up time, sleep duration, and number of awakenings per night.

Graphic Feedback

A "graphs" section of the app displayed individuals' daily sleep duration (Figure 2). Individuals were also given feedback about "streaks" of days in a row when they achieved their goals of completing a sleep diary, target bedtime, wake-up time, and sleep duration.

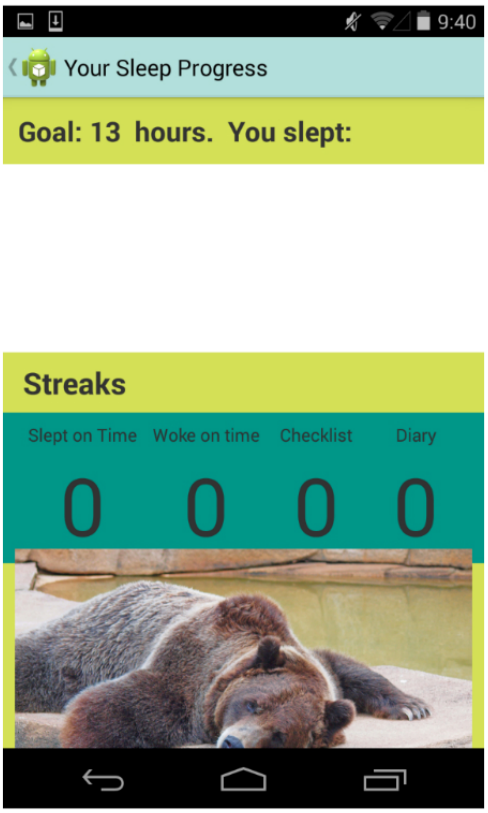
Reminders and Notifications

Participants received a prompt to complete sleep diaries if the diary was not completed within 4 hours of their scheduled wake-up time via a notification that was presented on the home screen. The app also included an alarm clock, tied into the wake-up time goals set in the app. Participants could clear the notification from their home screen, similar to a text message. The alarms could be silenced but could only be changed by changing the goals in the app.

Coaching

Participants were assigned to a sleep coach to monitor their progress during the study (KB or LC) and were provided weekly telephone coaching sessions related to their sleep-related goals. The coaching protocol, developed by Drs Duffecy and Baron, is based on the principles of supportive accountability and based on a previous coaching protocol [24,25]. The coaches worked with participants to establish sleep-related goals with the participants based on the participant's values and beliefs, including the particular sleep schedule goals and also usage goals (eg, number of Fitbit wear days or sleep logs per week or goal bedtime/wake-up time). Coaches asked participants to enter their bedtime and wake-up time goals into the app, which would ensure the delivery of reminders and alarms at the appropriate time. Coaches monitored participants' intervention usage through an online dashboard. The first coaching session was a 20-min engagement session, which included introductions, rational for the program, clarifying roles of the coach, and the participants' goals for the program, such as their target bedtime and wake-up time. For weeks 2-4, participants had weekly brief (10 min) follow-up support calls to review their weekly Fitbit data and troubleshoot any problems with the app or Fitbit as well as answer any questions about the weekly content. Weeks 3 and 4 coaching sessions could be completed over email or text if the participant preferred these modes of communication. In between sessions, the coaches were available, mostly over email, to troubleshoot any problems with the app or Fitbit.

Figure 2. Feedback and streaks from the mobile phone app.



Measures

Sleep Disorders Screening

Before enrollment into the study, participants completed the STOP questionnaire to be screened for sleep apnea risk [26]. Participants scoring as high risk on this measure were excluded.

Psychiatric Disorders Screening

Participants completed self-reported questions on the presence of psychiatric conditions and medications and completed the patient health questionnaire 8-item (PHQ-8) version. Participants were excluded if they reported the presence of serious or unstable psychiatric disorders (bipolar or schizophrenia) or dementia or scored >10 on the PHQ-8.

Sleep

Participants wore an Actiwatch [27] Spectrum (Philips/Respironics, Inc, Bend, Oregon) on the nondominant wrist during the 4-week intervention to provide a validated measure of sleep duration. Due to poor specificity for detecting sleep among consumer sleep-tracking devices, actigraphy was considered the sleep outcome assessment despite participants wearing a Fitbit to deliver the intervention. Actiwatches were set with 30-second epoch length and medium sensitivity. Actigraphic sleep parameters were calculated using Actiware-Sleep 6.0 software with default settings and included the following variables: sleep onset time, sleep offset time, sleep duration, wake after sleep onset (WASO), and sleep efficiency (sleep duration/time in bed). Off-wrist time was excluded based on the Spectrum's off-wrist detection. Actigraphy profiles were scored using procedures previously reported [28]. Participants were trained on the use of the event marker. When the event marker or sleep diary was not available, research staff used decrease in light and activity as a guide to delineate the rest period.

Daytime sleepiness was measured using the Epworth Sleepiness Scale (ESS), an 8-item self-report measure [29]. Scores on the ESS range from 0 to 24, and scores ≥10 are considered to be excessive sleepiness [30].

Participants responded to open-ended questions on a user experience survey at the end of user testing and intervention. The survey asked participants to provide comments on the content, layout, graphics, and general feedback about the app. Responses were analyzed by thematic analysis.

Results

User Testing

We conducted user testing with 6 individuals. Participants were primarily female (4 women, 2 men) and in mid-20s (average age 24.6 years, standard deviation [SD] 4.4 years). Of the participants who attended the first study visit, 2 individuals were excluded or dropped out (1 participant was excluded due to overnight work not disclosed at screening, and 1 participant withdrew without reason). An additional participant arrived for the baseline visit but did not provide consent because she had changed her sleep duration since the time she had answered the screening questions. In total, 4 participants completed the 4-week intervention. During this testing period, we discovered and fixed problems in the app (eg, lessons not advancing each week, problems with the app not integrating with Fitbit data) and tested the coaching procedures. Approximately half of the participants used their own android phones and the other half borrowed study phones (Wi-Fi only, no cellular plan).

Field Testing

We recruited 3 participants for the small field test and 2 completed the 4-week intervention and assessments. The participant who did not complete the 4-week intervention and assessments because of technical issues (unable to load the app on her phone or the study phone) was withdrawn from the intervention. All the 3 participants who volunteered for the target population user testing were female: 1 participant was black, 1 was white, and 1 was Asian. Average age was 51 (SD 2.1) years. All were working full time. Daytime sleepiness ratings on the ESS ranged from 3 to 16, with an average of 9.7 and SD of 5.3. Of the 3 volunteers, 2 had ESS scores ≥10.

App Feedback (From User Testing and Field Testing)

A summary of user feedback is presented in Textbox 1. In general, participants reported that the format was pleasant and the lessons were understandable. All participants reported enjoying use of the wearable sleep tracker. The greatest amount of constructive feedback was focused on improving the notifications. Participants reported they were either missed or inappropriate (eg, did not know how to turn off the alarm on weekends).

Field Test Results: Adherence and Response to Intervention in Two Cases

The participants in the field test completed 100% of coaching sessions and 50% to 60% of sleep diary days and wore Fitbit 50% to 80% of nights. Table 1 reports changes in actigraphy and subjective sleepiness. The 2 participants who completed the field test demonstrated a large increase in sleep duration and a large decrease in ESS score. Changes in WASO and sleep efficiency were in opposite directions for the 2 participants: 1 participant demonstrated small improvements in WASO and sleep efficiency, and the other participant had a moderate increase in WASO (+23 min) but a small change in sleep efficiency (−4%).

Textbox 1. Responses to open-ended questions during user testing and field testing.

Appearance

- "Pleasant"
- "Animals were cute"
- "I liked the little dog"
- "I would like videos"

Lessons

- "Too long"
- "It was basic but a good refresher and reinforced in the coaching"
- Terminology
- "Bedtime procrastination, I didn't know what that was"
- "I don't look at it as procrastination because I have so many things to do"

Notifications

- "The evening prompt was nice"
- "I wanted to turn it off [the morning alarm] on the weekends but didn't know how"
- "I never saw the notifications but was not using my phone [was a study phone]"

Ease of use

- "I didn't know how to change the goals"
- "The goals were easy to adjust on the phone but hard in life"
- "The diary was tedious to record"

Duration of intervention

- "4 weeks is a reasonable time"
- "3-4 weeks"
- "I think it would take 2 months to figure out how to change my life''

Other comments

- "This was a stressful time and the intervention changed my life. I didn't meet my goal but I would have been sleeping so much less if I wasn't in the study"

Table 1. Actigraphy and sleepiness scores.

Participant	Baseline sleep duration (hours)	Week 4 sleep duration (hours)	Baseline sleep efficiency (%)	Week 4 sleep efficiency (%)	Baseline WASO[a] (min)	Week 4 WASO (min)	Baseline ESS[b]	Week 4 ESS
1	5.75	7.35	87	90	42	32	7	0
2	4.30	6.0	85	81	25	48	18	9

[a]Wake after sleep onset.

[b]Epworth Sleepiness Scale.

Discussion

Principal Findings

This study outlines the theoretical foundation and development process of a novel technology-assisted behavioral intervention to extend sleep duration. Results indicate that we have developed an app that is visually pleasing to participants and content is appropriate. Coaching sessions were well attended and not burdensome to participants. Participants enjoyed the use of the wearable sleep tracker most of all. We pilot tested the intervention in a small field test of participants and reported a case series of 2 participants. These participants demonstrated a substantial improvement in sleep duration and a reduction in self-reported daytime sleepiness, but changes to WASO and sleep efficiency were not consistent.

The improvements in sleep duration in our 2 participants were larger than those previously reported in several sleep extension

interventions [7,8], and on par with the findings of Tasali and colleagues [9]. The magnitude of change may be high due to the low baseline sleep duration in our target population participants, which allowed for greater change in sleep and the use of weekly brief telephone coaching. The reason we selected participants with BMI>25 was to ensure that there was a health issue linked to sleep that we could discuss in the coaching, to enhance motivation. The addition of technology alone does not always improve adherence and outcomes. A recent weight loss trial demonstrated lower weight loss at 2-year follow-up among participants randomized to wear activity trackers [31]. Future research is needed to determine which components of sleep extension are most effective as well as cost-effective.

Our study also demonstrated variability in response to the intervention, even within the 2 cases studied. Although sleep duration increased in both participants, 1 participant had an increase in WASO after 4 weeks of the intervention and the other participant had a decrease. In this case, both participants improved in their daytime sleepiness, but there may be some individuals who respond poorly to sleep extension. For example, among patients with insomnia, restricting time in bed rather than extending it is the recommended treatment [32].

It is also important to note that studies comparing consumer sleep-tracking technology have found that these devices are far less accurate than actigraphy or polysomnography [27]. Given that consumer devices overestimate sleep duration due to being less sensitive to brief awakenings in the night, it is possible that they may provide false security about sleep duration to consumers. On the other hand, our experience in this development and field testing was that participants felt the measures reflected their sleep behaviors and the feedback was helpful with being far less intrusive than polysomnography. It may be that even flawed information is better than no information, because of the increase in awareness and self-monitoring. For example, it is well known that food diaries significantly underestimate caloric intake [33] but are the cornerstone of effective weight loss interventions [34]. Furthermore, although actigraphy is widely accepted as a valid estimation of sleep/wake-up patterns and sleep duration in naturalistic settings, actigraphy itself is less sensitive to awakenings and thus overestimates sleep duration compared with polysomnography [28].

Strengths and Limitations

Limitations to our intervention include that our app was compatible with android only, and therefore excluded about half of all mobile phone users (iPhone), and our participants were highly educated, which may limit generalizability to other populations, particularly those with less familiarity with technology and mobile phone apps and may have a different response to the tracking and reminders in the app. Participant feedback was clear that they felt the notifications could be more targeted (eg, missed hearing bedtime reminder) or less annoying (did not know how to turn off the alarm on weekends, when they would have preferred to sleep later than on weekdays). Finally, although these results support the initial feasibility of our intervention, they provide only preliminary feedback and results of cases who participated in our early testing.

Conclusions

In conclusion, this study outlines the theoretical foundation and development and presents a case series from early user testing of a technology-assisted sleep extension intervention. Future research is needed to continue to develop and refine this intervention and also explore maintenance of sleep behavior change.

Acknowledgments

The authors would like to thank David Mohr, PhD, for his assistance and guidance in this research. This study was supported by grant no 1K23HL109110 and a pilot grant provided by the Center for Behavioral Intervention Technology at Northwestern University.

Conflicts of Interest

None declared.

References

1. Ford ES, Cunningham TJ, Croft JB. Trends in self-reported sleep duration among US adults from 1985 to 2012. Sleep 2015 May 01;38(5):829-832 [FREE Full text] [doi: 10.5665/sleep.4684] [Medline: 25669182]
2. Legramante JM, Galante A. Sleep and hypertension: a challenge for the autonomic regulation of the cardiovascular system. Circulation 2005 Aug 09;112(6):786-788 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.105.555714] [Medline: 16087808]
3. Pepin J, Borel A, Tamisier R, Baguet J, Levy P, Dauvilliers Y. Hypertension and sleep: overview of a tight relationship. Sleep Med Rev 2014 Dec;18(6):509-519. [doi: 10.1016/j.smrv.2014.03.003] [Medline: 24846771]
4. Guo X, Zheng L, Wang J, Zhang X, Zhang X, Li J, et al. Epidemiological evidence for the link between sleep duration and high blood pressure: a systematic review and meta-analysis. Sleep Med 2013 Apr;14(4):324-332. [doi: 10.1016/j.sleep.2012.12.001] [Medline: 23394772]
5. Watson NF. Sleep duration: a consensus conference. Sleep 2015 Jan;38(1):5 [FREE Full text] [Medline: 25515114]
6. Office of Disease Prevention and Health Promotion. 2010. Healthy People 2020: U.S. Department of Health and Human Services URL: http://www.healthypeople.gov/hp2020/ [accessed 2017-12-08] [WebCite Cache ID 6vZ0eeN4w]

7. Haack M, Serrador J, Cohen D, Simpson N, Meier-Ewert H, Mullington JM. Increasing sleep duration to lower beat-to-beat blood pressure: a pilot study. J Sleep Res 2013 Jun;22(3):295-304 [FREE Full text] [doi: 10.1111/jsr.12011] [Medline: 23171375]
8. Leproult R, Deliens G, Gilson M, Peigneux P. Beneficial impact of sleep extension on fasting insulin sensitivity in adults with habitual sleep restriction. Sleep 2015 May 01;38(5):707-715 [FREE Full text] [doi: 10.5665/sleep.4660] [Medline: 25348128]
9. Tasali E, Chapotot F, Wroblewski K, Schoeller D. The effects of extended bedtimes on sleep duration and food desire in overweight young adults: a home-based intervention. Appetite 2014 Sep;80:220-224 [FREE Full text] [doi: 10.1016/j.appet.2014.05.021] [Medline: 24858836]
10. Mah CD, Mah KE, Kezirian EJ, Dement WC. The effects of sleep extension on the athletic performance of collegiate basketball players. Sleep 2011 Jul 01;34(7):943-950 [FREE Full text] [doi: 10.5665/SLEEP.1132] [Medline: 21731144]
11. Dewald-Kaufmann JF, Oort FJ, Meijer AM. The effects of sleep extension and sleep hygiene advice on sleep and depressive symptoms in adolescents: a randomized controlled trial. J Child Psychol Psychiatry 2014 Mar;55(3):273-283. [doi: 10.1111/jcpp.12157] [Medline: 24252173]
12. Dewald-Kaufmann JF, Oort FJ, Meijer AM. The effects of sleep extension on sleep and cognitive performance in adolescents with chronic sleep reduction: an experimental study. Sleep Med 2013 Jun;14(6):510-517 [FREE Full text] [doi: 10.1016/j.sleep.2013.01.012] [Medline: 23523432]
13. Grandner MA, Jackson NJ, Izci-Balserak B, Gallagher RA, Murray-Bachmann R, Williams NJ, et al. Social and behavioral determinants of perceived insufficient sleep. Front Neurol 2015;6:112 [FREE Full text] [doi: 10.3389/fneur.2015.00112] [Medline: 26097464]
14. Lauderdale DS, Knutson KL, Yan LL, Rathouz PJ, Hulley SB, Sidney S, et al. Objectively measured sleep characteristics among early-middle-aged adults: the CARDIA study. Am J Epidemiol 2006 Jul 01;164(1):5-16 [FREE Full text] [doi: 10.1093/aje/kwj199] [Medline: 16740591]
15. Hale L, Do DP. Racial differences in self-reports of sleep duration in a population-based study. Sleep 2007 Sep;30(9):1096-1103 [FREE Full text] [Medline: 17910381]
16. Whinnery J, Jackson N, Rattanaumpawan P, Grandner MA. Short and long sleep duration associated with race/ethnicity, sociodemographics, and socioeconomic position. Sleep 2014 Mar 01;37(3):601-611 [FREE Full text] [doi: 10.5665/sleep.3508] [Medline: 24587584]
17. Basner M, Fomberstein KM, Razavi FM, Banks S, William JH, Rosa RR, et al. American time use survey: sleep time and its relationship to waking activities. Sleep 2007 Sep;30(9):1085-1095 [FREE Full text] [Medline: 17910380]
18. Knowlden AP, Sharma M. Health belief structural equation model predicting sleep behavior of employed college students. Fam Community Health 2014;37(4):271-278. [doi: 10.1097/FCH.0000000000000043] [Medline: 25167067]
19. Kroese FM, De Ridder DT, Evers C, Adriaanse MA. Bedtime procrastination: introducing a new area of procrastination. Front Psychol 2014;5:611 [FREE Full text] [doi: 10.3389/fpsyg.2014.00611] [Medline: 24994989]
20. NPD. 2016. Year-Over-Year Wearables Spending Doubles, According to NPD URL: https://www.npd.com/wps/portal/npd/us/news/press-releases/2016/year-over-year-wearables-spending-doubles-according-to-npd/ [accessed 2017-12-25] [WebCite Cache ID 6vyE8rDhV]
21. Ritterband LM, Thorndike FP, Gonder-Frederick LA, Magee JC, Bailey ET, Saylor DK, et al. Efficacy of an internet-based behavioral intervention for adults with insomnia. Arch Gen Psychiatry 2009 Jul;66(7):692-698 [FREE Full text] [doi: 10.1001/archgenpsychiatry.2009.66] [Medline: 19581560]
22. Espie CA, Kyle SD, Williams C, Ong JC, Douglas NJ, Hames P, et al. A randomized, placebo-controlled trial of online cognitive behavioral therapy for chronic insomnia disorder delivered via an automated media-rich web application. Sleep 2012 Jun;35(6):769-781 [FREE Full text] [doi: 10.5665/sleep.1872] [Medline: 22654196]
23. Baron KG, Reid KJ, Kim T, Van Horn L, Attarian H, Wolfe L, et al. Circadian timing and alignment in healthy adults: associations with BMI, body fat, caloric intake and physical activity. Int J Obes (Lond) 2017 Feb;41(2):203-209 [FREE Full text] [doi: 10.1038/ijo.2016.194] [Medline: 27795550]
24. Mohr DC, Duffecy J, Ho J, Kwasny M, Cai X, Burns MN, et al. A randomized controlled trial evaluating a manualized TeleCoaching protocol for improving adherence to a web-based intervention for the treatment of depression. PLoS One 2013 Aug;8(8):e70086 [FREE Full text] [doi: 10.1371/journal.pone.0070086] [Medline: 23990896]
25. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing human support to enhance adherence to eHealth interventions. J Med Internet Res 2011 Mar 10;13(1):e30 [FREE Full text] [doi: 10.2196/jmir.1602] [Medline: 21393123]
26. Chung F, Abdullah HR, Liao P. STOP-Bang Questionnaire: a practical approach to screen for obstructive sleep apnea. Chest 2016 Mar;149(3):631-638 [FREE Full text] [doi: 10.1378/chest.15-0903] [Medline: 26378880]
27. Montgomery-Downs HE, Insana SP, Bond JA. Movement toward a novel activity monitoring device. Sleep Breath 2012 Sep;16(3):913-917. [doi: 10.1007/s11325-011-0585-y] [Medline: 21971963]
28. Ancoli-Israel S, Martin JL, Blackwell T, Buenaver L, Liu L, Meltzer LJ, et al. The SBSM guide to actigraphy monitoring: clinical and research applications. Behav Sleep Med 2015;13(Suppl 1):S4-S38. [doi: 10.1080/15402002.2015.1046356] [Medline: 26273913]

29. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep 1991 Dec;14(6):540-545. [Medline: 1798888]
30. Johns MW. Sensitivity and specificity of the multiple sleep latency test (MSLT), the maintenance of wakefulness test and the epworth sleepiness scale: failure of the MSLT as a gold standard. J Sleep Res 2000 Mar;9(1):5-11 [FREE Full text] [Medline: 10733683]
31. Jakicic JM, Rogers RJ, Kovacs SJ, Byard TD, Collins KA, Creasy SA, et al. A commercial program is effective for weight loss and improving health-related outcomes in adults. Med Sci Sports Exerc 2016;48:1083-1084. [doi: 10.1249/01.mss.0000488260.34379.33]
32. Morgenthaler T, Kramer M, Alessi C, Friedman L, Boehlecke B, Brown T. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An american academy of sleep medicine report. Sleep 2006;29(11):1415-1419.
33. Schoeller DA. Limitations in the assessment of dietary energy intake by self-report. Metabolism 1995 Feb;44(2):18-22. [Medline: 7869932]
34. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. J Am Diet Assoc 2011 Jan;111(1):92-102 [FREE Full text] [doi: 10.1016/j.jada.2010.10.008] [Medline: 21185970]

Abbreviations

BMI: body mass index
ESS: Epworth Sleepiness Scale
PHQ-8: patient health questionnaire 8-item
WASO: wake after sleep onset

Edited by I Barnett; submitted 02.08.17; peer-reviewed by J Cook, J Di; comments to author 10.09.17; revised version received 10.10.17; accepted 19.10.17; published 10.01.18.

Please cite as:
Baron KG, Duffecy J, Reid K, Begale M, Caccamo L
Technology-Assisted Behavioral Intervention to Extend Sleep Duration: Development and Design of the Sleep Bunny Mobile App
JMIR Ment Health 2018;5(1):e3
URL: http://mental.jmir.org/2018/1/e3/
doi:10.2196/mental.8634
PMID:29321122

Original Paper

Acute Effect of Alcohol Intake on Cardiovascular Autonomic Regulation During the First Hours of Sleep in a Large Real-World Sample of Finnish Employees: Observational Study

Julia Pietilä[1], MSc; Elina Helander[1], PhD; Ilkka Korhonen[1,2], PhD; Tero Myllymäki[2,3], MSc; Urho M Kujala[4], MD, PhD; Harri Lindholm[5,6], MD, PhD

[1]Faculty of Biomedical Sciences and Engineering, BioMediTech Institute, Tampere University of Technology, Tampere, Finland
[2]Firstbeat Technologies, Jyväskylä, Finland
[3]Department of Psychology, University of Jyväskylä, Jyväskylä, Finland
[4]Faculty of Sport and Health Sciences, University of Jyväskylä, Jyväskylä, Finland
[5]Finnish Institute of Occupational Health, Helsinki, Finland
[6]Nokia Technologies, Espoo, Finland

Corresponding Author:
Julia Pietilä, MSc
Faculty of Biomedical Sciences and Engineering
BioMediTech Institute
Tampere University of Technology
Korkeakoulunkatu 3
Tampere, 33720
Finland
Phone: 358 405475334
Fax: 358 331153015
Email: julia.pietila@tut.fi

Abstract

Background: Sleep is fundamental for good health, and poor sleep has been associated with negative health outcomes. Alcohol consumption is a universal health behavior associated with poor sleep. In controlled laboratory studies, alcohol intake has been shown to alter physiology and disturb sleep homeostasis and architecture. The association between acute alcohol intake and physiological changes has not yet been studied in noncontrolled real-world settings.

Objective: The aim of this study was to assess the effects of alcohol intake on the autonomic nervous system (ANS) during sleep in a large noncontrolled sample of Finnish employees.

Methods: From a larger cohort, this study included 4098 subjects (55.81%, 2287/4098 females; mean age 45.1 years) who had continuous beat-to-beat R-R interval recordings of good quality for at least 1 day with and for at least 1 day without alcohol intake. The participants underwent continuous beat-to-beat R-R interval recording during their normal everyday life and self-reported their alcohol intake as doses for each day. Heart rate (HR), HR variability (HRV), and HRV-derived indices of physiological state from the first 3 hours of sleep were used as outcomes. Within-subject analyses were conducted in a repeated measures manner by studying the differences in the outcomes between each participant's days with and without alcohol intake. For repeated measures two-way analysis of variance, the participants were divided into three groups: low (≤0.25 g/kg), moderate (>0.25-0.75 g/kg), and high (>0.75 g/kg) intake of pure alcohol. Moreover, linear models studied the differences in outcomes with respect to the amount of alcohol intake and the participant's background parameters (age; gender; body mass index, BMI; physical activity, PA; and baseline sleep HR).

Results: Alcohol intake was dose-dependently associated with increased sympathetic regulation, decreased parasympathetic regulation, and insufficient recovery. In addition to moderate and high alcohol doses, the intraindividual effects of alcohol intake on the ANS regulation were observed also with low alcohol intake (all P<.001). For example, HRV-derived physiological recovery state decreased on average by 9.3, 24.0, and 39.2 percentage units with low, moderate, and high alcohol intake, respectively. The effects of alcohol in suppressing recovery were similar for both genders and for physically active and sedentary subjects but stronger among young than older subjects and for participants with lower baseline sleep HR than with higher baseline sleep HR.

Conclusions: Alcohol intake disturbs cardiovascular relaxation during sleep in a dose-dependent manner in both genders. Regular PA or young age do not protect from these effects of alcohol. In health promotion, wearable HR monitoring and HRV-based analysis of recovery might be used to demonstrate the effects of alcohol on sleep on an individual level.

(JMIR Ment Health 2018;5(1):e23) doi:10.2196/mental.9519

KEYWORDS

heart rate; heart rate variability; sleep; alcohol drinking; autonomic nervous system; wearable electronic device

Introduction

Background

Sleep is a crucial period of physiological restoration, and it is the optimal state to assess the tonic component or the most relaxed state of the autonomic nervous system (ANS) in real-life conditions [1]. Poor sleep attenuates relaxation in the ANS [2], impairs regenerative physiological processes, causes metabolic disturbances, and has been associated with negative health outcomes [3]. Alcohol intake disturbs recovery, sleep homeostasis, and sleep architecture in several ways [4]. Alcohol affects negatively on stress-related cardiovascular adaptation in the ANS and hypothalamus-pituitary-adrenal axis [5]. Still, alcohol is used to relieve stress [6] or as sleep medicine [4]. Increased alcohol consumption is associated with long working hours, poor social support, and low job control [7].

Heart rate variability (HRV) is a widely used marker of cardiac autonomic regulation reflecting fluctuations in R-R intervals in short or extended time recordings [8] and is modulated by respiration, central vasoregulatory centers, peripheral baroreflex loops, and genetic factors [9]. HRV decreases with age, although differently in men and women [8]. In addition, suppressed HRV has been shown to predict occurrence of different diseases and conditions such as diabetic neuropathy or left ventricular dysfunction after acute myocardial infarction [10]. Traditionally, the HRV analysis is performed in time or frequency domains [10] but also novel analysis methods exist [11]. A widely used time domain measure of HRV is the root mean square of the successive differences (RMSSD) between adjacent R-R intervals, which mainly reflects the parasympathetic input of cardiac regulation [10]. In the frequency domain analysis, the high frequency (HF) band of HRV is considered to indicate parasympathetic regulation [10], whereas the low frequency (LF) band reflects both parasympathetic and sympathetic regulation [10,12]. The ratio between LF power and HF power (LF/HF ratio) has been suggested to reflect the balance between the two branches of the ANS, but this suggestion has not received a consensus [10,12]. Recently, a standardized reporting system in HRV-related behavioral studies was proposed [13].

In addition to the cardiac autonomic regulation, HRV analysis may also provide useful information on sleep [14], the sleeping brain [15], and stress-related insufficient recovery [16], even though autonomic regulation during sleep is complex and varies during different sleep stages [14]. During slow wave sleep (so-called deep sleep), the parasympathetic regulation has been reported to be dominating and the sympathetic regulation to be attenuated, whereas the opposite is true for rapid eye movement sleep [14]. The sufficient amount of slow wave sleep has been associated with good physical and mental recovery [1]. Unconscious stress may be detected in physiological recordings made during cardiovascular stress recovery [17], and HRV may usefully reflect the adaptive resources of the ANS [18]. However, the limitations and pitfalls of HRV analysis as well as the physiological nature of HRV have to be taken into account in all interpretations.

Prior Work

The effect of acute alcohol intake on the ANS using heart rate (HR) and HRV parameters has been shown in the previous studies. In laboratory settings, high acute alcohol consumption (0.7 g/kg-1.0 g/kg) was associated with decreased HRV and increased HR in awake subjects [19]. The effect was also observed with lower doses (two drinks, not reported in g/kg units) [20]. In one laboratory study, both HRV and polysomnography were monitored after alcohol consumption [21]. The young healthy male subjects (n=10) were given no (0 g/kg, control), low (0.5 g/kg of ethanol), or high (1.0 g/kg) dose of alcohol. A dose-related effect of alcohol on HR and HRV during sleep was found, and the highest HR and lowest HRV were observed for high dose.

However, the effect of acute alcohol intake on the ANS during sleep has not been studied in noncontrolled free-living conditions or with large samples. Most published studies considering the effects of acute alcohol intake on HRV have involved only males, been rather small in number of participants, and included no comparison between genders or objective measurements of physical activity (PA) and recordings during sleep [9]. Thus, studies employing larger number of participants with both genders and considering the background parameters of the subjects such as age, body mass index (BMI) and PA, are needed.

Goal of This Study

The widespread use of wearable and connected consumer devices enables unobtrusive collection of massive amounts of data from large number of individuals during their daily life. These health-related datasets gathered under normal day-to-day circumstances outside of traditional clinical trials represent so called real-world data [22]. This real-world data collected in uncontrolled settings and outside of clinical trials may be exploited in research to complement the knowledge gained from the traditional clinical trials [23]. The multitude and variety of individuals and information included in real-world datasets allow studying aspects that cannot be studied to that extent in traditional clinical trials [23]. The real-world data has also the prospect to assess the generalizability of the findings from traditional clinical trials with specific populations and circumstances to broader populations and circumstances [22]. On the other hand, the associations found in real-world data can

serve as hypotheses for further clinical trials [22]. To gain valid results from the real-world data, the data characteristics such as the sample bias, missing data, confounding, uncertainties and provenance of the data, must, however, be taken into account in the analysis [24].

Alcohol consumption is a universal health behavior associated with poor sleep [4], but to the authors' knowledge, there is not yet any study employing real-world data [9]. This study analyzes the effects of alcohol intake on the ANS during sleep in a large free-living population. An observational real-world dataset of continuous beat-to-beat R-R interval recordings and self-reported sleep times and alcohol consumption collected from over 40,000 subjects during their normal everyday life was employed for studying retrospectively the effect of acute alcohol intake on sleep. The intraindividual differences in the HRV during sleep associated with acute alcohol intake were studied from 4098 participants of various ages, BMI ranges, and PA levels in whom data with and without alcohol consumption during previous day was available. The purpose of the study was to assess the generalizability of the previous findings to broader population and to study associations between the characteristics of the subjects and the effects of acute alcohol intake on the HR and HRV parameters during sleep.

Methods

Data Collection

The original data sample contained 111,025 measurement days from 42,086 Finnish employees representing a wide range of blue- and white-collar workers in varying size companies. Employees had voluntarily participated in a preventive occupational health care program with the aim of improving their health habits and stress management. The program included a continuous beat-to-beat R-R interval recording for a few days during the participant's normal life. The R-R interval recordings were performed using Bodyguard (Firstbeat Technologies Ltd, Jyväskylä, Finland) wearable device that was attached on the chest with two electrodes. HRV indices, stress, recovery, and PA were computed with Firstbeat Analysis Server (Firstbeat Technologies Ltd) from the recorded R-R interval data, and together with other physiological measurements, they were used as health promotion tools at employees' workplaces. Employees were instructed not to participate in recordings if they had any disease stages or medications possibly affecting R-R intervals, for example, chronic heart rhythm disturbance, very high blood pressure (≥180/100 mm Hg), type 1 or 2 diabetes with autonomic neuropathy, severe neurological disease (eg, advanced multiple sclerosis or Parkinson disease), fever or other acute disease, or BMI >40 kg/m^2[25].

All the R-R interval recordings performed on the employees were analyzed and stored anonymously to a registry administered by Firstbeat Technologies Ltd. Each service provider conducting recordings for participants signed an agreement allowing Firstbeat Technologies Ltd to store the anonymized data and to use it for development and research purposes. The employers were responsible to inform their employees about the data usage. Following the agreements, a dataset was extracted from the registry for this study. The use of the dataset for research purposes was approved by the ethics committee of Tampere University Hospital (Reference No R13160).

Data Extraction

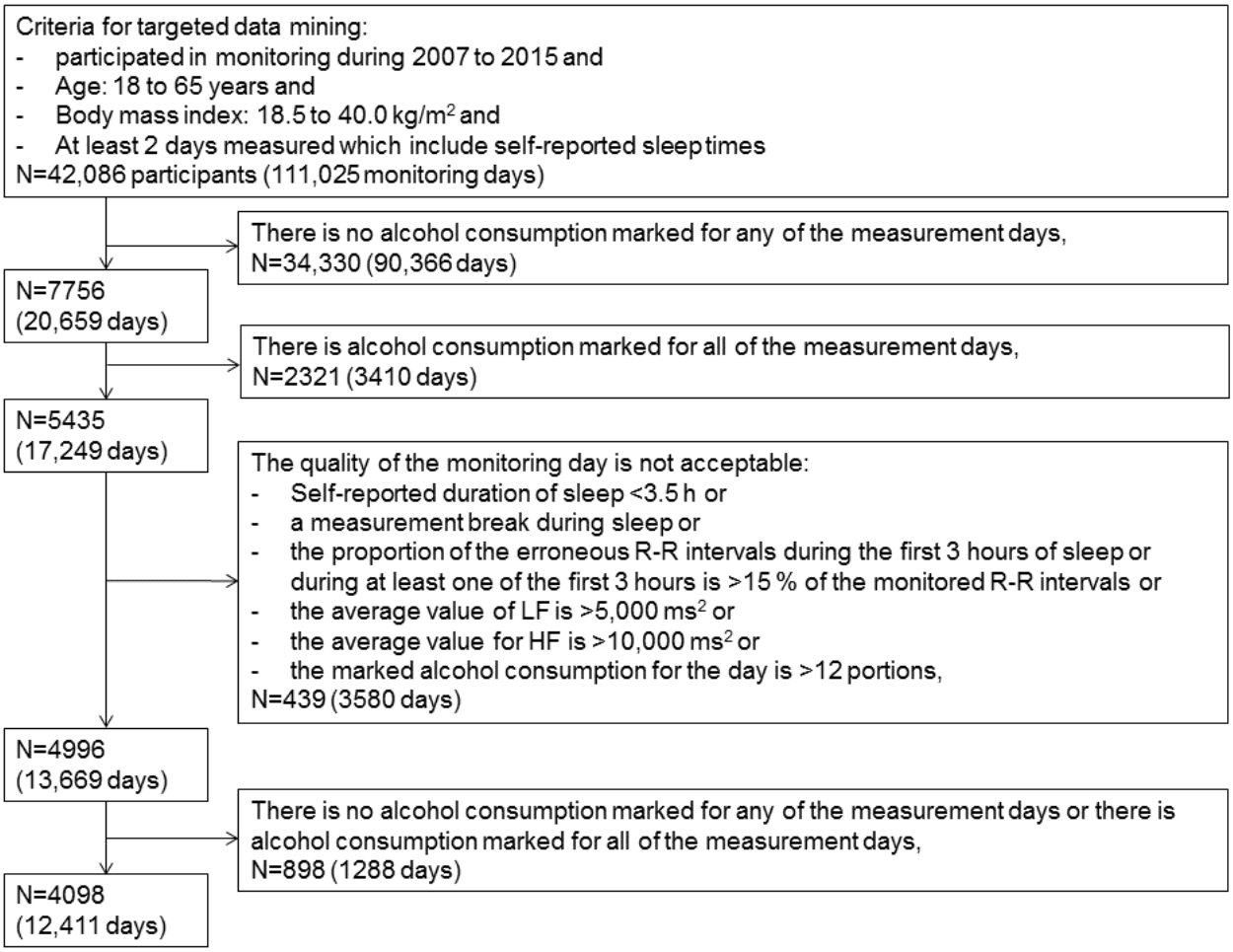
The dataset extracted from the registry to this study included the R-R interval recordings performed with the Bodyguard device (Firstbeat Ltd, Jyväskylä, Finland). The sampling frequency of the device is 1000 Hz for the R-R interval recording [26], and its mean absolute error for R-R intervals has been reported to be 4.45 ms [27]. An artifact correction was performed for the R-R intervals with Firstbeat Analysis Server [28], after which the mean absolute error of R-R intervals has been reported to be 2.27 ms [27]. For this study, the artifact-corrected beat-to-beat R-R intervals were analyzed for a 3-hour period starting 30 min after the self-reported onset of bedtime that is the most likely period for slow wave sleep.

From the artifact-corrected beat-to-beat R-R intervals, the average of HR in 10-min nonoverlapping windows and RMSSD with 5-min windows were calculated [10]. The frequency bands of HRV were assessed applying short-time Fourier transform on the artifact-corrected beat-to-beat R-R interval data. In addition to the traditional HRV measures, personalized HRV-derived indices of recovery were calculated with Firstbeat Analysis Server. The software detects the periods of recovery and thereafter estimates the magnitude of these recovery reactions based on a person's range of physiological reactions (eg, minimal and maximal HR) and time series variables related to parasympathetic and sympathetic modulation (eg, HR, HF power, LF power, and HRV-derived respiration rate) [29]. During recovery reactions, parasympathetic regulation predominates in the ANS [29]. The momentary absolute level of recovery reactions is estimated with parameters describing the magnitude of parasympathetic modulation, and it is high when HR is individually low and parasympathetic HRV is individually high [30].

For this study, the exclusion criteria were unknown or very high reported alcohol consumption (>12 portions of alcohol) during the recording day, unknown or very short self-reported sleeping time, and poor quality of HRV recordings (Figure 1). If a subject reported more than one sleep periods per day, only the longest sleep period was analyzed. Only subjects having a day with at least one portion of alcohol and a day with no alcohol intake were analyzed. The final analysis included 12,411 HRV recording days from 4098 individuals.

As background information, age, gender, and self-reported weight, height, and PA class modified from Ross and Jackson [31] were available. Participants were asked to note their alcohol intake as portions (1 portion=12 g of ethanol) for each measurement day preceding sleep. The exact timing of alcohol intake and smoking history were not available.

Figure 1. The selection of study population for the analyses.



Statistical Analyses

HR, RMSSD, LF/HF ratio, time considered as recovery (recovery percentage), and average of the momentary absolute levels of recovery reactions (recovery index) from a 3-hour period starting 30 min after the self-reported bedtime onset were considered as the outcome variables. Only the first 3 hours of sleep were analyzed, as most of the slow wave sleep typically occurs during the first hours of sleep [1]. During slow wave sleep, the parasympathetic regulation is dominating, and sufficient amount of slow wave sleep has been associated with both good physical and mental recovery [1].

All analyses were conducted in a within-subject repeated-measures manner by comparing the participants' outcome variables between days with and without alcohol intake. The within-subject design was used, as it allows studying the intraindividual effects of acute alcohol intake and controls for possible unknown confounders.

For the within-subject repeated-measures two-way analysis of variance (ANOVA), the participants' hourly averages of outcome variables were calculated for days with and without alcohol intake, and the participants were categorized into low (≤0.25 g/kg), moderate (>0.25-0.75 g/kg), and high (>0.75 g/kg) dose groups according to their alcohol intake during the day. Note that the groups also include the participant's reference with no alcohol, and the participants may have data in one, two, or all three dose groups. If a participant had more than 1 day with low, moderate, or high or with no alcohol intake, the outcome variables were averaged over those days. A repeated-measures two-way ANOVA was performed separately for each dose group to evaluate the difference and the shape of the hour-by-hour pattern in the outcome variables between the days with and without alcohol intake.

In the second analysis, the linear regression model was fitted for the difference in the average of the 3-hour HR and HRV parameters between the participant's days with and without alcohol intake. First, the 3-hour averages of the outcome variables were calculated for each measurement day. Thereafter, the difference in the participant's averages between the days with and without alcohol intake was calculated. If the participant had more than one measurement day without alcohol intake, the average of the measurement days' 3-hour outcome variable averages was employed. A dataset including the measurement day with the highest amount of reported alcohol intake from each participant was extracted, and a linear regression was fitted to the data using the difference in the outcome variables between the days with and without alcohol intake as a dependent variable. In addition to alcohol intake, all information available about the subjects was employed as independent variables in the regression models. The independent variables were continuous variables of alcohol dose (g/kg), age, PA class, BMI, and the 3-hour average of HR (bpm) during a night after a day without alcohol intake (baseline sleep HR) and gender as a categorical

variable. Age, BMI, and the baseline sleep HR were subtracted to baseline levels of 18 years, 18.5 kg/m^2, and 38 bpm, respectively. In addition, a linear regression with interactions between alcohol doses and other predictors was fitted.

All statistical analyses were conducted using R (The R Foundation for Statistical Computing) version 3.2.2. The level of significance in all analyses was set at <0.05. However, with data of this size, it is more important to focus on effect sizes than *P* values [32].

Results

Characteristics of the Study Population

From a larger cohort, this study included 4098 subjects who had continuous beat-to-beat R-R interval recordings of good quality with for at least 1 day with and for at least 1 day without alcohol intake. There was a significant proportion of female subjects in this study (Table 1). On average, the subjects were middle-aged, slightly overweight, and had regular PA 2 to 3 times per week, and the total weekly training amount being approximately 1 hour.

Neither PA class nor BMI differed significantly between the dose groups (*P*>.05, Table 2). High alcohol intake was more common among males (*P*<.001) and young subjects (*P*<.001). Average daily alcohol intake in the low, moderate, and high groups was 0.17, 0.45, and 1.1 g/kg, respectively, with the corresponding average number of reported alcohol portions being 1.1, 2.9, and 7.0 drinks.

Repeated-Measures Analysis of Variance Analyses

The means and 99% CIs for HR, the LF/HF ratio, RMSSD, the recovery percentage, and recovery index calculated from intraindividual HRV recordings during the first 3 hours of sleep in low, moderate, and high dose groups were calculated (Figures 2 and 3). Low HR and LF/HF ratio reflect increased parasympathetic regulation, and low RMSSD indicates increased sympathetic regulation in the ANS.

High alcohol intake had the greatest effect on the outcome variables. On average, HR was increased by 1.4 bpm with low, 4.0 bpm with moderate, and 8.7 bpm with high alcohol intake. The LF/HF ratio was increased by 0.1 with low, 0.3 with moderate, and 0.5 with high alcohol intake. RMSSD was decreased by 2.0 ms with low, 5.7 ms with moderate, and 12.9 ms with high alcohol intake. The recovery percentage was decreased by 9.3 percentage units with low, 24.0 percentage units with moderate, and 39.2 percentage units with high alcohol intake. The recovery index was decreased by 7.1 with low, 20.8 with moderate, and 40.2 with high alcohol intake.

For each dose group, the within-subject repeated-measures two-way ANOVA showed significant differences in all outcome variables (all *P*<.001) between the days with and without alcohol intake. In addition, the hourly HRV parameters differed significantly from each other (all *P*<.001). In high dose group comparisons, the interactions between the hour of sleep and alcohol intake were statistically significant for all outcome parameters (all *P*<.001), indicating that the hour-by-hour pattern in the HRV parameters during sleep was different for subjects between the days with high and no alcohol intake. For days with high alcohol intake, the average LF/HF ratio increased hour-by-hour during sleep, whereas the average LF/HF ratio increased from the first to the second hour of sleep but decreased from the second to the third hour of sleep for days with no alcohol intake. For days without alcohol intake, the recovery percentage and recovery index increased as the sleep progressed, but this did not occur after high alcohol intake. In moderate dose group comparisons, the interactions between hour and alcohol intake were statistically significant for the LF/HF ratio (*P*=.002) and recovery percentage (*P*=.01).

Table 1. Characteristics of the study population.

Demographic characteristic	All (N=4098), mean (SD; range)	Males (N=1811), mean (SD; range)	Females (N=2287), mean (SD; range)
Age (years)	45.1 (9.6; 19-65)	45.2 (9.4; 19-65)	44.9 (9.8; 19-65)
Physical activity class[a]	4.8 (1.8; 0-10)	4.9 (1.7; 0-10)	4.8 (1.8; 0-10)
Body mass index (kg/m^2)	26.0 (4.0; 18.5-39.9)	26.7 (3.5; 18.9-39.5)	25.4 (4.3; 18.5-39.9)

[a]Physical activity class range: 0 (physically inactive) to 10 (physically very active).

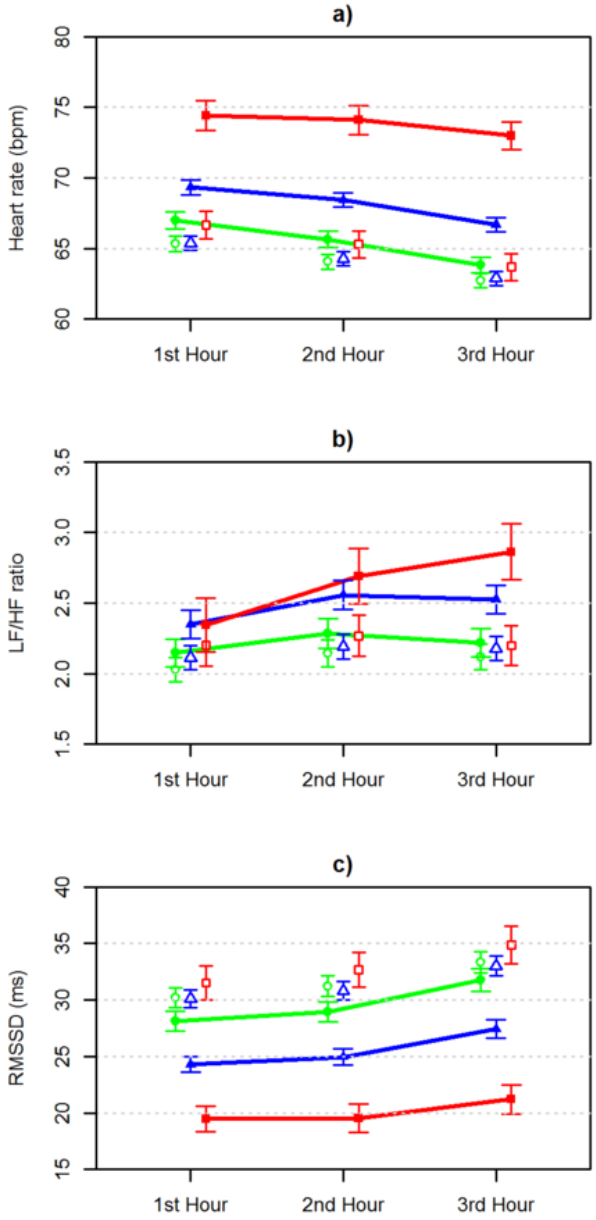
Table 2. Characteristics of low, moderate, and high dose groups during the heart rate variability (HRV) recordings.

Demographic characteristic	Low ≤0.25 g/kg (n=1752)	Moderate >0.25-0.75 g/kg (n=2194)	High >0.75 g/kg (n=716)	*P* value
Number of male subjects, n (%)	671 (38.29)	1010 (46.03)	380 (53.1)	<.001[a]
Age in years, mean (SD)	45.6 (9.0)	46.3 (9.3)	42.3 (10.7)	<.001[b]
Physical activity class, mean (SD)	4.9 (1.6)	4.9 (1.7)	4.6 (1.9)	.59[b]
Body-mass index in kg/m^2, mean (SD)	25.9 (4.2)	26.0 (3.8)	25.8 (3.7)	.10[b]
Weight in kg, mean (SD)	77.5 (16.2)	77.9 (14.3)	78.1 (14.1)	.31[b]

[a]Chi-square test.

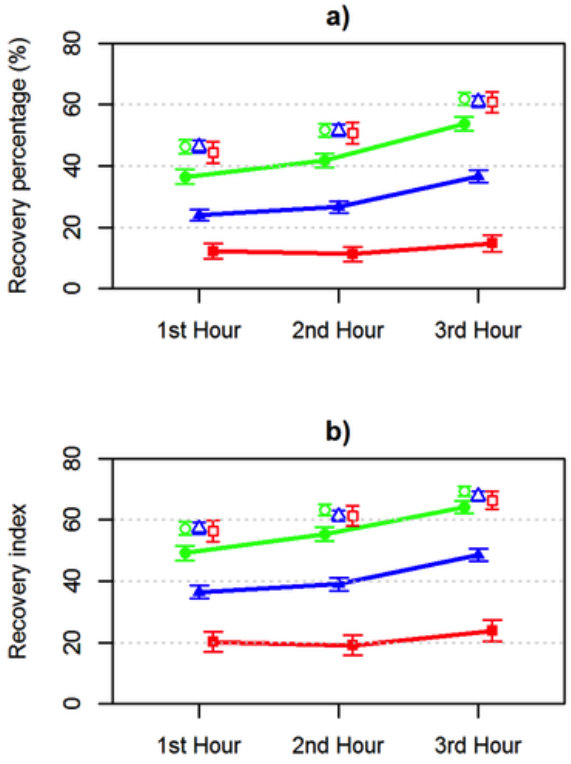
[b]One-way analysis of variance (ANOVA) adjusted for gender.

Figure 2. The effect of alcohol intake during the three first hour of sleep on a) heart rate, b) low frequency/high frequency (LF/HF) ratio, and c) root mean square of the successive differences (RMSSD). The marks green ●=low dose (≤0.25 g/kg), blue ▲=medium dose (>0.25-0.75 g/kg), and red ■=high dose (>0.75 g/kg) denote the averages, and corresponding white symbols denote the measures for the same persons without alcohol. Due to the size of the data and clarity of the figure, 99% CIs are shown, and the lines between hours are only shown for alcohol dose groups.



This shows that the hour-by-hour pattern was different between the days with moderate and no alcohol intake only for the LF/HF ratio and recovery percentage. In low dose comparisons, the hour-by-hour pattern in the LF/HF ratio (P=.51), RMSSD (P=.06), and recovery percentage (P=.08) during sleep was similar between the days with low and no alcohol intake. The HR (P<.001) and recovery index (P=.01) variables had a statistically significant interaction between the hour and alcohol intake, ie, their hour-by-hour pattern during sleep differed between the days with low and no alcohol intake. Visual inspection (Figures 2 and 3) showed that after low alcohol intake, the levels of outcome variables during the third hour approach their reference levels.

Figure 3. The effect of alcohol intake during the three first hour of sleep on a) recovery percentage, and b) recovery index. The marks green ●=low dose (≤0.25 g/kg), blue ▲=medium dose (>0.25-0.75 g/kg), and red ■=high dose (>0.75 g/kg) denote the averages, and corresponding white symbols denote the measures for the same persons without alcohol. Due to the size of the data and clarity of the figure, 99% CIs are shown, and the lines between hours are only shown for alcohol dose groups.



Linear Models

In linear model analysis, alcohol intake significantly affected the outcome variables (Tables 3 and 4). The results show that HR was increased with acute alcohol intake. For example, alcohol intake of 0.75 g/kg increased HR for subjects on average by 6.8 bpm compared with their nights without alcohol intake (Table 3). Alcohol intake increased the HR significantly more among young than older subjects: alcohol intake of 0.75 g/kg increased HR on average by 1.8 bpm more for a 30-year old person than for a 60-year old person (Table 4). In addition, alcohol intake increased HR significantly more among subjects with lower than higher baseline sleep HR: alcohol intake of 0.75 g/kg and an increase of 10 bpm in baseline HR decreased the difference in HR by 3.4 bpm, on average (Table 4). The increase in HR with alcohol intake was similar for subjects despite their gender, PA level, or BMI (Table 4).

Alcohol intake increased the LF/HF ratio, and this effect was slightly stronger among males and subjects with higher PA level (Table 4). However, the coefficients of determination for the LF/HF ration linear regression models were low (Tables 3 and 4), indicating that the input variables employed in the models did not explain the variation in the LF/HF ratio well. RMSSD was decreased by alcohol intake at all ages, but the effect was stronger in younger than older subjects (Table 4). On average, RMSSD was decreased with high alcohol intake (0.75 g/kg) by 10.9 ms for a 30-year old subject but only by 4.7 ms for a 60-year old subject (Table 4). In addition, alcohol intake decreased RMSSD more for subjects with lower baseline HR (Table 4).

Recovery percentage decreased significantly by increased alcohol intake (Tables 3 and 4). An 80-kg person drinking five portions of alcohol (0.75 g/kg) has on average 45 min less recovery (25.25 percentage units) during the first 3 hours of sleep than without alcohol (Table 3). The recovery percentage was decreased significantly more by alcohol intake for subjects with lower baseline HR than with higher baseline HR (Table 4). The decrease in recovery percentage with alcohol was similar regarding the other background parameters of the subjects (Table 4). In addition, the recovery index was attenuated with alcohol intake (Tables 3 and 4). Alcohol intake attenuated the recovery index slightly more in subjects with higher BMI than with lower BMI (Table 4). The other background parameters did not have a significant interaction with alcohol intake (Table 4).

When the effects for alcohol and background characteristics were controlled, the difference in recovery percentage was strongly correlated with the difference in HR (Pearson partial correlation coefficient and the coefficient of determination: r=−.70, R^2=.486, P<.001) and in RMSSD (r=.51, R^2=.262, P<.001) but only moderately correlated with the change in LF/HF ratio (r=−.27, R^2=.071, P<.001). Similarly, the difference in the recovery index was strongly correlated with the difference in HR (r=−.63, R^2=.388, P<.001) and in RMSSD (r=.49, R^2=.236, P<.001) but only moderately correlated with the change in LF/HF ratio (r=−.27, R^2=.074, P<.001). The partial correlation between the difference in the recovery percentage and the recovery index was moderate (r=.48, R^2=.229, P<.001).

Table 3. The linear regression models without interaction components for the average of heart rate (HR), low frequency/high frequency (LF/HF) ratio, root mean square of the successive differences (RMSSD), recovery percentage, and recovery index during the first 3 hours of sleep. BMI: body mass index.

Outcome	HR	LF/HF ratio	RMSSD	Recovery percentage	Recovery index
Intercept, estimate (SE)	10.87 (0.66)[a]	0.715 (0.115)[a]	−15.32 (0.98)[a]	−56.09 (3.25)[a]	−28.27 (3.70)[a]
Alcohol (g/kg), estimate (SE)	8.49 (0.29)[a]	0.425 (0.051)[a]	−12.24 (0.44)[a]	−33.67 (1.45)[a]	−36.63 (1.65)[a]
Physical activity class, estimate (SE)	−0.48 (0.06)[a]	−0.019 (0.011)	0.37 (0.09)[a]	1.62 (0.31)[a]	1.81 (0.35)[a]
Age (0=18 years), estimate (SE)	−0.03 (0.01)[b]	−0.001 (0.002)[a]	0.14 (0.02)[a]	−0.06 (0.05)	−0.08 (0.06)
BMI (0=18.5 kg/m^2), estimate (SE)	0.22 (0.03)[a]	0.002 (0.005)	−0.26 (0.04)[a]	−0.81 (0.14)[a]	−0.89 (0.15)[a]
Gender (0=female, 1=male), estimate (SE)	−1.70 (0.21)[a]	0.014 (0.037)	2.09 (0.32)[a]	7.22 (1.06)[a]	5.24 (1.21)[a]
Baseline sleep HR (0=38 bpm), estimate (SE)	−0.33 (0.01)[a]	−0.021 (0.002)[a]	0.41 (0.02)[a]	1.67 (0.06)[a]	0.86 (0.07)[a]
Adjusted coefficient of determination for the model	0.267	0.039	0.245	0.230	0.135

[a]*P*<.001.

[b]*P*<.01.

Table 4. The linear regression models with interaction components for the average of heart rate (HR), low frequency/high frequency (LF/HF) ratio, root mean square of the successive differences (RMSSD), recovery percentage, and recovery index during the first 3 hours of sleep.

Outcome	HR	LF/HF ratio	RMSSD	Recovery percentage	Recovery index
Intercept, estimate (SE)	7.61 (1.04)[a]	0.724 (0.182)[a]	−10.55 (1.55)[a]	−49.34 (5.13)[a]	−26.73 (5.86)[a]
Alcohol (g/kg), estimate (SE)	14.47 (1.56)[a]	0.386 (0.272)	−20.68 (2.32)[a]	−46.05 (7.69)[a]	−38.48 (8.78)[a]
Physical activity class, estimate (SE)	−0.33 (0.10)[b]	−0.051 (0.018)[b]	0.51 (0.15)[a]	2.29 (0.51)[a]	2.57 (0.59)[a]
Age (0=18 years), estimate (SE)	0.03 (0.02)	0.004 (0.003)	−0.008 (0.03)	0.07 (0.09)	−0.05 (0.10)
BMI (0=18.5 kg/m^2), estimate (SE)	0.19 (0.04)[a]	0.005 (0.008)	−0.18 (0.07)[b]	−0.60 (0.22)[b]	−0.42 (0.25)
Gender (0=female, 1=male), estimate (SE)	−1.38 (0.35)[a]	−0.010 (0.062)	2.04 (0.53)[a]	6.47 (1.75)[a]	2.95 (2.00)
Baseline sleep HR (0=38 bpm), estimate (SE)	−0.28 (0.02)[a]	−0.019 (0.004)[a]	0.31 (0.03)[a]	1.25 (0.10)[a]	0.71 (0.11)[a]
Alcohol x physical activity class, estimate (SE)	−0.27 (0.17)	0.065 (0.029)[c]	−0.32 (0.25)	−1.47 (0.83)	−1.59 (0.95)
Alcohol x age	−0.12 (0.03)[a]	−0.009 (0.005)	0.26 (0.04)[a]	−0.04 (0.14)	0.27 (0.16)
Alcohol x BMI, estimate (SE)	0.08 (0.08)	−0.009 (0.014)	−0.15 (0.12)	−0.39 (0.39)	−1.05 (0.45)[c]
Alcohol x gender, estimate (SE)	−0.56 (0.60)	0.251 (0.104)[c]	−0.13 (0.89)	1.35 (2.95)	4.87 (3.37)
Alcohol x baseline sleep HR, estimate (SE)	−0.08 (0.03)[c]	−0.005 (0.005)	0.18 (0.05)[a]	0.83 (0.15)[a]	0.30 (0.17)
Adjusted coefficient of determination for the model	0.271	0.042	0.255	0.236	0.137

[a]*P*<.001.

[b]*P*<.01.

[c]*P*<.05.

Discussion

Principal Findings

Impact of alcohol on autonomic nervous system control during sleep has been earlier demonstrated in controlled conditions with relatively small samples. This study demonstrated that this effect is also clearly seen in noncontrolled conditions with wearable HR monitoring and HRV analysis. In the large heterogeneous, noncontrolled, and free-living study population, alcohol intake caused a dose-dependent effect in cardiac autonomic regulation during the first 3 hours of self-reported sleep time. Intraindividually, HR remained elevated, parasympathetic recovery was delayed, and sympathetic dominance was prolonged after alcohol intake compared with recordings with no alcohol. The effects in cardiac autonomic regulation were observed already with low doses of alcohol.

These findings accord with previous studies reporting dose-related effects of alcohol on parasympathetic indices of HRV during sleep in laboratory conditions [21]. Increased HR partly explains the attenuated HRV indices during sleep following alcohol intake [33], and prolonged elevation in the

LF/HF ratio supports the role of sympathetic regulation in alcohol-related delayed HRV recovery [34]. Even a moderate amount of alcohol was shown to attenuate recovery in the ANS in this study. This accords with the results of a previous study where two drinks caused significantly decreased RMSSD and increased HR and LF/HF ratio, and one drink altered RMSSD but not HR or LF/HF ratio [20]. In this study, HR and the LF/HF ratio were affected also in the low dose (≤0.25 g/kg) group where about 90% of the measurement days involved one drink and the rest two drinks.

The strength of this study was the large study population representing a sample of Finnish employees with the whole span of working age, different BMI categories and PA levels, and both genders. With the large free-living sample, this study provided real-world evidence and enabled further studying the effects of personal background parameters on the effects of alcohol intake on the ANS. The main limitations of the study were not knowing the exact alcohol doses and the exact times of alcohol consumption and sleep. The higher alcohol intakes may have been underestimated. In addition, the alcohol drinking habits of the participants were not known.

Most previous studies considering the effects of alcohol on the ANS have used male subjects only, and differences between the sexes have not been examined [9]. With a significant proportion of female participants, this study showed alcohol mainly affecting the ANS similar among men and women, although the LF/HF ratio showed sympathetic dominance being slightly stronger in men than in women after alcohol intake. The large age range of the participants allowed studying the interaction effect of age and alcohol intake on the ANS. The effect of alcohol intake on the change in HR and RMSSD was stronger in young subjects than in older subjects, but the effect of alcohol on the LF/HF ratio, the recovery percentage, or the recovery index was not age-dependent.

Our findings on the modifiable disease risk factors are in agreement with previous data on that physical inactivity and high BMI reduce HRV [35] and show that consumption of alcohol reduces HRV in all the PA and BMI categories. In fact, this study showed that regular PA does not attenuate the effects of alcohol intake on the ANS. The changes in HR and RMSSD because of alcohol intake were similar for physically active and sedentary participants in this study. The physically active participants actually displayed in LF/HF ratio even stronger intraindividual sympathetic dominance because of alcohol intake than the sedentary subjects did. Consequently, being physically active does not seem to protect from the negative effects of alcohol intake on the ANS during sleep. This aspect is important to consider given that the alcohol consumption is common also among physically active individuals, and there may even be a dose-response relationship between alcohol consumption and level of PA [36]. Even though exercise is beneficial for general health among alcohol users [37], alcohol has been reported to negatively affect HRV recovery after exercise [38]. Thus, clinically important is to note that the risk of exercise-related cardiac events might be raised by prolonged sympathetic tone during recovery. PA on the current day of alcohol intake, a factor that might affect HRV parameters [9], was not estimated, although it would be possible with our material. However, the effect of alcohol on the amount of recovery during sleep has been reported to strongly overwhelm the effect of other daily activities, including PA [39].

Poor sleep associates with negative health behaviors, ill health, and decreased work ability [40,41]. This study might offer some new tools for health promotion in occupational and primary health care to show practically, on individual and personal level, based on wearable HRV monitoring, the negative effects of alcohol on sleep. Demonstration of the insufficient recovery after using alcohol may be very important for individuals who consume alcohol repeatedly day after day and may suffer from accumulated consequences of insufficient recovery. The personalized indices of recovery, recovery percentage, and recovery index were found to accord with the RMSSD and HR. Importantly, the recovery percentage was found to be independent of age, and the recovery index had only a slight interaction effect between alcohol intake and BMI. These personalized recovery parameters can be used as a tool of health promotion in occupational health care to better manage interindividual differences in HRV and to visualize the associations between alcohol consumption and sleep.

Conclusions

The study demonstrates, with big uncontrolled data from unobtrusive wearable monitoring, that alcohol intake results in suppression of parasympathetic regulation of the ANS in a dose-response manner. Being physically active and young appears to provide no protection from alcohol-induced suppression of parasympathetic regulation, a finding that needs to be considered given the literature evidence that increased PA associates with higher alcohol usage among nonalcoholics. Personalized HRV measures such as recovery percentage may be more practical in occupational health settings to demonstrate the effect of alcohol on sleep than, eg, RMSSD, which is strongly age-dependent.

Acknowledgments

This study was supported by the Finnish Funding Agency for Technology and Innovation (TEKES).

Conflicts of Interest

HL is currently employed in the Digital Health Lab of Nokia Technologies, and TM and I are currently employed by Firstbeat Technologies Ltd, Jyväskylä, Finland.

References

1. von Bonin D, Grote V, Buri C, Cysarz D, Heusser P, Moser M, et al. Adaption of cardio-respiratory balance during day-rest compared to deep sleep--an indicator for quality of life? Psychiatry Res 2014 Nov 30;219(3):638-644. [doi: 10.1016/j.psychres.2014.06.004] [Medline: 25011731]
2. Burton AR, Rahman K, Kadota Y, Lloyd A, Vollmer-Conna U. Reduced heart rate variability predicts poor sleep quality in a case-control study of chronic fatigue syndrome. Exp Brain Res 2010 Jul;204(1):71-78. [doi: 10.1007/s00221-010-2296-1] [Medline: 20502886]
3. Porkka-Heiskanen T, Zitting K, Wigren H. Sleep, its regulation and possible mechanisms of sleep disturbances. Acta Physiol (Oxf) 2013 Aug;208(4):311-328. [doi: 10.1111/apha.12134] [Medline: 23746394]
4. Thakkar MM, Sharma R, Sahota P. Alcohol disrupts sleep homeostasis. Alcohol 2015 Jun;49(4):299-310 [FREE Full text] [doi: 10.1016/j.alcohol.2014.07.019] [Medline: 25499829]
5. Thayer JF, Hall M, Sollers JJ, Fischer JE. Alcohol use, urinary cortisol, and heart rate variability in apparently healthy men: Evidence for impaired inhibitory control of the HPA axis in heavy drinkers. Int J Psychophysiol 2006 Mar;59(3):244-250. [doi: 10.1016/j.ijpsycho.2005.10.013] [Medline: 16325293]
6. Rod NH, Grønbaek M, Schnohr P, Prescott E, Kristensen TS. Perceived stress as a risk factor for changes in health behaviour and cardiac risk profile: a longitudinal study. J Intern Med 2009 Nov;266(5):467-475 [FREE Full text] [doi: 10.1111/j.1365-2796.2009.02124.x] [Medline: 19570055]
7. Virtanen M, Jokela M, Nyberg ST, Madsen IE, Lallukka T, Ahola K, et al. Long working hours and alcohol use: systematic review and meta-analysis of published studies and unpublished individual participant data. Br Med J 2015 Jan 13;350:g7772 [FREE Full text] [Medline: 25587065]
8. Bonnemeier H, Richardt G, Potratz J, Wiegand UK, Brandes A, Kluge N, et al. Circadian profile of cardiac autonomic nervous modulation in healthy subjects: differing effects of aging and gender on heart rate variability. J Cardiovasc Electrophysiol 2003 Aug;14(8):791-799. [Medline: 12890036]
9. Romanowicz M, Schmidt JE, Bostwick JM, Mrazek DA, Karpyak VM. Changes in heart rate variability associated with acute alcohol consumption: current knowledge and implications for practice and research. Alcohol Clin Exp Res 2011 Jun;35(6):1092-1105. [doi: 10.1111/j.1530-0277.2011.01442.x] [Medline: 21332532]
10. Task Force of the European Society of Cardiology the North American Society of Pacing Electrophysiology. Heart rate variability: standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation 1996 Mar 01;93(5):1043-1065 [FREE Full text] [Medline: 8598068]
11. Sassi R, Cerutti S, Lombardi F, Malik M, Huikuri HV, Peng C, et al. Advances in heart rate variability signal analysis: joint position statement by the e-Cardiology ESC Working Group and the European Heart Rhythm Association co-endorsed by the Asia Pacific Heart Rhythm Society. Europace 2015 Sep;17(9):1341-1353. [doi: 10.1093/europace/euv015] [Medline: 26177817]
12. Billman GE. The LF/HF ratio does not accurately measure cardiac sympatho-vagal balance. Front Physiol 2013;4:26 [FREE Full text] [doi: 10.3389/fphys.2013.00026] [Medline: 23431279]
13. Quintana DS, Alvares GA, Heathers JA. Guidelines for Reporting Articles on Psychiatry and Heart rate variability (GRAPH): recommendations to advance research communication. Transl Psychiatry 2016 May 10;6:e803 [FREE Full text] [doi: 10.1038/tp.2016.73] [Medline: 27163204]
14. Tobaldini E, Nobili L, Strada S, Casali KR, Braghiroli A, Montano N. Heart rate variability in normal and pathological sleep. Front Physiol 2013 Oct 16;4:294 [FREE Full text] [doi: 10.3389/fphys.2013.00294] [Medline: 24137133]
15. Chouchou F, Desseilles M. Heart rate variability: a tool to explore the sleeping brain? Front Neurosci 2014;8:402 [FREE Full text] [doi: 10.3389/fnins.2014.00402] [Medline: 25565936]
16. Rieger A, Stoll R, Kreuzfeld S, Behrens K, Weippert M. Heart rate and heart rate variability as indirect markers of surgeons' intraoperative stress. Int Arch Occup Environ Health 2014 Feb;87(2):165-174. [doi: 10.1007/s00420-013-0847-z] [Medline: 23370764]
17. Brosschot JF, Geurts SA, Kruizinga I, Radstaak M, Verkuil B, Quirin M, et al. Does unconscious stress play a role in prolonged cardiovascular stress recovery? Stress Health 2014 Aug;30(3):179-187. [doi: 10.1002/smi.2590] [Medline: 25100269]
18. Föhr T, Tolvanen A, Myllymäki T, Järvelä-Reijonen E, Rantala S, Korpela R, et al. Subjective stress, objective heart rate variability-based stress, and recovery on workdays among overweight and psychologically distressed individuals: a cross-sectional study. J Occup Med Toxicol 2015;10:39 [FREE Full text] [doi: 10.1186/s12995-015-0081-6] [Medline: 26504485]
19. Koskinen P, Virolainen J, Kupari M. Acute alcohol intake decreases short-term heart rate variability in healthy subjects. Clin Sci (Lond) 1994 Aug;87(2):225-230. [Medline: 7924168]
20. Spaak J, Tomlinson G, McGowan CL, Soleas GJ, Morris BL, Picton P, et al. Dose-related effects of red wine and alcohol on heart rate variability. Am J Physiol Heart Circ Physiol 2010 Jun;298(6):H2226-H2231 [FREE Full text] [doi: 10.1152/ajpheart.00700.2009] [Medline: 20418480]

21. Sagawa Y, Kondo H, Matsubuchi N, Takemura T, Kanayama H, Kaneko Y, et al. Alcohol has a dose-related effect on parasympathetic nerve activity during sleep. Alcohol Clin Exp Res 2011 Nov;35(11):2093-2100. [doi: 10.1111/j.1530-0277.2011.01558.x] [Medline: 21848959]
22. Sherman RE, Anderson SA, Dal Pan GJ, Gray GW, Gross T, Hunter NL, et al. Real-world evidence - what is it and what can it tell us? N Engl J Med 2016 Dec 08;375(23):2293-2297. [doi: 10.1056/NEJMsb1609216] [Medline: 27959688]
23. Booth CM, Tannock IF. Randomised controlled trials and population-based observational research: partners in the evolution of medical evidence. Br J Cancer 2014 Feb 04;110(3):551-555 [FREE Full text] [doi: 10.1038/bjc.2013.725] [Medline: 24495873]
24. Garrison Jr LP, Neumann PJ, Erickson P, Marshall D, Mullins CD. Using real-world data for coverage and payment decisions: the ISPOR Real-World Data Task Force report. Value Health 2007;10(5):326-335 [FREE Full text] [doi: 10.1111/j.1524-4733.2007.00186.x] [Medline: 17888097]
25. Mutikainen S, Helander E, Pietilä J, Korhonen I, Kujala UM. Objectively measured physical activity in Finnish employees: a cross-sectional study. Br Med J Open 2014 Dec 10;4(12):e005927 [FREE Full text] [doi: 10.1136/bmjopen-2014-005927] [Medline: 25500160]
26. Firstbeat Technologies Ltd. Bodyguard 2 technical details URL: https://support.firstbeat.com/en/support/solutions/articles/9000114468-bodyguard-2-technical-details [WebCite Cache ID 6vJNo6JbP]
27. Parak J, Korhonen I. Firstbeat Technologies Ltd. 2013. Accuracy of Firstbeat Bodyguard 2 beat-to-beat heart rate monitor URL: https://assets.firstbeat.com/firstbeat/uploads/2015/11/white_paper_bodyguard2_final.pdf [WebCite Cache ID 6vJJnrXG6]
28. Saalasti S. Neural Networks for Heart Rate Time Series Analysis. Jyväskylä, Finland: University of Jyväskylä; 2003.
29. Kettunen J, Saalasti S. Patent Images. 2008. Procedure for detection of stress by segmentation and analyzing a heart beat signal URL: https://patentimages.storage.googleapis.com/c0/da/86/0013898102e400/US20050256414A1.pdf [WebCite Cache ID 6xsx0lFJX]
30. Firstbeat Technologies Ltd. 2014. Stress and Recovery Analysis Method Based on 24-hour Heart Rate Variability URL: https://assets.firstbeat.com/firstbeat/uploads/2015/10/Stress-and-recovery_white-paper_20145.pdf [WebCite Cache ID 6vJCwTnzu]
31. Ross RM, Jackson AS. Exercise Concepts, Calculations, and Computer Applications. Carmel, Indiana, USA: Benchmark Press; 1990.
32. Lin M, Lucas Jr HC, Shmueli G. Research commentary—too big to fail: large samples and the p-value problem -Value Problem. Inf Syst Res 2013 Dec;24(4):906-917. [doi: 10.1287/isre.2013.0480]
33. Ryan JM, Howes LG. Relations between alcohol consumption, heart rate, and heart rate variability in men. Heart 2002 Dec;88(6):641-642 [FREE Full text] [Medline: 12433903]
34. Boschloo L, Vogelzangs N, Licht CM, Vreeburg SA, Smit JH, van den Brin W, et al. Heavy alcohol use, rather than alcohol dependence, is associated with dysregulation of the hypothalamic-pituitary-adrenal axis and the autonomic nervous system. Drug Alcohol Depend 2011 Jul 01;116(1-3):170-176. [doi: 10.1016/j.drugalcdep.2010.12.006] [Medline: 21330066]
35. Rennie K, Hemingway H, Kumari M, Brunner E, Malik M, Marmot M. Effects of moderate and vigorous physical activity on heart rate variability in a British study of civil servants. Am J Epidemiol 2003 Jul 15;158(2):135-143. [Medline: 12851226]
36. Piazza-Gardner AK, Barry AE. Examining physical activity levels and alcohol consumption: are people who drink more active? Am J Health Promot 2012;26(3):e95-104. [doi: 10.4278/ajhp.100929-LIT-328] [Medline: 22208422]
37. Leasure JL, Neighbors C, Henderson CE, Young CM. Exercise and alcohol consumption: what we know, what we need to know, and why it is important. Front Psychiatry 2015;6:156 [FREE Full text] [doi: 10.3389/fpsyt.2015.00156] [Medline: 26578988]
38. Wiklund U, Karlsson M, Oström M, Messner T. Influence of energy drinks and alcohol on post-exercise heart rate recovery and heart rate variability. Clin Physiol Funct Imaging 2009 Jan;29(1):74-80. [doi: 10.1111/j.1475-097X.2008.00837.x] [Medline: 19016812]
39. Pietila J, Helander E, Myllymaki T, Korhonen I, Jimison H, Pavel M. Exploratory analysis of associations between individual lifestyles and heart rate variability -based recovery during sleep. Conf Proc IEEE Eng Med Biol Soc 2015;2015:2339-2342. [doi: 10.1109/EMBC.2015.7318862] [Medline: 26736762]
40. Clark AJ, Salo P, Lange T, Jennum P, Virtanen M, Pentti J, et al. Onset of impaired sleep as a predictor of change in health-related behaviours; analysing observational data as a series of non-randomized pseudo-trials. Int J Epidemiol 2015 Jun;44(3):1027-1037. [doi: 10.1093/ije/dyv063] [Medline: 25969504]
41. Paunio T, Korhonen T, Hublin C, Partinen M, Koskenvuo K, Koskenvuo M, et al. Poor sleep predicts symptoms of depression and disability retirement due to depression. J Affect Disord 2015 Feb 01;172:381-389 [FREE Full text] [doi: 10.1016/j.jad.2014.10.002] [Medline: 25451441]

Abbreviations

ANS: Autonomic nervous system
ANOVA: Analysis of variance

BMI: Body mass index
HF: high frequency
LF: low frequency
HR: heart rate
HRV: heart rate variability
PA: physical activity
RMSSD: root mean square of the successive differences

Edited by G Eysenbach; submitted 29.11.17; peer-reviewed by J Spaak, S Bhatlekar, T Riestra; comments to author 16.12.17; revised version received 01.02.18; accepted 27.02.18; published 16.03.18.

Please cite as:
Pietilä J, Helander E, Korhonen I, Myllymäki T, Kujala UM, Lindholm H
Acute Effect of Alcohol Intake on Cardiovascular Autonomic Regulation During the First Hours of Sleep in a Large Real-World Sample of Finnish Employees: Observational Study
JMIR Ment Health 2018;5(1):e23
URL: http://mental.jmir.org/2018/1/e23/
doi:10.2196/mental.9519
PMID:29549064

Original Paper

A Mobile Health Platform for Clinical Monitoring in Early Psychosis: Implementation in Community-Based Outpatient Early Psychosis Care

Divya Kumar[1*], BA; Laura M Tully[1*], PhD; Ana-Maria Iosif[2], PhD; Lauren N Zakskorn[1], BA; Kathleen E Nye[1], BA; Aqsa Zia[1], MD; Tara Ann Niendam[1], PhD

[1]Department of Psychiatry and Behavioral Sciences, University of California, Davis, Sacramento, CA, United States

[2]Division of Biostatistics, Department of Public Health Sciences, University of California, Davis, Sacramento, CA, United States

[*]these authors contributed equally

Corresponding Author:
Laura M Tully, PhD
Department of Psychiatry and Behavioral Sciences
University of California, Davis
4701 X Street
Sacramento, CA, 95817
United States
Phone: 1 916 734 7927
Email: lmtully@ucdavis.edu

Abstract

Background: A growing body of literature indicates that smartphone technology is a feasible add-on tool in the treatment of individuals with early psychosis (EP) . However, most studies to date have been conducted independent of outpatient care or in a research clinic setting, often with financial incentives to maintain user adherence to the technology. Feasibility of dissemination and implementation of smartphone technology into community mental health centers (CMHCs) has yet to be tested, and whether young adults with EP will use this technology for long periods of time without incentive is unknown. Furthermore, although EP individuals willingly adopt smartphone technology as part of their treatment, it remains unclear whether providers are amenable to integrating smartphone technology into treatment protocols.

Objective: This study aimed to establish the feasibility of implementing a smartphone app and affiliated Web-based dashboard in 4 community outpatient EP clinics in Northern California.

Methods: EP individuals in 4 clinics downloaded an app on their smartphone and responded to daily surveys regarding mood and symptoms for up to 5 months. Treatment providers at the affiliated clinics viewed survey responses on a secure Web-based dashboard in sessions with their clients and between appointments. EP clients and treatment providers filled out satisfaction surveys at study end regarding usability of the app.

Results: Sixty-one EP clients and 20 treatment providers enrolled in the study for up to 5 months. Forty-one EP clients completed the study, and all treatment providers remained in the study for their duration in the clinic. Survey completion for all 61 EP clients was moderate: 40% and 39% for daily and weekly surveys, respectively. Completion rates were slightly higher in the participants who completed the study: 44% and 41% for daily and weekly surveys, respectively. Twenty-seven of 41 (66%) EP clients who completed the study and 11 of 13 (85%) treatment providers who responded to satisfaction surveys reported they would continue to use the app as part of treatment services. Six (15%; 6/41) clients and 3 providers (23%; 3/13) stated that technological glitches impeded their engagement with the platform.

Conclusions: EP clients and treatment providers in community-based outpatient clinics are responsive to integrating smartphone technology into treatment services. There were logistical and technical challenges associated with enrolling individuals in CMHCs. To be most effective, implementing smartphone technology in CMHC EP care necessitates adequate technical staff and support for utilization of the platform.

(JMIR Ment Health 2018;5(1):e15) doi:10.2196/mental.8551

KEYWORDS

mHealth; schizophrenia; smartphone; ecological momentary assessment; experience sampling

Introduction

Utilizing smartphone technology to record real-world experiences as a supplement to mental health treatment can aid with insight and symptom management [1-3]. Treatment providers' engagement with client-level information collected via smartphone and mobile health (mHealth) technology has the potential to provide useful insights regarding real-time symptoms that may differ from what clients express in session [4]. This integration of smartphone data with treatment services is particularly relevant in the context of psychotic illness, in which knowledge of current symptom severity is critical for rapid symptom and relapse management support [4,5].

Previous studies demonstrate that individuals with psychosis are amenable to incorporating smartphone technology into treatment and demonstrate high compliance [6-12]. Preliminary research also suggests that treatment providers will integrate information generated from smartphone technology into treatment plans [13]. Given the importance of early intervention in the treatment of psychotic disorders [14,15], focusing on integrating novel technological interventions with younger individuals experiencing psychosis is warranted. Our previous work indicates early psychosis (EP) individuals (ie, individuals within the first 3 years of psychosis onset or individuals at high risk for developing psychosis) are amenable to responding to daily surveys via smartphone app for up to 14 months, have high compliance rates, and provide self-report symptom data that are consistent with gold-standard clinician assessments [10].

Despite this growing body of research supporting the use of smartphone technology in the treatment of psychosis, 3 key questions remain. First, it is unclear whether consistent use of smartphone technology would be viable in outpatient clinics that are unaffiliated with a research center. These include community mental health centers (CHMCs) that are predominantly supported by federal and state funds (eg, Medicaid), and private-pay or insurance-based outpatient clinics. These types of clinics provide care to the majority of individuals with psychosis, not research-based programs. Implementation of smartphone technology in community-based care in the absence of an established research infrastructure is the next step in the dissemination of smartphone technology. Second, it is uncertain whether providers will be open to implementing this new technology into current treatment approaches. Provider integration is crucial to the successful implementation of mHealth technology into the broader scope of behavioral health care; without provider buy-in, even the best smartphone and mHealth platforms will flounder. Third, it is important to determine whether participants will continue to engage with this technology for long periods without being reimbursed for survey responses.

This study addresses these issues by testing the feasibility of implementing an mHealth platform as an add-on treatment tool in 4 community-based outpatient EP programs in Northern California that range from private-pay/insurance-based clinics to CMHCs. Individuals enrolled in treatment completed daily and weekly surveys assessing symptoms via a smartphone app for up to 5 months. Treatment providers then viewed client survey responses on a secure Web-based dashboard between appointments and in treatment sessions. Providers also completed surveys regarding feasibility and acceptability. We hypothesized the following: (1) EP clients would show high enrollment and low dropout, as well as high satisfaction and endorsement of continued use of the app as part of their treatment; (2) EP clients would show high survey completion in the absence of monetary incentives; and (3) treatment providers would endorse high utilization and acceptability of incorporating the technology into treatment. This paper establishes a protocol for implementing a smartphone app and affiliated Web-based dashboard as a supplement to treatment in EP care and details difficulties in scheduling, implementation, and technological challenges.

Methods

Setting

Treatment providers and EP clients were recruited from 4 EP clinics in Northern California: the Aldea Solano Supportive Outreach and Access to Resources (SOAR) program—a county-contracted CMHC supported by state and federal funds to provide services to residents of Solano County aged 12-25 years, regardless of insurance status; the Aldea Napa SOAR program—a CMHC funded by private donor money, state and federal funds, and private insurance to provide services to residents of Napa County aged 8-25 years; and the University of California (UC) Davis Early Psychosis Program, comprising 2 clinics embedded in the university setting: the Early Detection and Preventative Treatment (EDAPT) clinic, a self-pay or insurance-based clinic for individuals aged 12-40 years, regardless of county of residence, and the SacEDAPT clinic, a county-contracted clinic supported by federal and state funds, which provides care to Sacramento County residents aged 12-30 years, regardless of insurance status or ability to pay. All clinics provide coordinated specialty care [16] services to adolescents and young adults with EP, including individuals at clinical high risk for psychosis (ie, individuals displaying clinically significant but attenuated psychotic symptoms) and individuals within 2 years of their first psychotic episode, either in the context of a primary mood disorder (eg, bipolar disorder with psychotic features, major depressive disorder with psychotic features) or primary psychotic disorder (eg, schizophrenia, schizoaffective disorder). The coordinated specialty care model emphasizes early intervention for individuals experiencing psychosis via comprehensive support from a variety of mental health providers, including psychiatrists, therapists, supported education and employment specialists, case managers, and peer and family advocates.

Participants

Two groups of participants were enrolled: clients (EP individuals enrolled in treatment) and treatment providers (clinical and support staff providing direct treatment services to EP clients).

EP clients consisted of individuals receiving care at any of the 4 EP clinics. Eligibility criteria for EP clients mirrored those required for enrollment in the clinics, that is, all clients enrolled in the clinics were eligible for participation. Eligibility criteria were as follows: English fluency, aged between 12 and 30 years at enrollment, WASI (Wechsler Abbreviated Scale of Intelligence) IQ score greater than 70 [17], no current substance abuse or dependence, and engagement with the clinic (attending at least one appointment a month). Owning a smartphone was not a requirement for participation in the study. Those who did not have a smartphone were provided an Android phone by the study for the duration of their participation in the study (see later sections for details). Spanish language consent processes were implemented to enable Spanish-speaking guardians of minor participants to enroll their child in the study.

Treatment providers included therapists (both licensed practitioners and unlicensed trainees), case managers, psychiatrists, supported education and employment specialists, and family advocates. Therapists included social workers, marriage and family therapists, and clinical psychologists (with both PsyD and PhD terminal degrees).

Recruitment

Flyers detailing the study were placed around the clinics and in welcome packets for new clients. Treatment providers were approached about participation first; EP clients whose treatment providers agreed to participate were then approached. Treatment providers also informed their clients about the research opportunity and provided information to those who were interested. Enrollment for the study was ongoing for 8 months in the UC Davis Early Psychosis Program clinics (December 2015-June 2016 and December 2016), 8 months in the Aldea Solano SOAR clinic (May 2016-December 2016), and 6 months in the Aldea Napa SOAR clinic (July 2016-December 2016).

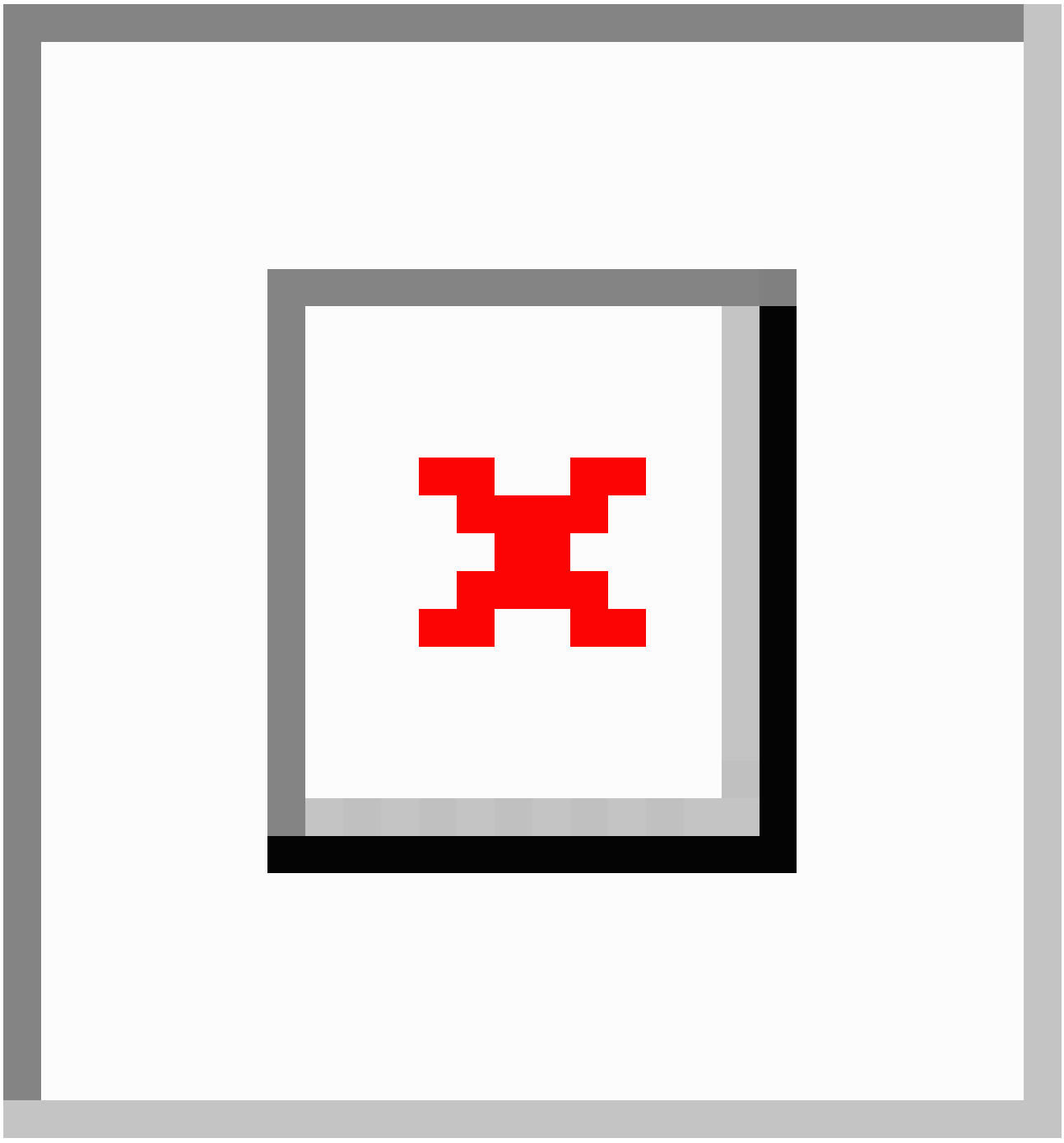
Smartphones

We provided Android smartphones with a T-Mobile cell plan including unlimited calls, text, and data, to participants who did not possess their own. Due to changes in the standard hardware costs and smartphone handsets available from T-Mobile, 4 different types of Android smartphones were used over the course of the study: the Kyocera Hydro Life, the Kyocera XTRM, the Samsung Core Prime, and the Samsung On5. All smartphones had 4G/LTE (fourth-generation long-term evolution) data capabilities.

The LifeData System

EP clients and treatment providers used the LifeData system [18], a mobile technology suite comprising 2 parts: a secure Web-based provider dashboard and the smartphone app RealLife Exp. EP clients responded to individual survey sets, called “LifePaks,” via RealLife Exp and providers viewed these responses on the dashboard. LifePaks contained standard survey questions (see following sections). The RealLife Exp app was downloaded via the App Store (iPhone) or GooglePlay store (Android). EP clients chose a time to receive their survey and had up to 90 min to complete it. LifePaks could be sent to each EP client at a specified time that best suited the client’s daily schedule; in this study, clients chose a survey notification time between 5:00 PM and 10:30 PM so as to capture their survey responses at the end of their day. They were advised to align the time of their survey notification with the time of their nighttime medication (if applicable), to use it as a reminder.

Figure 1. Screenshots of smartphone app and Web-based dashboard. (A) Example app view. EP clients responded to daily and weekly surveys in the app. Responses were summarized on the dashboard and discussed with treatment providers as part of regular clinic appointments. (B) Example dashboard view. Treatment providers could view plots of symptoms over time (daily mood and daily medication shown).



Responses to survey questions were displayed for treatment providers on the dashboard as a graph/chart, termed a "widget" in the LifeData System. Treatment providers could change the time frame of responses displayed to options ranging from the last 30 days, the last 7 days, the last 24 hours, or a custom period between 2 dates for specific questions of interest. Treatment providers could individualize the display of dashboards for each client. For example, if sleep was a symptom of interest for a particular client, a provider could move survey questions relating to amount of sleep to the top of the dashboard for quick viewing. EP clients were only able to review responses to survey questions on the dashboard during sessions with their treatment provider. See Figure 1 for illustrations of client app and treatment provider dashboard.

Smartphone Surveys

Daily and weekly surveys were sent via the app to EP clients at their chosen time between 5:00 PM and 10:30 PM. Survey questions were developed based on previous literature examining symptoms and functioning in individuals with schizophrenia-spectrum disorders [19-23] and have been implemented in our previous study testing the validity of gathering self-report symptom data via smartphone in EP populations [10]. The daily survey comprised questions pertaining to mood, medication use, socialization, and conflict;

questions regarding medication use were removed for clients not taking medications. The weekly survey asked participants to rate on a 1-5 Likert scale (1=not at all, 3=half of the time, and 5=most of the time) how often in the past week they felt a range of symptoms. Surveys took approximately 1 to 3 minutes to complete. See Figure 2 for daily survey questions and Textbox 1 for weekly survey questions.

Clinical Assessments and Self-Report Measures

Clients completed a series of self-report questionnaires and clinical assessments during the enrollment and study-end research appointments. Therapeutic alliance from the perspective of the EP client and treatment provider was obtained using the Scale to Assess Therapeutic Relationship [24]. Medication adherence was assessed via the Medication Adherence Rating Scale [25], and medication side effects were assessed using the Glasgow Antipsychotic Side-Effect Scale [26]. Client insight into clinical symptoms was measured via the Insight Scale [27]. Comfort with and utilization of smartphone/mobile technology in daily life was assessed using a Comfort with Technology questionnaire, modified from the Technology Readiness Index [28]. Drug and cannabis use were assessed using the Drug Use Screening Inventory [29] and the Cannabis Use Problems Identification Test [30], respectively.

Clinical symptoms were assessed by research staff at enrollment and study-end appointments using the Global Functioning Social and Role Scales [31,32], the Brief Psychiatric Rating Scale (BPRS) [33], and the Clinical Global Impression Scale [34]. BPRS item scores were summed to create composite symptoms scores for positive symptoms (7 items: grandiosity, unusual thought content, bizarre behavior, disorientation, hallucinations, suspiciousness, and conceptual disorganization), negative symptoms (3 items: blunted affect, motor retardation, and emotional withdrawal), depression/anxiety symptoms (4 items: depression, anxiety, suicidality, and guilt), and symptoms of agitation/mania (6 items: motor hyperactivity, excitement, distractibility, tension, uncooperativeness, and mannerisms and posturing) [35]. Good reliability for composite symptom scores has been demonstrated in prior publications [10]. BA-level research staff conducted assessments, supervised by licensed clinical psychologists (TAN and LMT). Staff were trained to good-to-excellent reliability (intra class correlations>.75) via independent ratings of 4 videotaped interviews.

Treatment providers (excluding psychiatrists) were asked to fill out weekly surveys regarding their utilization of the dashboard, either via a paper questionnaire or a Web-based survey using the Qualtrics platform (Qualtrics, Provo, UT).

Both EP clients and treatment providers filled out satisfaction surveys upon completion of the study, detailing their experiences using the app. Satisfaction survey questions asked about ease of use of the app, usefulness of responses, and any suggestions of potential changes for continued use.

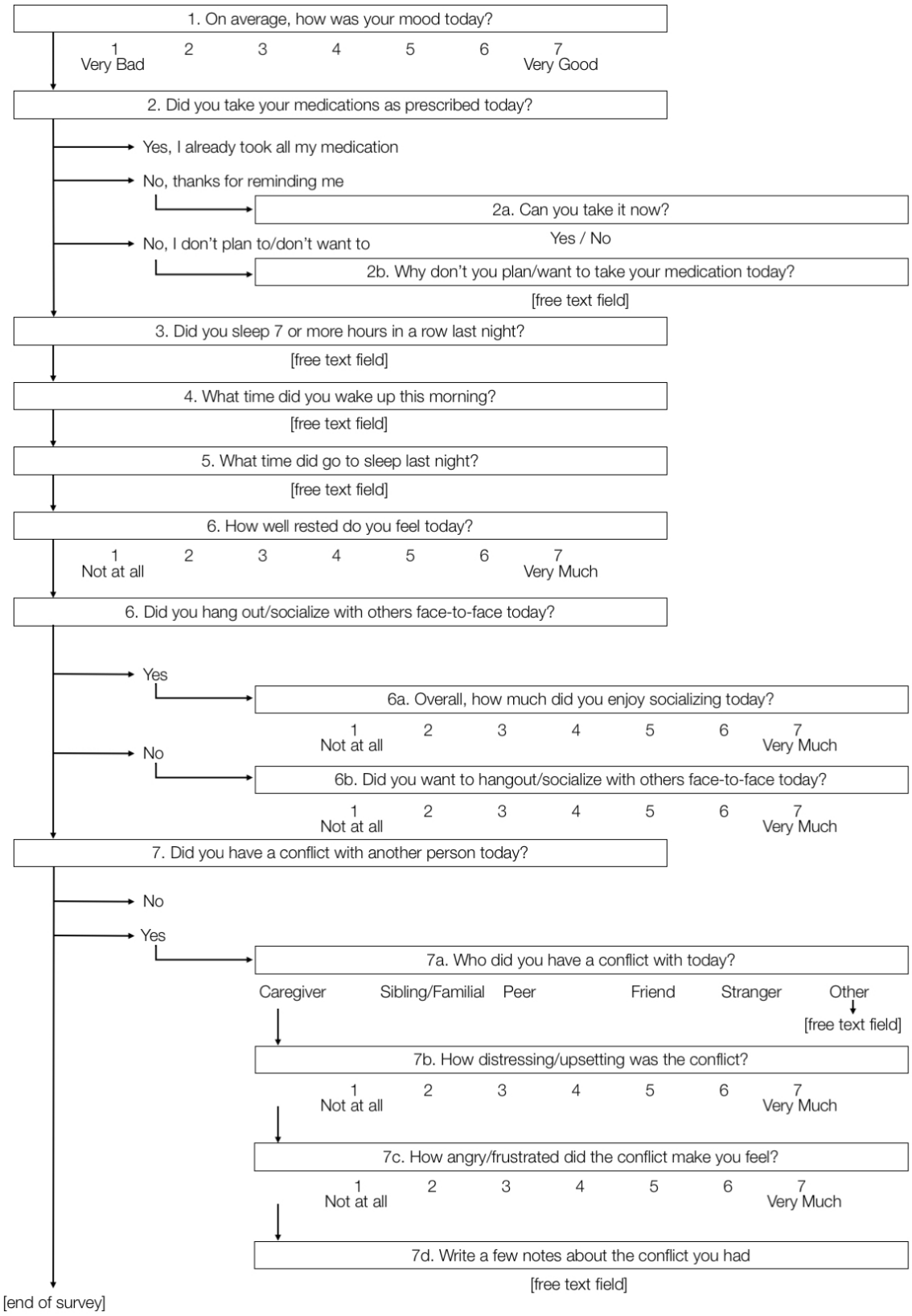
Procedures

EP clients enrolled in the study for up to 5 months and attended an assessment appointment at enrollment and study-end appointments. All study procedures were approved by the UC Davis Institutional Review Board.

At enrollment, EP clients completed all clinical assessments and questionnaires and downloaded the RealLife Exp app to their smartphone. They then created a RealLife Exp account, which was linked to a unique LifePak designed for them with agreed upon survey times. All clients completed a practice survey set on the phone with research staff at this appointment. EP clients who did not own their own phone set up a study-provided phone with the assistance of research staff.

Treatment providers were oriented to the visualization of responses on the LifeData dashboard during a 1-hour study enrollment session. Research staff demonstrated how to access the dashboard, what individual clients' responses would look like, and how to interpret the different visualizations of survey responses. To ensure providers had an accurate understanding of the dashboard, they were asked to explain different responses to questions on the dashboard and to navigate through the process on their own at the end of the enrollment. Providers were also given a 1-page reference document that contained log-in information, how to customize dashboards, and solutions to common technical glitches. Upon completion of an EP client's enrollment appointment, their treatment provider received access to the dashboard for that client. Treatment providers were instructed to review survey responses with clients during regular treatment sessions, as well as between appointments. Treatment providers were encouraged to use dashboard/survey data to prompt contact with clients between sessions per their clinical judgment or supervisor's recommendations. Treatment providers were instructed to review survey data with participants solely in the context of treatment; treatment providers were not instructed to persuade people to do the study or complete surveys.

Figure 2. Daily survey questions. EP clients completed 7 to 14 questions daily between 5:00 PM and 10:30 PM. The daily survey took about 1 to 3 minutes to complete.



Textbox 1. Weekly survey questions. Participants completed 16 questions each Sunday via the app.

This week I…

1. Felt sad or depressed
2. Felt anxious or worried
3. Felt cheerful or happy
4. Felt confused or distracted
5. Felt I had to be "on guard" with others, even my friends
6. Felt friendly or social
7. Felt lively or energetic
8. Felt like I did not care about anything
9. Felt unmotivated and could not get things done
10. Felt challenged and overwhelmed by my usual daily activities
11. Saw people, shadows, or things and then realized they were not really there
12. Felt hopeful about my future
13. Felt supported by my family and friends
14. Heard sounds, voices, or whispers but then realized there was nothing there
15. What percentage of your prescribed medication have you taken the past week? (0-100%)
16. Tell us about any other experiences you had this week (Response: free text entry)

EP clients were prompted once a day to answer a survey; on Sundays, they were prompted twice, once to answer the daily survey and once for the weekly survey. Research staff did not systematically engage with EP clients during their time in the study, with the exception of responding to technical errors with the app or the study-provided smartphone. These errors were commonly reported by the client or their treatment provider and were also occasionally noticed by a research staff member while exporting survey response data for analysis.

Consistent with Institutional Review Board guidelines, EP clients were compensated US $50 for completing the enrollment assessment and US $50 for completing the study-end assessment. EP clients were not reimbursed for completing surveys over the course of the study. Treatment providers were not compensated for taking part in the study.

Dashboards remained active until the clinical appointment following an EP client's study-end appointment. The app was deleted from the client's phone at study end. If the client borrowed a study phone, it was returned and reset to factory settings, removing all identifiable data. Study-owned smartphones were reused with new EP clients.

Data Analysis

Descriptive statistics were used to summarize client and provider characteristics, study enrollment, daily and weekly survey completion, and length of time participants were enrolled in the app, as well as participant ratings on satisfaction and perceived impact on clinical care. Daily and weekly survey completion rates were calculated for each participant by summing the number of daily/weekly surveys completed and dividing this value by the total number of daily/weekly surveys they were sent during the entire period that participants were enrolled in app (ie, length of time in study). We examined differences in baseline symptom severity (baseline BPRS composite symptom scores) and survey completion between completers and noncompleters (ie, individuals who completed a study-end assessment appointment vs individuals who did not) using the Wilcoxon two-sample test. We used Spearman rank correlation coefficient (ρ) to examine relationships between baseline symptom severity, length of time in study, and survey completion rates, both in the overall sample and in the subset of participants who completed the study.

Results

Early Psychosis Client Enrollment

Of the 108 EP clients eligible across the 4 sites, 61 (56%) enrolled in the study. Specifically, 59% (16/27) of clients in the EDAPT clinic participated; 62% (28/45) of clients in the SacEDAPT clinic participated; 44% (11/25) of clients in the Aldea Solano SOAR clinic participated; and 55% (6/11) of clients in the Aldea Napa SOAR clinic participated. Lack of consent from individuals who did not enroll in the study precludes analyses of group differences between those who declined and those who enrolled. Demographic and clinical characteristics of EP clients are displayed in Table 1.

Forty-one EP clients (67%; 41/61) completed the study ("completers"): 33 completed all 5 months of data collection and 8 completed 3 to 4 months (including enrollment and study-end appointments) and were discontinued early due to the end of data collection in the grant-funded period. Twenty (33%; 20/61) EP clients did not finish the study ("noncompleters"): 18 (5 EDAPT, 9 SacEDAPT, 1 Napa, 3 Solano) were withdrawn from the study by research staff because they discontinued services with the clinic; 2 (2 EDAPT) withdrew from the study on their own due to lack of interest in

continuing to participate. Average length of time in study for all 61 EP clients was 138 days (SD 49.2, range 25-232). Average length of time in study for the 41 completers was 156.2 days (SD 36.5, range 67-232) vs 100.5 days (SD 51.5, range 25-153) for the 20 noncompleters.

In the overall sample (n=61), length of time in study was not related to baseline positive (ρ=−0.03, *P*=.80), negative (ρ=0.02, *P*=.90), or depression/anxiety (ρ=−0.08, *P*=.55) symptoms, but was correlated with agitation/mania symptoms (ρ=0.25, *P*=.0495). A similar pattern was observed in the 41 completers, with no significant relationships between time in study and baseline positive (ρ=0.06, *P*=.69), negative (ρ=0.23, *P*=.15), or depression/anxiety (ρ=0.01, *P*=.97) symptoms, but a statistically significant correlation with agitation/mania symptoms (ρ=0.35, *P*=.03). There were no differences in positive (Wilcoxon two-sample test *P*=.58), negative (*P*=.24), or agitation/mania (*P*=.37) symptoms between study completers and noncompleters. Noncompleters showed more severe depression/anxiety symptoms at trend level (*P*=.08).

Treatment Provider Enrollment

Demographics of treatment providers are displayed in Table 2. Of the 20 eligible treatment providers across all sites, 20 (100%) enrolled in the study. Twenty-five percent (5/20) of treatment providers provided care in both the EDAPT and SacEDAPT clinics, 5% (1/20) in the EDAPT clinic alone, 35% (7/20) in the SacEDAPT clinic alone, 5% (1/20) provided care in both the Aldea SOAR Solano and Napa programs, 20% (4/20) provided care in the Aldea SOAR Solano program alone, and 10% (2/20) provided care in the Napa SOAR Solano program alone.

Table 1. Demographic and clinical characteristics of enrolled early psychosis clients (N=61). Due to rounding, percentages might not sum to 100.

Characteristic	UC[a] Davis EDAPT[b] clinic (n=16)	UC Davis SacEDAPT clinic (n=28)	Napa Aldea SOAR[c] clinic (n=6)	Solano Aldea SOAR clinic (n=11)
Age (years), mean (SD)	18.6 (2.9)	17.5 (3.8)	17.5 (3.6)	15.1 (2.5)
Education (years), mean (SD)	13.4 (2.0)	10.3 (2.8)	11.5 (4.9)	11.3 (1.2)
Parental education (years), mean (SD)	13.8 (2.5)	12.7 (2.3)	12.5 (3.5)	14.0 (5.6)
Male gender, n (%)	7 (44)	16 (57)	3 (50)	6 (55)
Race, n (%)				
African American	0 (0)	8 (29)	0 (0)	1 (9)
Asian American	3 (19)	7 (25)	0 (0)	0 (0)
White	9 (56)	8 (29)	2 (33)	3 (27)
Native American	0 (0)	1 (4)	0 (0)	0 (0)
Multiple/Other	3 (19)	4 (14)	4 (67)	7 (64)
Hispanic ethnicity, n (%)	5 (31)	3 (11)	4 (67)	7 (64)
Loaned phone, n (%)	2 (13)	18 (64)	1 (17)	8 (73)
Type of phone, n (%)				
Android	11 (69)	25 (89)	3 (50)	8 (73)
iPhone	5 (31)	3 (11)	3 (50)	3 (27)
Diagnosis, n (%)				
Schizophrenia spectrum disorder	9 (56)	18 (64)	0 (0)	7 (64)
Mood disorder with psychotic features	1 (6)	6 (21)	1 (17)	0 (0)
Clinical high risk	6 (38)	4 (14)	5 (83)	4 (36)
Baseline BPRS[d] symptoms, mean (SD)				
Positive symptoms	13.4 (4.4)	13.5 (5.6)	14.2 (4.6)	13.1 (4.4)
Negative symptoms	4.8 (1.7)	6.8 (2.9)	5.0 (3.1)	6.3 (2.6)
Depression/anxiety symptoms	10.1 (4.3)	10.0 (5.0)	7.3 (3.8)	9.5 (4.8)
Agitation/mania symptoms	8.3 (1.8)	10.3 (2.7)	8.5 (2.1)	8.1 (1.5)

[a]UC: University of California.

[b]EDAPT: Early Detection and Preventative Treatment.

[c]SOAR: Supportive Outreach and Access to Resources.

[e]BPRS: Brief Psychiatric Rating Scale.

Table 2. Demographic characteristics of enrolled early psychosis treatment providers (N=20). Due to rounding, percentages might not sum to 100.

Demographic characteristic	All treatment providers (n=20)	UC[a] Davis EDAPT[b] clinic (n=1)	UC Davis SacEDAPT clinic (n=7)	Napa Aldea SOAR[c] clinic (n=2)	Solano Aldea SOAR clinic (n=4)	Multiple clinics (n=6)[d]
Age group[e], n (%)						
25-34	10 (56)	0 (0)	5 (83)	1 (50)	1 (25)	3 (60)
35-44	4 (22)	0 (0)	0 (0)	1 50)	1 (25)	2 (40)
45-54	2 (11)	0 (0)	1 (17)	0 (0)	1 (25)	0 (0)
55-64	2 (11)	1 (100)	0 (0)	0 (0)	1 (25)	0 (0)
Male gender, n (%)	3 (15)	1 (100)	1 (14)	0 (0)	0 (0)	1 (17)
Race, n (%)						
Asian American	4 (20)	0 (0)	1 (14)	0 (0)	1 (25)	2 (33)
White	16 (80)	1 (100)	6 (67)	2 (100)	3 (75)	4 (67)
Hispanic ethnicity, n (%)	5 (25)	0 (0)	2 (29)	1 (50)	0 (0)	2 (33)
Degree obtained, n (%)						
MFT[f]	6 (30)	0 (0)	1 (14)	2 (100)	1 (25)	2 (33)
MSW[g]	3 (15)	0 (0)	0 (0)	0 (0)	2 (50)	1 (17)
PsyD[h]	4 (20)	0 (0)	3 (43)	0 (0)	0 (0)	1 (17)
PhD[i]	2 (10)	1 (100)	1 (14)	0 (0)	0 (0)	0 (0)
MD[j]	4 (20)	0 (0)	2 (29)	0 (0)	0 (0)	2 (33)
Other	1 (5)	0 (0)	0 (0)	0 (0)	1 (25)	0 (0)
Bilingual practitioner[k], n (%)	9 (45)	0 (0)	4 (57)	1 (50)	1 (25)	3 (50)
Licensed practitioners, n (%)	11 (55)	1 (100)	2 (29)	1 (50)	1 (25)	6 (100)

[a]UC: University of California.

[b]EDAPT: Early Detection and Preventative Treatment.

[c]SOAR: Supportive Outreach and Access to Resources.

[d]Six treatment providers provided care in more than one clinic: 5 provided care in both the UC Davis SacEDAPT and EDAPT clinics; 1 provided care in both the Napa and Solano Aldea SOAR clinics.

[e]Frequency missing=2, 1 in the Multi clinics and 1 in SacEDAPT.

[f]MFT: Marriage and Family Therapist.

[g]MSW: Master's in Social Work.

[h]PsyD: Doctor of Psychology.

[i]PhD: Doctor of Philosophy.

[j]MD: Medical Doctor.

[k]Bilingual practitioners were providers who spoke 1 or more languages fluently (in addition to English) and used them as part of the clinical practice with clients. Nine providers identified as bilingual practitioners, languages included were as follows: Mandarin (n=1), Punjabi (n=1), Spanish (n=5), Korean (n=1), and Turkish (n=1).

All treatment providers remained in the study from the point they were enrolled until either the end of data collection (n=10) or until they left their position as a provider at one of the affiliated clinics (n=10). Over the course of the study, 26% (16/61) of EP clients had a change in 1 or more of their treatment providers: 18% (11/61) had a change in their primary therapist only (8 in SacEDAPT, 1 in EDAPT, 2 in Aldea SOAR Solano), 3% (2/61) had a change in their psychiatrist only (2 in SacEDAPT), and 5% (3/ 61) had a change in both their primary therapist and their psychiatrist (3 in SacEDAPT). The average number of enrolled clients per treatment provider overall was 6.5 (SD 6.1, minimum=1, maximum=25). Therapists (n=16) had an average of 4.8 enrolled clients (SD 3.9, range 1-15); psychiatrists (n=4) had an average of 13.5 enrolled clients (SD 8.5, range 1-25).

Survey Completion Rates

In the overall sample (n=61), average daily survey completion rate was 41% (SD 25%, median 41%, range 0-89%) and average weekly survey completion rate was 39% (SD 28%, median 40%, range 0-100%). Daily survey completion was not related to baseline positive (ρ=0.21, P=.11), negative (ρ=−0.09, P=.49), depression/anxiety (ρ=0.10, P=.43), or agitation/mania (ρ=−0.14, P=.27) symptoms. Similarly, weekly survey

completion was not related to baseline positive (ρ=0.15, *P*=.24), negative (ρ=−0.15, *P*=.25), depression/anxiety (ρ=0.03, *P*=.83), or agitation/mania (ρ=−0.22, *P*=.09) symptoms. There were no differences in daily or weekly survey completion rates between EP clients who had their own smartphone (n=32) and EP clients who were given a study smartphone (n=29) (all *P* s>.3), indicating that the provision of a smartphone was not an incentive to complete surveys in and of itself.

Survey completion was higher in the 41 completers (mean daily 44% [SD 25%], median 44%, range 0-82%; mean weekly 42% [SD 28%], median 46%, range 0-92%) compared with the 20 noncompleters (mean daily 35% [SD 25%], median 33%, range 0-89%; mean weekly 33% [SD 27%], median 31%, range 0-100%), but the difference did not reach statistical significance (*P*=.22 for daily and .15 for weekly). In the 41 completers, daily survey completion was not related to baseline symptoms (all *P* s>.1); however, weekly survey completion rates were related to baseline negative (ρ=−0.31, *P*=.047) and agitation/mania (ρ=−0.32, *P*=.04) symptoms, such that more severe symptoms were associated with lower weekly survey completion rates. No relationships between weekly survey completion and positive or depression/anxiety symptoms were observed in completers (all *P* s>.3).

Treatment Provider Use of Dashboard

Treatment providers (n=16), excluding psychiatrists (because of time constraints), were asked to complete weekly surveys regarding their use of the dashboard in regular treatment sessions with enrolled clients. Seventy-five percent (12/16) of the treatment providers completed at least one survey over the course of the study; response rate was lower than expected due to the many competing demands placed on community-provider time, thus data should be viewed as preliminary and interpreted with caution. We summarized data after first averaging within provider. Treatment providers reported that they had treatment sessions with an average of 2 enrolled clients per week (2.0 [SD 2.1], range 1-8) and incorporated the dashboard into an average of 1 session per week (1.4 [SD 0.4], range 1.0-2.3). When they incorporated the dashboard as part of regular treatment sessions, providers reported discussing it for an average of 16% of session time (SD 9%, range 10-33%)—approximately 8-10 min of a standard 50-min session—and rated the dashboard data as moderately useful (on a 1-7 Likert scale) as a treatment enhancement tool (3.9 [SD 1.4], range 1.3-6.0).

Satisfaction Surveys

All of the 41 EP clients that completed the study, as well as 13 of 16 treatment providers, completed surveys at the end of the study assessing satisfaction with the app and perceived effect of the app on treatment and behavior. Results of these surveys can be viewed in Tables 3-6. Of note, 66% (27/41) of EP clients stated they would continue to use the app as part of treatment services if it was made available and 61% (25/41) stated they would recommend the app to a friend. Thirty-seven percent (15/41) of EP clients found the app to be extremely helpful, 44% (18/41) found it to be a little helpful, and 20% (8/41) found it made no difference. Overall, 27% (11/41) of EP clients reported that the data provided by the app had at least some effect on their behavior (see Table 3). A small minority of clients (12%, 5/41) stated that they would not continue to use the app and 22% (9/41) reported that they might continue to use the app if it was better. Similarly, 15% (6/41) reported that they would not recommend the app to a friend and 24% (10/41) reported that they might recommend it if it was better. Satisfaction surveys from treatment providers included the following results: 85% (11/13) reported they would continue to use the app as part of treatment services, whereas 15% (2/13) reported that they might continue to use the app if it was better. Similarly, 85% (11/13) reported that they would recommend the app to a client, and 15% (2/13) reported they might recommend it if it was better. Fifty-four percent (7/13) stated the app was extremely helpful, 46% (6/13) stated it was a little helpful, and 0% (0/13) stated it made no difference. Finally, 15% (6/41) of EP clients and 23% (3/13) of treatment providers noted that technical glitches in the RealLife Exp platform caused frustration and limited engagement.

Fifty-one percent (21/41) of EP clients suggested improvements for the app (see Table 5): 15% (6/41) suggested improvements to the technical stability of the app (eg, reduce app crashes, improve reminder notification stability, facilitate easier sign-in after forced log-outs); 17% (7/41) suggested product enhancements to the app (eg, improved user interface, inclusion of data summaries and graphs in the app to track self-progress, online community engagement with peers); 32% (13/41) suggested improvements to the surveys (eg, increased number of questions regarding symptoms, more flexibility on when surveys must be completed during the day, wider range of response options to sliding scale questions); and 3% (1/41) suggested the treatment provider team should use the dashboard more in sessions to enhance care.

Thirty-eight percent (5/13) of treatment providers suggested improvements for the app and dashboard (see Table 6): 15% (2/13) suggested improvements to technical stability (eg, fix missing data on dashboard, fix glitches that prevented clients from completing surveys); 8% (1/13) suggested dashboard enhancements (more user-friendly graphs); 8% (1/13) suggested including rewards/badges for surveys to facilitate survey completion; and 8% (1/13) suggested making access to the dashboard easier to facilitate provider use in treatment sessions (eg, create a mobile app to access the dashboard for tablet/smartphone).

Table 3. Summary of early psychosis clients' perceived effect of the use of surveys (N=41). Due to rounding, percentages might not sum to 100.

Survey questions	A lot, n (%)	A little, n (%)	Somewhat, n (%)	Not at all, n (%)
To what extent did RealLife Exp improve the quality of your treatment services?	10 (24)	12 (29)	13 (32)	6 (15)
Did RealLife Exp improve your relationship with your treatment team?	8 (20)	13 (32)	11 (27)	9 (22)
Did RealLife Exp help you understand your symptoms?	9 (22)	7 (17)	14 (34)	11 (27)
Did RealLife Exp help you and your treatment team improve your symptoms and overall well-being?	9 (22)	8 (20)	19 (46)	5 (12)
Did RealLife Exp help you remember to take your medication?	20 (49)	11 (27)	7 (17)	3 (7)
Did RealLife Exp help you manage your symptoms?	9 (22)	10 (24)	15 (37)	7 (17)
Did RealLife Exp help you feel more in control of your symptoms?	9 (22)	10 (24)	14 (34)	8 (20)
Are you more motivated to keep up with your symptom management and medication routine?	16 (39)	16 (39)	6 (15)	3 (7)

Table 4. Summary of early psychosis clients' (N=41) and treatment providers' (N=13) satisfaction surveys. Due to rounding, percentages may not sum to 100. Satisfaction data are missing from 7 treatment providers.

Survey questions	Early psychosis clients, n (%)	Treatment providers, n (%)
How easy was it to use RealLife Exp?		
Extremely Easy	25 (61)	5 (38)
Fairly Easy	15 (37)	8 (62)
Somewhat Difficult	1 (2)	0 (0)
Extremely Difficult	0 (0)	0 (0)
How easy was it to complete the surveys on RealLife Exp?		
Extremely Easy	27 (66)	9 (69)
Fairly Easy	13 (32)	4 (31)
Somewhat Difficult	1 (2)	0 (0)
Extremely Difficult	0 (0)	0 (0)

Table 5. Summary of the features that early psychosis clients desired in an app for early psychosis care (N=41). Due to rounding, percentages might not sum to 100.

Survey questions	n (%)
Please circle ALL the features you would like from an application like RealLife Exp	
Connection to a community	14 (34)
Connection to your care team	25 (61)
Helpful information about symptoms	34 (83)
Personal insights about your behavior	36 (88)
Rewards and badges for survey completion	18 (44)
Please circle the ONE feature you would like most from an application like RealLife Exp	
Connection to a community	3 (7)
Connection to your care team	9 (22)
Helpful information about symptoms	10 (24)
Personal insights about your behavior	18 (44)
Rewards and badges for survey completion	1 (2)

Table 6. Summary of the features that treatment providers desired in a mobile health platform for early psychosis care (N=41).

Survey questions	n (%)
What feature(s) of LifeData did you find useful? Choose all that apply:	
Graphs of client daily symptoms	12 (92)
Graphs of client weekly symptoms	10 (77)
Information on medication habits of clients	12 (92)
Information on sleeping habits of clients	10 (77)
Free-response information on conflicts	8 (62)
Free-response on social interactions	7 (54)
Please circle all the features you would like most from an application like RealLife Exp	
Connection to a community	6 (46)
Connection to a care team	8 (62)
Helpful information about symptoms	11 (85)
Personal insights about behavior	11 (85)
Rewards and badges for survey completion	7 (54)
Please check the one feature you would like most from an application like RealLife Exp	
Connection to a community	0 (0)
Connection to a care team	5 (38)
Helpful information about symptoms	4 (31)
Personal insights about behavior	3 (23)
Rewards and badges for survey completion	1 (8)

Implementation Costs

Forty-seven percent (29/61) of EP clients used a study phone, the majority of whom (n=26) were in county/state-funded clinics. The breakdown of study phones by clinic was as follows: 2 in EDAPT, 18 in SacEDAPT, 1 in Napa, and 8 in Solano. Two EP clients used a parent's smartphone to participate in the study and 1 used a compatible Apple iPad device.

Costs to keep a smartphone line active for a month were US $17 per line. The Kyocera Hydro XTRM and Hydro Life phones cost US $149.99 per phone, whereas the Samsung Core Prime and On5 phones were US $139.99. Overall, the cost to provide smartphones to EP clients was US $7232.32; on average, the cost per client for the 5-month period in the study was US $249.39.

Research staff and LifeData technical staff provided technical support throughout the protocol. For this trial, research staff spent an average of 26 hours a week working on EP client and provider support, including recruitment, enrollment, and study-end appointments, and addressing technical glitches in the app and dashboard. The total cost for LifeData (including technical support and utilization of the app and dashboard) for the duration of data collection was US $4483.30.

Discussion

Principal Findings

This paper details a protocol for implementing mHealth technology in community outpatient EP clinics and reports initial feasibility data. Sixty-one EP clients (56% of the 108 eligible individuals) and 20 treatment providers (100% of eligible providers) enrolled in the study. Only 3% (2/61) of EP clients withdrew from the protocol due to lack of interest in participating and no providers withdrew, demonstrating significant commitment to using mHealth technology in treatment on the part of both clients and providers. These enrollment and dropout rates are comparable to our previous study (53% enrollment; 5% dropout) [10], in which participants received monetary compensation for completing surveys and staying in the study each month. This indicates that monetary incentives for completing surveys is not a factor in whether EP clients choose to enroll and remain in an mHealth technology protocol for up to 5 months as part of their treatment. Although survey completion rates in this study (~40%) are lower than those observed in our previous study (~70%) [10], ~40% survey completion over the course of 5 months in the absence of monetary incentives is encouraging, particularly in light of the frequent technical challenges posed by the app itself. This is a solvable problem for the field; we posit that with improved user experience and technical stability of an mHealth platform, survey completion will be higher. Future studies will directly test this hypothesis. Additionally, the finding that, in the 41 EP clients who completed the study, weekly survey completion was associated with negative and agitation/mania symptoms suggests that individuals with more severe symptoms may need additional support for successful integration of mHealth technology into their outpatient care. One way to achieve this could be to incorporate family/caregivers into the protocol, both in terms of supporting the client in completing surveys and for

completing their own observational symptom ratings via smartphone.

All eligible treatment providers enrolled in the study, demonstrating significant interest in incorporating new technologies for enhancing care. Although the study was originally intended only to include therapists, interest by other treatment team members led to an expansion of enrollment to include psychiatrists across the sites. Similarly, preliminary data indicate that, when used as part of regular treatment sessions, survey data from EP clients were moderately useful in informing treatment decisions and addressing client needs. This level of interest, agreement to participate, and endorsed usefulness of dashboard data suggest an openness across provider roles to applying this type of technology as a part of routine EP care in the future. This is important because successful implementation and dissemination of mHealth technology as part of EP care will rely on provider uptake as well as client participation. Future research will need to address how to increase provider uptake and evaluate the impact of provider engagement with mHealth technology on client outcomes.

Our data indicate that a significant portion of participants (52%), particularly those in county/state-funded CMHCs, do not possess a smartphone that can support mHealth apps. Successful integration of mHealth technology will likely require budget consideration of the costs of providing smartphones and accompanying cell plans to a portion of clients for the duration of services (2 years for most EP programs). Although the cost per client is relatively low (approximately US $1250 per client for 2 years), this is a financial burden to CMHCs that will need to be offset by benefits such as increased billing productivity, reduced costs of care, and reduced rates of chronic disability. Additional costs will also need to be adjusted for, such as the cost of additional staffing support necessary to implement and integrate mHealth technology into standard clinic protocols. Cost-benefit analyses of the impact of implementing mHealth technology in EP care will be addressed in future publications.

An important question for smartphone technology implementation research is how to increase client enrollment. Results show that 56.5% (61/108) of clients across the 4 clinics were willing to participate in the study and 67% (41/61) of enrolled clients completed the study. Within each clinic, approximately half of eligible individuals enrolled, regardless of clinic capacity, location, and type. While this level of engagement and completion is meaningful, successful dissemination and integration of mHealth platforms in CMHCs will require higher enrollment rates. In this study, 3 key factors impacted enrollment: notifying clients of the research opportunity without violating privacy, staff turnover, and technical glitches. Given that this technology was implemented as part of a research study, recruitment heavily relied on the support of participating treatment providers at the clinics to inform clients of the protocol before research staff were able to approach the client. It is possible that this limitation on enrollment would be removed if the mHealth platform was introduced as part of standard clinical practice during intake procedures. That is, if mHealth technology is introduced entirely independent of research, with no additional appointments and requirements to liaise with research staff, these barriers might not exist. Additionally, there was significant turnover of treatment providers during the course of the study; both the UC Davis and Aldea Solano clinics experienced staff turnover during the recruitment period. This resulted in delays in scheduling clients and increased time between treatment sessions. Unfortunately, this negatively impacted client retention in the study, as affected clients oftentimes stopped responding to study outreach. Finally, difficulty with the mHealth platform (eg, failed notification deliveries, screen freezes, repeated forced log-outs) also likely impeded client engagement with the study, survey response rates, and satisfaction with the platform. Participants and treatment providers often required research staff aid to resolve technical glitches and engagement with the protocol was halted until technical glitches were resolved, causing frustration. A stable, user-friendly app, combined with real-time, in-house technical support and a clear protocol for resolving technical issues will be necessary for successful integration of mHealth platforms in community-based EP care.

Barriers regarding staff turnover and technological difficulties are ones that will likely affect implementation of a similar protocol in outpatient community settings, regardless of the relationship to research. Effective implementation of mHealth technology in the context of these barriers likely requires additional staffing/person-hours, such as a client-technology liaison, and technical support to counter the challenges of staff turnover and technology glitches. EP clients also made additional suggestions for improvements to the app that might increase engagement and satisfaction, including enhancing the user experience (eg, inclusion of visual summaries of survey responses) and increasing the flexibility of user engagement with the app (eg, increased variety of survey items, increased flexibility in response times). Similarly, providers suggested improved technical stability and dashboard enhancements that could facilitate greater incorporation of the platform during treatment sessions. Future studies attempting to use this technology in EP care should prioritize a flexible user-interface that presents accessible summaries of user data, on both provider and client ends, and technological support staff to ensure highest satisfaction and usability.

Limitations

Four key limitations must be acknowledged. First, because this study only sought to establish feasibility of implementing a smartphone app in community outpatient care settings, rather than determine treatment efficacy, a control group was not included. To test treatment effects, future studies will need to include a treatment as usual control condition (ie, no mHealth add-on tool). Second, the shorter enrollment period at the Aldea sites restricted enrollment rates in those clinics due to limited research staff resources, highlighting the need for adequate staffing for such a protocol. Third, because individuals who declined to participate did not consent to research, we are unable to assess clinical or demographic factors associated with not consenting to use smartphone technology as part of clinical care. Finally, although many of the survey questions used in this protocol are broadly applicable across mental health diagnoses (eg, anxiety, depression, medication adherence, social interactions), future work is needed to determine the

generalizability of similar platforms across a variety of behavioral health populations and care settings.

Conclusions

These results provide preliminary data to support 3 conclusions: first, use of smartphone technology in EP outpatient clinics that are unaffiliated with a research center appears feasible; second, treatment providers are amenable to implementing smartphone technology into EP treatment protocols; and third, EP clients are willing to use smartphone technology as part of their care without reimbursement for survey responses. While this suggests that implementing smartphone technology is achievable and desirable in CMHCs, it is also important to highlight the importance of adequate staffing and technical support. Future studies must evaluate optimal methods of meeting this requirement while maintaining appropriate returns on investment in mHealth technology.

Acknowledgments

The authors would like to thank all EP individuals and treatment providers who participated in this study, Kevin Eklund and the LifeData team for their technical support, and Darrin Meintser at TMobile for helping set up smartphones and new cell plans. This research was supported by grants from the UC Davis Behavioral Health Center of Excellence through state (CA) funds from the Mental Health Services Act and the Robert Wood Johnson Foundation (RWJF Grant #: 71391), both awarded to TAN, and by a Building Interdisciplinary Research Careers in Women's Health award (K12 HD051958) awarded to LMT, funded by the National Institute of Child Health and Human Development (NICHD), Office of Research on Women's Health, Office of Dietary Supplements, and the National Institute of Aging.

Conflicts of Interest

None declared.

References

1. Depp CA, Moore RC, Perivoliotis D, Granholm E. Technology to assess and support self-management in serious mental illness. Dialogues Clin Neurosci 2016 Jun;18(2):171-183 [FREE Full text] [Medline: 27489457]
2. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
3. Torous J, Friedman R, Keshavan M. Smartphone ownership and interest in mobile applications to monitor symptoms of mental health conditions. JMIR Mhealth Uhealth 2014;2(1):e2 [FREE Full text] [doi: 10.2196/mhealth.2994] [Medline: 25098314]
4. Palmier-Claus JE, Rogers A, Ainsworth J, Machin M, Barrowclough C, Laverty L, et al. Integrating mobile-phone based assessment for psychosis into people's everyday lives and clinical care: a qualitative study. BMC Psychiatry 2013;13:34 [FREE Full text] [doi: 10.1186/1471-244X-13-34] [Medline: 23343329]
5. Ben-Zeev D, Scherer EA, Gottlieb JD, Rotondi AJ, Brunette MF, Achtyes ED, et al. mHealth for Schizophrenia: patient engagement with a mobile phone intervention following hospital discharge. JMIR Ment Health 2016;3(3):e34 [FREE Full text] [doi: 10.2196/mental.6348] [Medline: 27465803]
6. Ben-Zeev D. Mobile technologies in the study, assessment, and treatment of schizophrenia. Schizophr Bull 2012 May;38(3):384-385 [FREE Full text] [doi: 10.1093/schbul/sbr179] [Medline: 22234487]
7. Ben-Zeev D, Brenner CJ, Begale M, Duffecy J, Mohr DC, Mueser KT. Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. Schizophr Bull 2014 Nov;40(6):1244-1253. [doi: 10.1093/schbul/sbu033] [Medline: 24609454]
8. Firth J, Torous J. Smartphone apps for Schizophrenia: a systematic review. JMIR Mhealth Uhealth 2015 Nov 06;3(4):e102 [FREE Full text] [doi: 10.2196/mhealth.4930] [Medline: 26546039]
9. Forchuk C, Donelle L, Ethridge P, Warner L. Client perceptions of the mental health engagement network: a secondary analysis of an intervention using smartphones and desktop devices for individuals experiencing mood or psychotic disorders in Canada. JMIR Ment Health 2015;2(1):e1 [FREE Full text] [doi: 10.2196/mental.3926] [Medline: 26543906]
10. Niendam T, Tully LM, Iosif A, Kumar D, Nye K, Denton J, et al. Enhancing early psychosis treatment using smartphone technology: a longitudinal feasibility and validity study. J Psychiatr Res 2018 Jan;96:239-246. [doi: 10.1016/j.jpsychires.2017.10.017] [Medline: 29126059]
11. Palmier-Claus JE, Ainsworth J, Machin M, Barrowclough C, Dunn G, Barkus E, et al. The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. BMC Psychiatry 2012;12:172 [FREE Full text] [doi: 10.1186/1471-244X-12-172] [Medline: 23075387]
12. Schlosser D, Campellone T, Kim D, Truong B, Vergani S, Ward C, et al. Feasibility of PRIME: a cognitive neuroscience-informed mobile app intervention to enhance motivated behavior and improve quality of life in recent onset Schizophrenia. JMIR Res Protoc 2016 Apr 28;5(2):e77 [FREE Full text] [doi: 10.2196/resprot.5450] [Medline: 27125771]

13. Kuhn E, Eftekhari A, Hoffman JE, Crowley JJ, Ramsey KM, Reger GM, et al. Clinician perceptions of using a smartphone app with prolonged exposure therapy. Adm Policy Ment Health 2014 Nov;41(6):800-807. [doi: 10.1007/s10488-013-0532-2] [Medline: 24398700]
14. International Early Psychosis Association Writing Group. International clinical practice guidelines for early psychosis. Br J Psychiatry Suppl 2005 Aug;48:s120-s124. [doi: 10.1192/bjp.187.48.s120] [Medline: 16055801]
15. Marshall M, Lewis S, Lockwood A, Drake R, Jones P, Croudace T. Association between duration of untreated psychosis and outcome in cohorts of first-episode patients: a systematic review. Arch Gen Psychiatry 2005 Sep;62(9):975-983. [doi: 10.1001/archpsyc.62.9.975] [Medline: 16143729]
16. Dixon LB, Goldman HH, Bennett ME, Wang Y, McNamara KA, Mendon SJ, et al. Implementing coordinated specialty care for early psychosis: the RAISE connection program. Psychiatr Serv 2015 Jul;66(7):691-698 [FREE Full text] [doi: 10.1176/appi.ps.201400281] [Medline: 25772764]
17. Wechsler D. Wechsler Abbreviated Scale of Intelligence. San Antonio, TX: The Psychological Corporation; 1999.
18. Lifedatacorp. URL: https://www.lifedatacorp.com/ [accessed 2017-07-25] [WebCite Cache ID 6sDv11Vhn]
19. Bauer M, Glenn T, Whybrow PC, Grof P, Rasgon N, Alda M, et al. Changes in self-reported sleep duration predict mood changes in bipolar disorder. Psychol Med 2008 Jul;38(7):1069-1071. [doi: 10.1017/S0033291708003280] [Medline: 18377675]
20. Bauer M, Grof P, Rasgon N, Bschor T, Glenn T, Whybrow PC. Temporal relation between sleep and mood in patients with bipolar disorder. Bipolar Disord 2006 Apr;8(2):160-167. [doi: 10.1111/j.1399-5618.2006.00294.x] [Medline: 16542186]
21. Hooker CI, Benson TL, Gyurak A, Yin H, Tully LM, Lincoln SH. Neural activity to positive expressions predicts daily experience of schizophrenia-spectrum symptoms in adults with high social anhedonia. J Abnorm Psychol 2014 Feb;123(1):190-204. [doi: 10.1037/a0035223] [Medline: 24661170]
22. Leibenluft E, Albert PS, Rosenthal NE, Wehr TA. Relationship between sleep and mood in patients with rapid-cycling bipolar disorder. Psychiatry Res 1996 Jul 31;63(2-3):161-168. [Medline: 8878312]
23. Tully LM, Lincoln SH, Hooker CI. Lateral prefrontal cortex activity during cognitive control of emotion predicts response to social stress in schizophrenia. Neuroimage Clin 2014;6:43-53 [FREE Full text] [doi: 10.1016/j.nicl.2014.08.012] [Medline: 25379415]
24. McGuire-Snieckus R, McCabe R, Catty J, Hansson L, Priebe S. A new scale to assess the therapeutic relationship in community mental health care: STAR. Psychol Med 2007 Jan;37(1):85-95. [doi: 10.1017/S0033291706009299] [Medline: 17094819]
25. Thompson K, Kulkarni J, Sergejew AA. Reliability and validity of a new Medication Adherence Rating Scale (MARS) for the psychoses. Schizophr Res 2000 May 5;42(3):241-247. [Medline: 10785582]
26. Waddell L, Taylor M. A new self-rating scale for detecting atypical or second-generation antipsychotic side effects. J Psychopharmacol 2008 May;22(3):238-243. [doi: 10.1177/0269881107087976] [Medline: 18541624]
27. Birchwood M, Smith J, Drury V, Healy J, Macmillan F, Slade M. A self-report Insight Scale for psychosis: reliability, validity and sensitivity to change. Acta Psychiatr Scand 1994 Jan;89(1):62-67. [Medline: 7908156]
28. Parasuraman A. Technology Readiness Index (TRI) a multiple-item scale to measure readiness to embrace new technologies. J. Serv. J service res 2000;2(4):307-320. [doi: 10.1177/109467050024001]
29. Tarter RE, Kirisci L. The Drug Use Screening Inventory for adults: psychometric structure and discriminative sensitivity. Am J Drug Alcohol Abuse 1997 May;23(2):207-219. [Medline: 9143634]
30. Bashford J, Flett R, Copeland J. The Cannabis Use Problems Identification Test (CUPIT): development, reliability, concurrent and predictive validity among adolescents and adults. Addiction 2010 Apr;105(4):615-625. [doi: 10.1111/j.1360-0443.2009.02859.x] [Medline: 20403014]
31. Auther A, Smith C, Cornblatt B. Global Functioning: Social Scale (GF: Social). Glen Oaks, NY: Zucker Hillside Hospital; 2006.
32. Niendam T, Bearden C, Johnson J, Cannon T. Global Functioning: Role Scale (GF:Role). Los Angeles: University of California, Los Angeles; 2006.
33. Ventura J, Lukoff D, Nuechterlein K, Liberman R, Green M, Shaner A. Manual for the expanded brief psychiatric rating scale. Int. J. Methods Psychiatr. Res 1993;3:221-224.
34. Haro JM, Kamath SA, Ochoa S, Novick D, Rele K, Fargas A, SOHO Study Group. The Clinical Global Impression-Schizophrenia scale: a simple instrument to measure the diversity of symptoms present in schizophrenia. Acta Psychiatr Scand Suppl 2003(416):16-23. [Medline: 12755850]
35. Kopelowicz A, Ventura J, Liberman RP, Mintz J. Consistency of Brief Psychiatric Rating Scale factor structure across a broad spectrum of schizophrenia patients. Psychopathology 2008;41(2):77-84. [doi: 10.1159/000111551] [Medline: 18033976]

Abbreviations

BPRS: Brief Psychiatric Rating Scale
CMHC: Community Mental Health Center

EDAPT: Early Detection and Preventative Treatment
EP: early psychosis
MD: Medical Doctor
MFT: Marriage and Family Therapist
mHealth: mobile health
MSW: Master's in Social Work
PhD: Doctor of Philosophy
PsyD: Doctor of Psychology
SOAR: Supportive Outreach and Access to Resources
UC: University of California

Edited by J Torous; submitted 25.07.17; peer-reviewed by E Moran, J Baker; comments to author 30.08.17; revised version received 23.11.17; accepted 25.11.17; published 27.02.18.

Please cite as:
Kumar D, Tully LM, Iosif AM, Zakskorn LN, Nye KE, Zia A, Niendam TA
A Mobile Health Platform for Clinical Monitoring in Early Psychosis: Implementation in Community-Based Outpatient Early Psychosis Care
JMIR Ment Health 2018;5(1):e15
URL: http://mental.jmir.org/2018/1/e15/
doi:10.2196/mental.8551
PMID:29487044

Original Paper

Standalone Effects of a Cognitive Behavioral Intervention Using a Mobile Phone App on Psychological Distress and Alcohol Consumption Among Japanese Workers: Pilot Nonrandomized Controlled Trial

Toshitaka Hamamura[1,2], MS; Shinichiro Suganuma[1], PhD; Mami Ueda[1], MA; Jack Mearns[3], PhD; Haruhiko Shimoyama[1], PhD

[1]Division of Clinical Psychology, University of Tokyo, Bunkyo, Tokyo, Japan

[2]Japan Society for the Promotion of Science, Chiyoda, Tokyo, Japan

[3]Department of Psychology, California State University, Fullerton, Fullerton, CA, United States

Corresponding Author:
Toshitaka Hamamura, MS
Division of Clinical Psychology
University of Tokyo
7-3-1 Hongo
Bunkyo, Tokyo, 113-0033
Japan
Phone: 81 3 5841 3904
Fax: 81 3 5841 3904
Email: hamamura@g.ecc.u-tokyo.ac.jp

Abstract

Background: Research that investigates standalone effects of a mobile phone-based cognitive behavioral therapy without any human contact for reducing both psychological distress and risky drinking has been advancing; however, the number of studies is still limited. A mobile phone app called Self Record that facilitates cognitive restructuring through self-monitoring of daily thoughts and activities was developed in Japan.

Objective: This study conducted a nonrandomized controlled pilot trial of the Self Record app to investigate standalone effects of the intervention on psychological distress and alcohol consumption among Japanese workers. Additionally, we examined moderating effects of negative mood regulation expectancies, which are beliefs about one's ability to control one's negative mood.

Methods: A quasi-experimental design with a 1-month follow-up was conducted online in Japan from February 2016 to March 2016. A research marketing company recruited participants. The selection criteria were being a Japanese full-time worker (age 20-59 years), experiencing mild to moderate psychological distress, and having some interest in self-record apps. Assignment to group was based on participants' willingness to use the app in the study. All participants completed outcome measures of negative mood regulation expectancies, positive well-being, general distress, depression, anxiety, and typical/most weekly alcohol consumption.

Results: From the recruitment, 15.65% (1083/6921) of participants met the inclusion criteria. Of these, 51.43% (557/1083) enrolled in the study: 54.9% (306/557) in the intervention group and 45.1% (251/557) in the control group. At the 1-month follow-up, 15.3% (85/557) of participants had dropped out. Intention-to-treat analyses revealed that participants in the intervention group reported increased typical drinking ($\eta 2$=.009) and heavy drinking ($\eta 2$=.001). Adherence to using the app was low; 64.8% (199/306) of participants in the intervention group discontinued using the app on the first day. Additionally, 65.7% (366/557) of the total sample did not correctly answer the validity checks in the outcome measures (eg, "Please select 'mildly agree' for this item"). Therefore, per-protocol analyses were conducted after removing these participants. Results showed that continuing app users (42/127) in the intervention group reported increases in anxiety ($\eta 2$=.006), typical drinking ($\eta 2$=.005), and heavy drinking ($\eta 2$=.007) compared to those in the control group (85/127). Negative mood regulation expectancies moderated the effects of the intervention for general distress (beta=.39).

Conclusions: Results were contrary to our hypotheses. Self-recording methods of standalone mobile phone interventions may heighten individuals' awareness of their pathological thought and drinking behavior, but may be insufficient to decrease them unless combined with a more intense or face-to-face intervention. Limitations include high attrition in this study; measures to improve the response rate are discussed.

(JMIR Ment Health 2018;5(1):e24) doi:10.2196/mental.8984

KEYWORDS

mobile phone intervention; cognitive behavioral therapy; psychological distress; drinking; Japanese workers

Introduction

Background

Computer-delivered interventions (CDIs) are therapeutic or quasi-therapeutic interactions delivered digitally rather than through interaction with another person. They have become widely available over the last decade and benefits of CDIs include cost-effectiveness and accessibility to a wider population [1]. Recent systematic reviews and meta-analyses have shown these interventions to be effective for treating depression [2] and anxiety [3]. For risky drinking, CDIs appear to have weak effects at 6 months, but none at 12 months [4].

Recent increases in the number of people carrying mobile phones have led to the development of psychological interventions through mobile apps. Evidence-based apps are only a small portion of available apps, but studies have shown that mobile phone-based CDIs have the potential to reduce psychological and physical symptoms [5-7] and possibly risky drinking [8]. In light of their cost-effectiveness and accessibility to many users, mobile phone-based interventions may be useful in a hierarchical model of treatment.

Cognitive Behavioral Therapy

Cognitive behavioral therapy (CBT) is a widely used psychological intervention and much evidence shows its effectiveness for a number of psychological disorders, including depression, anxiety [9], and substance abuse [10]. An important element of CBT is monitoring one's thoughts and activities. Daily behavioral and thought records are often assigned as homework to examine individuals' lifestyle and thinking patterns. Neimeyer and Feixas [11] found that homework assignments that included records of thoughts, activity, and emotional responses alleviated depression in the short term for participants diagnosed with unipolar depression. Hundt et al [12] found that cognitive awareness of dysfunctional thoughts meditated the effectiveness of CBT treatments for depression. The literature demonstrates that mobile-based CBT is effective for reducing various psychological symptoms [13-15]; however, studies that examined standalone effects without professional contacts seemed to be limited [16]. To our knowledge, no other studies have assessed standalone effects of mobile CBT or any theory-based intervention.

Mental Health Treatment in Japan

There are various reasons that people in Japan could benefit from CDIs. Many Japanese are unwilling to receive professional mental health services. Studies have shown that many Japanese view mental health problems as not a curable condition [17] and thus have little confidence in the effectiveness of treatment by mental health professionals. People may also avoid face-to-face mental health care in Japan because of societal stigmas [18]. Although advocating for receiving professional services for mental health problems is necessary for providing appropriate care, alternative forms of interventions such as CDIs may increase the accessibility of mental health services in Japan.

Recent research on Internet-based CBT has demonstrated reductions in depression among the Japanese [19,20]. People in the workforce are particularly vulnerable to psychological distress in Japan because overwork is common and predicts mental health problems [21]. To our knowledge, no studies have yet been conducted with CBT-based mobile interventions in Japan.

Negative Mood Regulation Expectancies

One possible explanation of the effect of CBT-based interventions on psychological distress and substance use may be that CBT-based interventions increase individuals' negative mood regulation expectancies. Negative mood regulation expectancies are defined as one's belief that, when feeling upset, one can use thought or action to improve one's mood [22]. Much research demonstrates that people with strong negative mood regulation expectancies cope more adaptively with stress and report fewer symptoms of anxiety and depression [23]. Negative mood regulation expectancies are also associated negatively with problematic drinking behavior, even after controlling for alcohol consumption, motivation, and coping styles [24]. Improvement in negative mood regulation expectancies during the early stages of CBT is associated with greater symptom reduction at the end of treatment and at follow-up [25,26]. Recent studies demonstrated that negative mood regulation expectancies operate in Japan in a similar way to how they do in the West [27,28].

Development of a Mobile Phone-Delivered Cognitive Behavioral Therapy App

We developed an app called " *jibun kiroku* " [Self Record], which allows users to receive a CBT-based intervention on their mobile phone (see Multimedia Appendix 1). This app focuses particularly on self-monitoring and awareness of negative thoughts, daily activities, and daily mood. It first provides psychoeducation about the relationships among negative thoughts, feelings, behavior, and physical responses (see Multimedia Appendix 2). Users can record their daily activities on an hourly basis, which promotes cognitive restructuring by helping users to identify automatic thoughts, emotions, and behavior from their daily activities (see Multimedia Appendix 3). Users can also evaluate the quality of their sleep, mood, and

energy level, and they can track changes over the week (see Multimedia Appendix 4).

Study Purpose

The purpose of this study was to conduct a pilot trial to evaluate feasibility of the Self Record mobile phone app. We were particularly interested in examining standalone effects of the Self Record app on psychological distress and alcohol consumption. Although the intervention in this study was not developed to treat alcohol-related problems directly, we expected that reduction in psychological distress would lead to reduction in alcohol consumption, because alcohol consumption is positively associated with stress due to the tension-reducing properties of alcohol [29] and negatively with negative mood regulation expectancies [24]. We hypothesized that participants who received the intervention would show decreased psychological distress and alcohol consumption and increased psychological well-being and negative mood regulation expectancies (hypothesis 1). We also hypothesized that negative mood regulation expectancies would moderate the effect of the intervention on distress and alcohol consumption (hypothesis 2). Self-awareness, by itself, may not necessarily ameliorate symptoms; rather, people must have confidence that they can successfully regulate the processes they become aware of (ie, have strong negative mood regulation expectancies) [23].

Methods

Participation Selection

A research marketing company recruited individuals aged between 20 and 60 years, who indicated working full time and being "interested" or "somewhat interested" in using a self-monitoring app on their mobile phone. We also used a Japanese version of the Kessler Psychological Distress Scale (K6) to select participants experiencing psychological distress (see subsequent section for a full description of the K6). Participants whose K6 score fell between 5 and 12, indicating mild to moderate psychological distress, were recruited for this study. A total of 6921 participants were screened for eligibility, and 1396 met criteria for study participation.

Outcome Measures

The Japanese Negative Mood Regulation Scale assessed negative mood regulation expectancies [27]. Forty items complete the stem: "When I'm mildly depressed or irritated..." Responses use a 5-point scale (1=strongly disagree to 5=strongly agree). An example item is "Telling myself it will pass will help me calm down." Alphas in this study ranged from .91 to .93.

A Japanese version of the WHO (Five) Well-Being Index (WHO-5) assessed positive well-being [30]. The scale consists of five items that use a 6-point scale (0=at no time to 5=all of the time). An example item is "I felt cheerful and in good spirits." The alphas in this study ranged from .89 to .92.

A Japanese version of the K6 was used to measure general distress [31]. The scale comprises six items that answer this question: "During the last 30 days, how did you feel about the following?" Examples items are "nervous" and "everything was an effort." Participants use a 5-point scale (0=none of the time to 4=all of the time). Alphas in this study ranged from .84 to .85.

A Japanese version of the Center for Epidemiological Studies Depression Scale (CES-D) [32] measured depressive symptoms. The scale consists of 20 items responded to with a 4-point scale (0=rarely or none of the time [less than 1 day] to 3=most or all of the time [5-7 days]). The items assess various depressive symptoms (eg, "I feel sad," "My sleep was restless," "I felt that people dislike me"). Alphas for this study ranged from .84 to .89.

Trait anxiety was assessed using the State-Trait Anxiety Inventory (STAI-Trait). A Japanese version was created by Shimizu and Imae [33]. The scale consists of 20 items responded to with a 4-point scale (1=almost never to 4=almost always). Items include "I lack self-confidence," "I worry over something that doesn't matter," and "I feel secure." Alphas in this study ranged from .88 to .89.

To assess typical drinking and heavy drinking in the last 30 days, the Daily Drinking Questionnaire was used [34]. For typical drinking, participants recall a typical week and indicate how many drinks they consumed and the time they spent drinking each day from Monday to Sunday. For heavy drinking, they recalled the week they drank the most alcohol. A sum score of typical drinking and heavy drinking was calculated by summing the drinking quantity of all seven days. Participants reported their drinking quantity by converting all their drinks to 500 mL of beer, which is equivalent to 1 unit of alcohol in Japan.

Procedure

The Life Science Research Ethics and Safety committee at the University of Tokyo in Tokyo, Japan, reviewed and approved this study (16-88). Participants, who were registered in the research marketing company's pool, received a notification about the study over the Internet. The screening for eligibility asked potential participants whether they were willing to use a self-monitoring app on their mobile phone. Specifics about the app were not revealed until after participants consented to be in the study. Because this study had to provide the intervention to those who were interested in using the app, this study implemented a quasi-experimental design. Participants who were willing to use the Self Record app represented the intervention condition, and those who were not represented the control condition.

After participants were screened for eligibility, they read the informed consent and then completed pretest measures in this order: general distress, negative mood regulation expectancies, depression, anxiety, alcohol consumption, and positive well-being. After the 4-week intervention period, participants in both conditions retook the identical battery of questionnaires.

Intervention

Participants in the intervention condition first read a psychoeducation section presenting the basic concepts of CBT, which included an explanation about how thoughts affect feelings, behavior, and physical reactions (see Multimedia Appendix 2). Then, they were instructed to record their daily

activities, thoughts, mood, and sleep quality, which would help them discover and modify dysfunctional thoughts as part of cognitive restructuring (see Multimedia Appendixes 3 and 4). To identify the frequency of their app use, they were instructed to send a screenshot of their weekly daily activity and thought records at the beginning of the trial period. All participation was conducted online.

Experimental Design and Statistical Analyses

All participants in the intervention and control groups were included for intention-to-treat analyses. Multiple imputations were performed to replace missing values that were lost at follow-up. Additionally, we performed per-protocol analyses because some variation in app use was expected and that inaccurate responses in outcome measures indicate lack of diligence.

For examining the effectiveness of the intervention (hypothesis 1), we treated the condition (intervention vs control), the time (pretest and posttest), and the condition × time interaction as independent variables. Dependent variables were general distress (K6), depression (CES-D), anxiety (STAI-Trait), positive well-being (WHO-5), negative mood regulation expectancies, typical drinking, and heavy drinking. Mixed-effect analyses of variance (ANOVA) were performed. The condition × time interaction examined the effect of using the intervention for 4 weeks compared to the assessment-only effect in the control condition. An R package called “nlme” was used to perform this analysis [35].

To examine the moderating effect of negative mood regulation expectancies (hypothesis 2), we implemented multiple regression analyses. Independent variables were condition (intervention vs control), negative mood regulation expectancies, and the condition × negative mood regulation expectancies interaction. For dependent variables, we used difference in the outcome variables between posttest and the pretest to simplify the statistical analyses. An R package called “car” was used to perform the multiple regression analyses [36]. For effect sizes, we calculated beta. All analyses used the .05 level of significance.

Power Analysis

Based on prior studies’ weak effect sizes for CDIs on alcohol consumption, we estimated at least a sample of 393 was needed for 80% statistical power at the $P<.05$ significance level. Because high attrition and poor quality of responses were expected, we collected beyond the number estimated by the power analysis.

Results

Attrition

Figure 1 shows the flowchart of this study. During recruitment beginning in February 2017, 6921 participants were approached for screening, 1083 of 6921 (15.65%) met eligibility criteria, and 557 of 6921 (8.05%) completed the baseline measure. Then, 306 of 557 participants (54.9%) were allocated to the intervention group and 251 of 557 (45.1%) to the control group based on their self-selection regarding willingness to use the mobile phone app. The 1-month follow-up occurred in March 2017; 58 of 306 participants (19.0%) in the intervention group and 27 of 251 (10.8%) participants in the control group were lost because they did not complete outcome measures.

For the frequency of the Self Record app use, 107 of 306 participants (35.0%) reported they continued using the app after the first day, 63 participants (20.6%) used it for more than a week, 37 participants (12.1%) used it for more than 2 weeks, 14 participants (4.6%) used it for more than 3 weeks, and 8 participants (2.6%) used it for more than 4 weeks.

Participant Characteristics

Of the 557 participants enrolled in the trial, 230 (41.2%) were women. The mean age was 38.82 (SD 9.58) years. Regarding work status, 399 of 557 (71.6%) reported employment by a company, 42 of 557 (7.5%) reported employment by the government or a nonprofit organization, 35 of 557 (6.3%) reported self-employment, and 17 of 557 (3.1%) reported working as a professional (eg, lawyer, accountant, and medical staff).

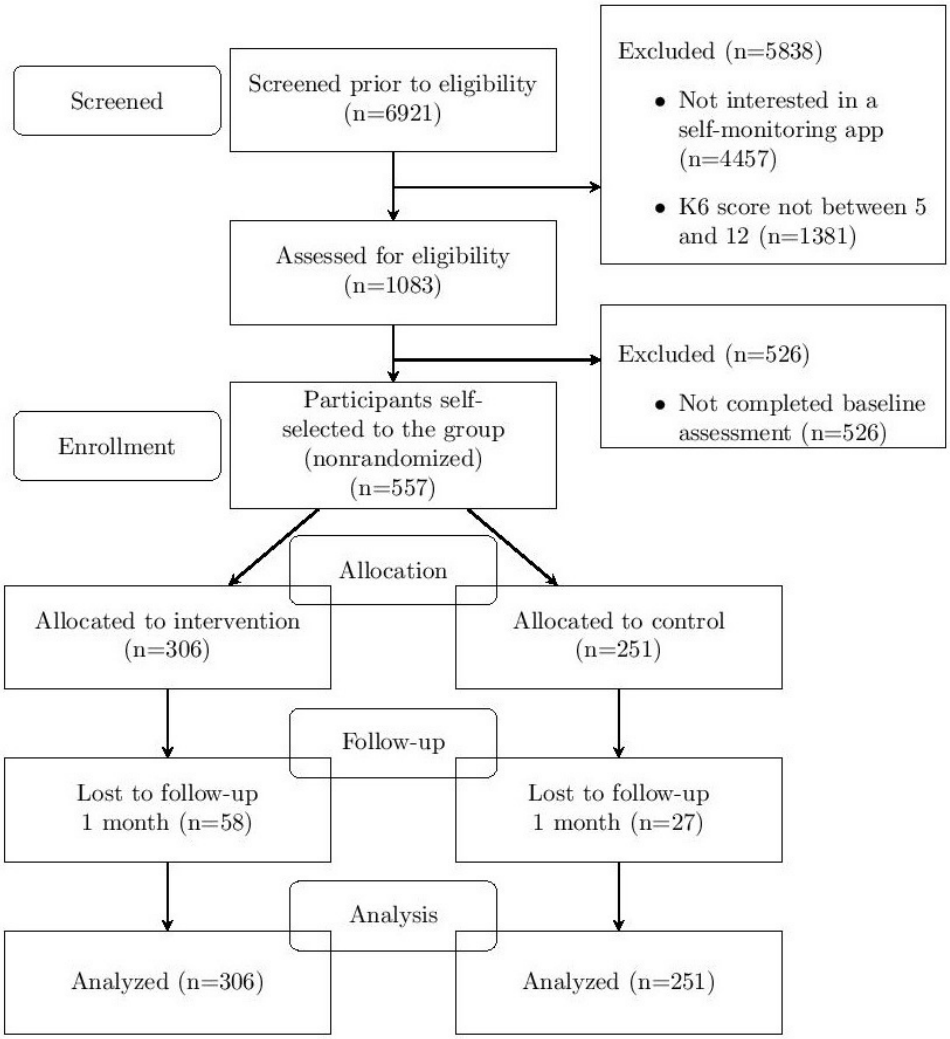
Data Screening

Data were screened for missingness, outliers, normality, and heteroscedasticity. All measures were winsorized to adjust outliers. For the K6, CES-D, and WHO-5, square-root transformation was used, and for typical drinking and heavy drinking, logarithmic transformation was used to adjust for positive skewness and kurtosis.

Descriptive Statistics

Descriptive statistics are shown in Table 1. Multivariate analysis of variance indicated no significant group differences in the pretest variables ($F_{7,549}=0.95$, $P=.47$). The mean scores on the K6 and CES-D were higher than in other studies that examined Japanese workers [19,20], indicating higher levels of psychological distress among participants in this study.

Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) extension flow diagram.



Intention-to-Treat Primary Analyses

For intention-to-treat analyses, mixed-effect ANOVA was used to assess the main effects of condition and time, and the condition × time interaction (hypothesis 1). Table 2 shows results of the analyses. The main effect of condition was significant for typical drinking (η^2<.001) and heavy drinking (η^2=.002). Participants in the intervention group reported higher typical and heavy drinking than did those in the control group. The main effect of time was significant for WHO-5 (η^2=.003), negative mood regulation expectancies (η^2=.004), K6 (η^2=.002), CES-D (η^2=.003), typical drinking (η^2<.001), and heavy drinking (η^2=.002). At the 1-month follow-up, participants reported higher scores on the WHO-5, K6, CES-D, typical drinking, and heavy drinking, and lower negative mood regulation expectancies compared to baseline. The condition × time interaction was significant for typical drinking (η^2=.009; see Figure 2) and heavy drinking (η^2=.001; see Figure 3). For both typical and heavy drinking, participants in the intervention group reported higher scores at the 1-month follow-up compared to the participants in the control group.

We also examined the moderation by negative mood regulation expectancies of the effect of the intervention (hypothesis 2). Because three-way interactions are often difficult to interpret, we implemented multiple regression analyses. Independent variables were group (intervention and control), negative mood regulation expectancies, and the group × negative mood regulation expectancies interaction. Dependent variables were changes from baseline to 1-month follow-up of outcome variables. None of the results were statistically significant.

Table 1. Mean and standard deviation of outcome measures (N=557).

Test[a]	Control, mean (SD)	Intervention, mean (SD)
NMRE		
Pretest	120.86 (12.59)	120.84 (14.70)
Posttest	119.66 (12.60)	118.58 (15.73)
WHO-5		
Pretest	14.25 (4.91)	14.65 (5.23)
Posttest	14.59 (4.73)	15.18 (5.25)
K6		
Pretest	7.40 (4.27)	7.43 (4.80)
Posttest	7.98 (4.76)	8.08 (4.75)
CES-D		
Pretest	19.44 (7.75)	19.62 (8.81)
Posttest	20.21 (8.24)	21.59 (9.32)
STAI-Trait		
Pretest	49.83 (7.30)	49.91 (8.29)
Posttest	49.57 (6.80)	50.53 (8.64)
Typical drinking		
Pretest	6.15 (7.63)	6.70 (8.93)
Posttest	5.67 (6.16)	6.60 (6.77)
Heavy drinking		
Pretest	6.96 (8.63)	8.89 (12.03)
Posttest	6.94 (7.51)	8.12 (8.21)

[a]CES-D: Centers for Epidemiological Studies Depression; K6: Kessler Psychological Distress Scale; NMRE: Negative mood regulation expectancies; STAI: State-Trait Anxiety Inventory; WHO-5: WHO (Five) Well-Being Index.

Table 2. Intention-to-treat primary analyses: effects of condition, time, and condition × time interaction on outcome variables.

Test[a]	Condition			Time			Condition × time		
	χ^2_5	*P*	η^2	χ^2_6	*P*	η^2	χ^2_7	*P*	η^2
NMRE	0.3	.61	<.001	10.7	.001	.004	1.0	.33	.002
WHO-5	1.4	.23	.001	5.0	.03	.003	0.1	.71	.006
K6	0.02	.89	<.001	5.9	.02	.002	0.6	.45	.01
CES-D	0.7	.40	<.001	14.2	<.001	.003	2.8	.10	.03
STAI-Trait	1.3	.52	<.001	0.5	.47	<.001	2.5	.29	.004
Typical drinking	9.5	.009	<.001	8.9	.003	<.001	13.9	.001	.009
Heavy drinking	10.1	.006	.002	8.0	.003	.002	8.7	.01	.001

[a]CES-D: Centers for Epidemiological Studies Depression; K6: Kessler Psychological Distress Scale; NMRE: Negative mood regulation expectancies; STAI: State-Trait Anxiety Inventory; WHO-5: WHO (Five) Well-Being Index.

Figure 2. Change in typical drinking as a function of condition and time in the intention-to-treat analysis.

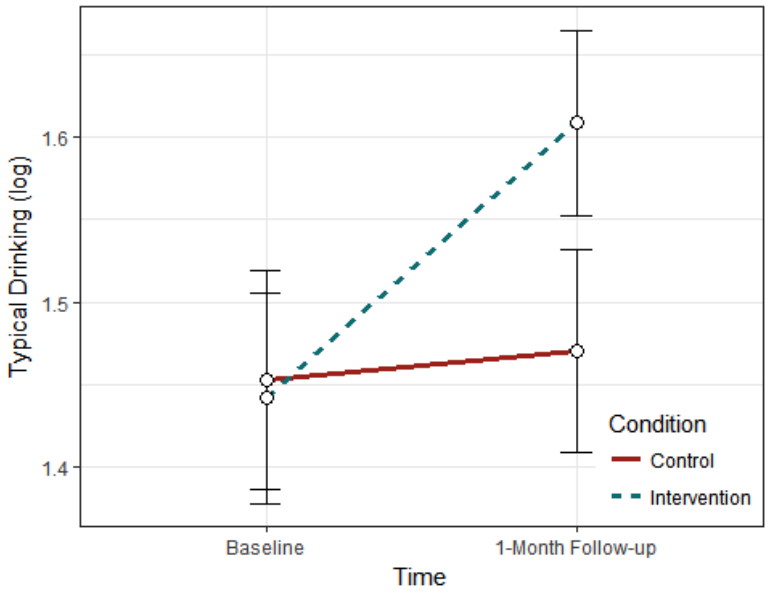
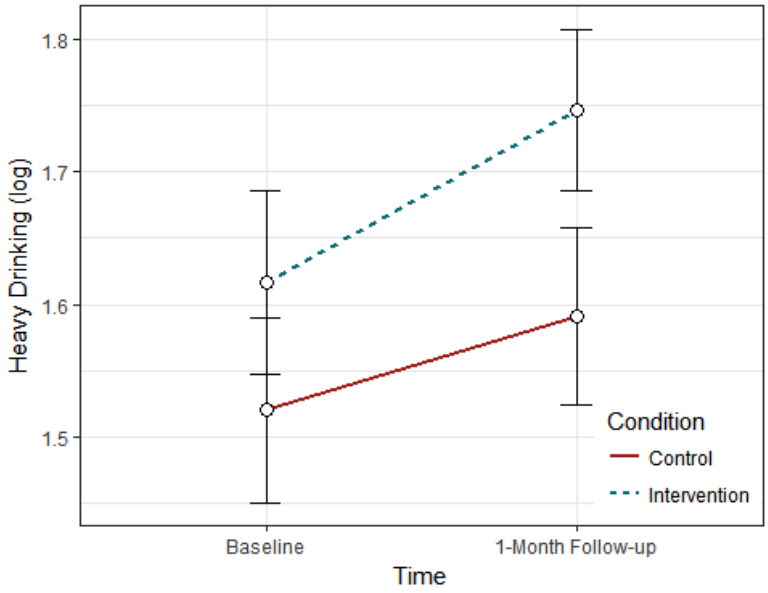


Figure 3. Change in heavy drinking as a function of condition and time in the intention-to-treat analysis.



Per-Protocol Secondary Analyses

The intention-to-treat analyses were problematic due to attrition; approximately two-thirds of the participants (65.0%, 199/306) in the intervention group discontinued using the app on the first day. In addition, two-thirds of the participants in both groups (65.7%, 366/557) incorrectly answered validity items. As a result, substantially lower alphas for outcome measures were observed when these participants were included in reliability analyses, suggesting random or inattentive responding. For these reasons, we conducted per-protocol analyses by excluding participants who discontinued using the app after the first day and answered the validity items incorrectly. Forty-two participants in the intervention and 85 participants in the control remained in the analyses.

Table 3 shows results of the per-protocol secondary analyses. A mixed-effect ANOVA revealed that the main effect of condition was significant for K6 (η^2=.09). Participants in the intervention group reported significantly lower K6 scores than did those in the control group. The main effect of time was significant for negative mood regulation expectancies (η^2=.009). Participants reported significantly lower negative mood regulation expectancies at the 1-month follow-up. The condition × time interaction was significant for anxiety (η^2=.04), typical drinking (η^2=.06), and heavy drinking (η^2=.09). Participants in the intervention group reported higher scores for all three outcome measures at the 1-month follow-up compared to the control group.

Table 3. Per-protocol secondary analyses: effects of condition, time, and condition × time interaction on outcome variables.

Test[a]	Condition			Time			Condition × time		
	χ^2_5	*P*	η^2	χ^2_6	*P*	η^2	χ^2_7	*P*	η^2
NMRE	1.4	.23	.02	4.6	.03	.009	1.5	.22	.01
WHO-5	1.4	.24	.01	0.2	.65	<.001	0.01	.92	<.001
K6	12.2	<.001	.09	0.7	.41	.009	0.5	.47	.04
CES-D	2.0	.16	.03	0.006	.94	.003	1.4	.23	.008
STAI-Trait	3.9	.14	.05	1.1	.29	.002	6.7	.04	.04
Typical drinking	0.4	.81	<.001	0.1	.82	.02	7.4	.03	.06
Heavy drinking	1.0	.60	<.001	0.2	.69	.04	12.2	.002	.09

[a]CES-D: Centers for Epidemiological Studies Depression; K6: Kessler Psychological Distress Scale; NMRE: Negative mood regulation expectancies; STAI: State-Trait Anxiety Inventory; WHO-5: WHO (Five) Well-Being Index.

For moderation by negative mood regulation expectancies (hypothesis 2), the condition × negative mood regulation expectancies interaction predicted general distress (beta=.39, *P*=.03). Among participants with high negative mood regulation expectancies, those in the intervention group reported higher general distress compared to those in the control group. However, there was no difference among those with low negative mood regulation expectancies.

Discussion

This study examined standalone effects of a CBT-based mobile intervention called Self Record on psychological distress and drinking consumption. The intention-to-treat analyses revealed that participants who used the Self Record app reported increased typical drinking and heavy drinking, which was contrary to our hypothesis. In the per-protocol secondary analyses, we removed participants who discontinued using the app on the first day and participants who showed inattentiveness in answering outcome measures. The per-protocol analysis revealed that participants who used the intervention more often over the 4-week trial period reported increases in anxiety, typical drinking, and heavy drinking compared to those who rarely used the intervention or members of the control group. The effect sizes were small to medium.

The goal of the intervention in this study was to raise participants' awareness of potentially pathological thinking and to discover solutions to it. The first objective may have succeeded, raising participants' awareness of their maladaptive patterns; however, the intervention apparently did not help participants self-treat their problematic thinking. Consequently, this heightened awareness may have affected results in two ways: (1) people may have reported increases in distress because they became more aware of their distress, and (2) such awareness may have started a vicious cycle in which heightened awareness led to greater distress, which the interventions focused their awareness on.

Our result was contrary to previous studies that demonstrated the positive effects of mobile phone-based interventions on psychological distress [14,15]. One difference of these studies' designs is that their participants had personal contacts with a mental health professional or researcher to discuss their experience with the interventions, whereas participants in this study focused on self-monitoring and had no personal contacts with any professional. It is possible that contact with the professional was more responsible for symptom improvement than was the CDI in prior studies. Gajecki et al [37] investigated a standalone mobile-based intervention for reducing risky drinking. They also found that using the mobile app led to more frequent alcohol use among men. Standalone use of CDIs was completely reliant on the participants for its success. Our findings and those of Gajecki et al highlight that, if participants are not capable of successfully using the information the intervention provides, the intervention may have unintended negative consequences.

We also investigated the moderating role of negative mood regulation expectancies on the effect of the intervention. The level of negative mood regulation expectancies affected the impact of the intervention on general distress. Among participants with high negative mood regulation expectancies, those in the control condition showed decreases, whereas those in the intervention condition showed increases in general distress. The unexpected effects of the Self Record app on general distress were more evident among those with high negative mood regulation expectancies than those with low negative mood regulation expectancies. More studies are necessary to investigate the moderating role of negative mood regulation expectancies on CDI psychological interventions.

There are several limitations of this study. First, this study used a quasi-experimental design, in which only those who were interested in using the mobile phone-based intervention were placed in the intervention group. Although there were no group differences in measures at pretest, it is still possible that some unmeasured factor was responsible for changes from pretest to posttest. More research needs to be conducted to confirm the findings of this study. Confounding variables, such as participants' willingness to use the intervention or other characteristics, might have contributed to the findings in this study. Also, the study was conducted during the last month of the fiscal year in Japan and the participants, who were all full-time workers, may have been experiencing workplace stress. This environmental factor may have contributed in the increase

in their stress in general and may have overshadowed the influence of personality variables.

Second, there was a high attrition rate in this study. Although attrition at 1-month follow-up was not relatively high (15.3%, 85/557), 65.0% (199/306) of the participants in the intervention group discontinued using the app on the first day. Furthermore, 65.7% (366/557) of the total sample incorrectly answered all the accuracy-check items. Some literature points to high attrition as a characteristic of many Internet-based studies [38], but this attrition may limit the generalizability of our results.

Nevertheless, this study may suggest unintended effects of standalone use of mobile-based CDIs for Japanese experiencing moderate stress. The mobile intervention may be beneficial when it is combined with other interventions that include contact with professionals to discuss thoughts and behaviors. This contact would allow clinicians to adjust interventions that lead countertherapeutically to higher distress. More intense computerized interventions or face-to-face psychotherapy may be necessary to alleviate psychological stress.

Future studies may use more rigorous research designs, such as a randomized controlled trial. If standalone computerized self-monitoring increases people's anxiety and drinking behavior, future studies may clarify mechanisms for such increases. There are several ways to improve low response rates. First, reminders can be sent to participants about using the app because this study did not provide any reminders. Second, participants could receive more specific instructions for using the app, so that they could focus on the daily activities and negative thoughts they prefer to work on with the app. This will focus their thinking on the most important thoughts for intervention. Third, future studies should design apps with more automatic functions, such as syncing with other apps to record sleep time, to reduce the manual entries needed to be done by users.

Acknowledgments

This research was supported in part by grants from the Graduate Program for Social ICT Global Creative Leaders at the University of Tokyo to TH and HS, grants from Grant-in-Aid for JSPS fellows (17J03078) to TH, and a Fulbright grant to JM.

Conflicts of Interest

None declared.

Multimedia Appendix 1

A screenshot of the download and the home screen.

[PNG File, 347KB - mental_v5i1e24_app1.png]

Multimedia Appendix 2

A screenshot of the psychoeducation component.

[PNG File, 846KB - mental_v5i1e24_app2.png]

Multimedia Appendix 3

A screenshot of the thought and behavior records.

[PNG File, 251KB - mental_v5i1e24_app3.png]

Multimedia Appendix 4

A screenshot of the mood records.

[PNG File, 105KB - mental_v5i1e24_app4.png]

References

1. Andersson G. Internet-delivered psychological treatments. Annu Rev Clin Psychol 2016;12:157-179. [doi: 10.1146/annurev-clinpsy-021815-093006] [Medline: 26652054]
2. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clin Psychol Rev 2012 Jun;32(4):329-342. [doi: 10.1016/j.cpr.2012.02.004] [Medline: 22466510]
3. Spek V, Cuijpers P, Nyklícek I, Riper H, Keyzer J, Pop V. Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. Psychol Med 2007 Mar;37(3):319-328. [doi: 10.1017/S0033291706008944] [Medline: 17112400]

4. Dedert EA, McDuffie JR, Stein R, McNiel JM, Kosinski AS, Freiermuth CE, et al. Electronic interventions for alcohol misuse and alcohol use disorders: a systematic review. Ann Intern Med 2015 Aug 4;163(3):205-214. [doi: 10.7326/M15-0285] [Medline: 26237752]
5. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
6. Lindhiem O, Bennett CB, Rosen D, Silk J. Mobile technology boosts the effectiveness of psychotherapy and behavioral interventions: a meta-analysis. Behav Modif 2015 Nov;39(6):785-804. [doi: 10.1177/0145445515595198] [Medline: 26187164]
7. Watts S, Mackenzie A, Thomas C, Griskaitis A, Mewton L, Williams A, et al. CBT for depression: a pilot RCT comparing mobile phone vs computer. BMC Psychiatry 2013;13:49 [FREE Full text] [doi: 10.1186/1471-244X-13-49] [Medline: 23391304]
8. Gustafson DH, McTavish FM, Chih M, Atwood AK, Johnson RA, Boyle MG, et al. A smartphone application to support recovery from alcoholism: a randomized clinical trial. JAMA Psychiatry 2014 May;71(5):566-572 [FREE Full text] [doi: 10.1001/jamapsychiatry.2013.4642] [Medline: 24671165]
9. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy: a review of meta-analyses. Clin Psychol Rev 2006 Jan;26(1):17-31. [doi: 10.1016/j.cpr.2005.07.003] [Medline: 16199119]
10. Windsor LC, Jemal A, Alessi EJ. Cognitive behavioral therapy: a meta-analysis of race and substance use outcomes. Cultur Divers Ethnic Minor Psychol 2015 Apr;21(2):300-313 [FREE Full text] [doi: 10.1037/a0037929] [Medline: 25285527]
11. Neimeyer RA, Feixas G. The role of homework and skill acquisition in the outcome of group cognitive therapy for depression. Behav Ther 1990 Sep;21:281-292. [doi: 10.1016/j.beth.2016.08.013] [Medline: 27816085]
12. Hundt NE, Mignogna J, Underhill C, Cully JA. The relationship between use of CBT skills and depression treatment outcome: a theoretical and methodological review of the literature. Behav Ther 2013 Mar;44(1):12-26. [doi: 10.1016/j.beth.2012.10.001] [Medline: 23312423]
13. Ly KH, Trüschel A, Jarl L, Magnusson S, Windahl T, Johansson R, et al. Behavioural activation versus mindfulness-based guided self-help treatment administered through a smartphone application: a randomised controlled trial. BMJ Open 2014;4(1):e003440 [FREE Full text] [doi: 10.1136/bmjopen-2013-003440] [Medline: 24413342]
14. Kauer SD, Reid SC, Crooke AHD, Khor A, Hearps SJC, Jorm AF, et al. Self-monitoring using mobile phones in the early stages of adolescent depression: randomized controlled trial. J Med Internet Res 2012;14(3):e67 [FREE Full text] [doi: 10.2196/jmir.1858] [Medline: 22732135]
15. Morris ME, Kathawala Q, Leen TK, Gorenstein EE, Guilak F, Labhard M, et al. Mobile therapy: case study evaluations of a cell phone application for emotional self-awareness. J Med Internet Res 2010;12(2):e10 [FREE Full text] [doi: 10.2196/jmir.1371] [Medline: 20439251]
16. Fitzpatrick KK, Darcy A, Vierhile M. Delivering cognitive behavior therapy to young adults with symptoms of depression and anxiety using a fully automated conversational agent (Woebot): a randomized controlled trial. JMIR Ment Health 2017 Jun 06;4(2):e19 [FREE Full text] [doi: 10.2196/mental.7785] [Medline: 28588005]
17. Ando S, Yamaguchi S, Aoki Y, Thornicroft G. Review of mental-health-related stigma in Japan. Psychiatry Clin Neurosci 2013 Nov;67(7):471-482 [FREE Full text] [doi: 10.1111/pcn.12086] [Medline: 24118217]
18. Desapriya EB, Nobutada I. Stigma of mental illness in Japan. Lancet 2002 May 25;359(9320):1866. [Medline: 12044414]
19. Imamura K, Kawakami N, Furukawa TA, Matsuyama Y, Shimazu A, Umanodan R, et al. Effects of an Internet-based cognitive behavioral therapy (iCBT) program in Manga format on improving subthreshold depressive symptoms among healthy workers: a randomized controlled trial. PLoS One 2014;9(5):e97167 [FREE Full text] [doi: 10.1371/journal.pone.0097167] [Medline: 24844530]
20. Kojima R, Fujisawa D, Tajima M, Shibaoka M, Kakinuma M, Shima S, et al. Efficacy of cognitive behavioral therapy training using brief e-mail sessions in the workplace: a controlled clinical trial. Ind Health 2010;48(4):495-502 [FREE Full text] [doi: 10.2486/indhealth.MS1135] [Medline: 20720342]
21. Yamauchi T, Yoshikawa T, Takamoto M, Sasaki T, Matsumoto S, Kayashima K, et al. Overwork-related disorders in Japan: recent trends and development of a national policy to promote preventive measures. Ind Health 2017 Jun 08;55(3):293-302 [FREE Full text] [doi: 10.2486/indhealth.2016-0198] [Medline: 28154338]
22. Catanzaro SJ, Mearns J. Measuring generalized expectancies for negative mood regulation: initial scale development and implications. J Pers Assess 1990;54(3-4):546-563. [doi: 10.1080/00223891.1990.9674019] [Medline: 2348341]
23. Catanzaro S, Mearns J. Generalized expectancies for negative mood regulation: development, assessment, and implications of a construct. In: Trusz S, Babel P, editors. Intrapersonal and Interpersonal Expectancies: Research, Applications and Future Directions. Hove, UK: Psychology Press; May 20, 2016:52-61.
24. Kassel JD, Jackson SI, Unrod M. Generalized expectancies for negative mood regulation and problem drinking among college students. J Stud Alcohol 2000 Jan;61(2):332-340. [doi: 10.15288/jsa.2000.61.332]
25. Backenstrass M, Schwarz T, Fiedler P, Joest K, Reck C, Mundt C, et al. Negative mood regulation expectancies, self-efficacy beliefs, and locus of control orientation: moderators or mediators of change in the treatment of depression? Psychother Res 2006 Mar;16(2):250-258. [doi: 10.1080/10503300500485474]

26. Cloitre M, Stovall-McClough KC, Nooner K, Zorbas P, Cherry S, Jackson CL, et al. Treatment for PTSD related to childhood abuse: a randomized controlled trial. Am J Psychiatry 2010 Aug;167(8):915-924. [doi: 10.1176/appi.ajp.2010.09081247] [Medline: 20595411]
27. Mearns J, Self E, Kono K. Measuring generalized expectancies for negative mood regulation in Japan: the Japanese language NMR Scale. Int J Quant Res Educ 2016;3:109-127. [doi: 10.1504/IJQRE.2016.073675]
28. Hamamura T, Mearns J. Depression and somatic symptoms in Japanese and American college students: negative mood regulation expectancies as a personality correlate. Int J Psychol 2017 Nov 26:1 (forthcoming). [doi: 10.1002/ijop.12467] [Medline: 29178129]
29. Greeley J, Oei T. Alcohol and tension reduction. In: Leonard K, Blane H, editors. Psychological Theories of Drinking and Alcoholism. New York: Guilford Press; May 21, 1999:14-53.
30. Awata S, Bech P, Koizumi Y, Seki T, Kuriyama S, Hozawa A, et al. Validity and utility of the Japanese version of the WHO-Five Well-Being Index in the context of detecting suicidal ideation in elderly community residents. Int Psychogeriatr 2007 Feb;19(1):77-88. [doi: 10.1017/S1041610206004212] [Medline: 16970832]
31. Furukawa TA, Kawakami N, Saitoh M, Ono Y, Nakane Y, Nakamura Y, et al. The performance of the Japanese version of the K6 and K10 in the World Mental Health Survey Japan. Int J Methods Psychiatr Res 2008;17(3):152-158. [doi: 10.1002/mpr.257] [Medline: 18763695]
32. Shima S, Shikano T, Kitamura T, Asai M. A new self-rating scales for depression [in Japanese]. Seishin Igaku 1985;27:717-723.
33. Shimizu H, Imae K. Development of a Japanese version of the State-Trait Anxiety inventory for college students [in Japanese]. Kyoiku shinrigaku kenkyu 1981;29:62-67.
34. Collins RL, Parks GA, Marlatt GA. Social determinants of alcohol consumption: the effects of social interaction and model status on the self-administration of alcohol. J Consult Clin Psychol 1985 Apr;53(2):189-200. [doi: 10.1037/0022-006X.53.2.189] [Medline: 3998247]
35. Pinheiro J, Bates D, DebRoy S, Sarkar D, EISPACK authors, Heisterkamp S, et al. Linear and nonlinear mixed effects models. 2017 Feb 6. Package “nlme” URL: https://cran.r-project.org/web/packages/nlme/nlme.pdf [WebCite Cache ID 6tRKJyh3g]
36. Fox J, Weisberg S, Adler D, Bates D, Baud-Bovy G, Ellison S, R-Core. Companion to applied regression. 2017 Jul 4. Package “car” URL: https://cran.r-project.org/web/packages/car/car.pdf [WebCite Cache ID 6tRKLc9NX]
37. Gajecki M, Berman AH, Sinadinovic K, Rosendahl I, Andersson C. Mobile phone brief intervention applications for risky alcohol use among university students: a randomized controlled study. Addict Sci Clin Pract 2014;9:11 [FREE Full text] [doi: 10.1186/1940-0640-9-11] [Medline: 24985342]
38. Eysenbach G. The law of attrition. J Med Internet Res 2005;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]

Abbreviations

CBT: cognitive behavioral therapy
CDI: computer-delivered intervention
CES-D: Centers for Epidemiological Studies Depression
K6: Kessler Psychological Distress Scale
STAI: State-Trait Anxiety Inventory
WHO-5: WHO (Five) Well-Being Index

Edited by J Torous; submitted 18.09.17; peer-reviewed by N Johnson, P Deluca; comments to author 11.10.17; revised version received 23.01.18; accepted 06.02.18; published 22.03.18.

Please cite as:
Hamamura T, Suganuma S, Ueda M, Mearns J, Shimoyama H
Standalone Effects of a Cognitive Behavioral Intervention Using a Mobile Phone App on Psychological Distress and Alcohol Consumption Among Japanese Workers: Pilot Nonrandomized Controlled Trial
JMIR Ment Health 2018;5(1):e24
URL: http://mental.jmir.org/2018/1/e24/
doi:10.2196/mental.8984
PMID:29567634

Review

Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors

Christiaan Vis[1,2], MA; Mayke Mol[2,3], MSc; Annet Kleiboer[1,2], PhD; Leah Bührmann[1,2], BSc; Tracy Finch[4], PhD; Jan Smit[2,3], PhD; Heleen Riper[1,2,3,5], PhD

[1]Department of Clinical, Neuro-, & Developmental Psychology, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam, Netherlands

[2]Department of Mental Health, Amsterdam Public Health Research Institute, Vrije Universiteit Medical Center / Vrije Universiteit Amsterdam, Amsterdam, Netherlands

[3]Department of Research and Innovation, Specialized Mental Health Care, GGZ InGeest, Amsterdam, Netherlands

[4]Healthcare & Implementation Science, Department of Nursing, Midwifery & Health, Northumbria University, Newcastle upon Tyne, United Kingdom

[5]Telepsychiatric Unit, Faculty of Health Science, University Hospital / University of Southern Denmark, Odense, Denmark

Corresponding Author:
Christiaan Vis, MA
Department of Clinical, Neuro-, & Developmental Psychology
Faculty of Behavioural and Movement Sciences
Vrije Universiteit Amsterdam
van der Boechorststraat 1
Amsterdam, 1081 BT
Netherlands
Phone: 31 646098094
Email: p.d.c.vis@vu.nl

Abstract

Background: Electronic mental health interventions (eMental health or eMH) can be used to increase accessibility of mental health services for mood disorders, with indications of comparable clinical outcomes as face-to-face psychotherapy. However, the actual use of eMH in routine mental health care lags behind expectations. Identifying the factors that might promote or inhibit implementation of eMH in routine care may help to overcome this gap between effectiveness studies and routine care.

Objective: This paper reports the results of a systematic review of the scientific literature identifying those determinants of practices relevant to implementing eMH for mood disorders in routine practice.

Methods: A broad search strategy was developed with high sensitivity to four key terms: implementation, mental health care practice, mood disorder, and eMH. The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework was applied to guide the review and structure the results. Thematic analysis was applied to identify the most important determinants that facilitate or hinder implementation of eMH in routine practice.

Results: A total of 13,147 articles were screened, of which 48 studies were included in the review. Most studies addressed aspects of the reach (n=33) of eMH, followed by intervention adoption (n=19), implementation of eMH (n=6), and maintenance (n=4) of eMH in routine care. More than half of the studies investigated the provision of mental health services through videoconferencing technologies (n=26), followed by Internet-based interventions (n=20). The majority (n=44) of the studies were of a descriptive nature. Across all RE-AIM domains, we identified 37 determinants clustered in six main themes: acceptance, appropriateness, engagement, resources, work processes, and leadership. The determinants of practices are expressed at different levels, including patients, mental health staff, organizations, and health care system level. Depending on the context, these determinants hinder or facilitate successful implementation of eMH.

Conclusions: Of the 37 determinants, three were reported most frequently: (1) the acceptance of eMH concerning expectations and preferences of patients and professionals about receiving and providing eMH in routine care, (2) the appropriateness of eMH in addressing patients' mental health disorders, and (3) the availability, reliability, and interoperability with other existing technologies such as the electronic health records are important factors for mental health care professionals to remain engaged in providing eMH to their patients in routine care. On the basis of the taxonomy of determinants of practices developed in this

review, implementation-enhancing interventions can be designed and applied to achieve better implementation outcomes. Suggestions for future research and implementation practice are provided.

(JMIR Ment Health 2018;5(1):e20) doi:10.2196/mental.9769

KEYWORDS

eMental health; implementation; routine practice; determinants of practices; RE-AIM; barriers and facilitators; mood disorders; review

Introduction

Background

Electronic mental health interventions (eMental health or eMH) for mood disorders such as depression can increase reach and accessibility of mental health services while maintaining comparable clinical outcomes as face-to-face interventions and superior outcomes compared with waiting lists [1-3]. eMH encompasses the use of digital technologies and new media for the delivery of screening, health promotion, prevention, early intervention, treatment, or relapse prevention, as well as for improvement of health care delivery (eg, electronic patient files), professional education (e-learning), and Web-based research in the field of mental health [4]. Research on the translation of the results of these studies into routine care is scarce. Translational research can have two dimensions: dissemination and implementation of an innovation in clinical practice. Dissemination concerns the passive and active spread of information about eMH to relevant stakeholders, including consumers, clinical care providers, and decision- and policy makers. Implementation refers to the process of embedding and integrating new practices into actual care settings [5,6]. It seems that eMH interventions are reasonably well disseminated to clinical practice given that a number of preconditions are fulfilled, such as the availability of technical infrastructures and proper reimbursement of these services [7]. Nevertheless, the actual use of eMH in routine mental health care lags behind expectations. It is unclear why implementation of eMH remains difficult.

A logical approach in addressing this implementation challenge is to identify the factors that might promote or inhibit implementation of eMH in routine practice [8]. On the basis of these determinants, implementation-enhancing interventions might be designed and applied with the aim to improve implementation processes and upscaling of eMH care. Many determinants of different care practices have been identified for a variety of clinical interventions. For example, Krause and colleagues [9] identified over 600 context-specific determinants thought to be relevant in implementing evidence-based interventions for patients with chronic health conditions, including depression in the elderly, chronic obstructive pulmonary disease, and obesity. Examples of these determinants are status and quality of evidence and clinical recommendations, characteristics of the innovation, delivery modalities, reimbursement modalities, implementation leadership, and organizational readiness [10-12]. Similarly, examples of implementation barriers for eMH include the perceived importance of computer literacy skills, knowledge and awareness of existing eMH services, as well as credibility of these services [13]. In turn, many of these determinants have been clustered and framed, currently resulting in more than 60 frameworks used to study and understand implementation processes [14,15]. Although such determinants and frameworks are valuable and comprehensive, they lack specificity to any category of intervention and therefore, provide little practical detail to prioritize determinants and guidance for action to improve the implementation of eMH interventions.

The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework provides a heuristic tool for bridging interventions' internal validity established in well-controlled conditions and their external validity in real-world conditions [16,17]. It is designed to evaluate the public health impact of health promoting interventions, and it is widely used in implementation research [18]. The framework covers five intervention-related areas of impact: (1) reach as the ability to address those in need of an intervention, (2) effectiveness in terms of the impact of interventions on health outcomes, (3) adoption as a decision to proceed with implementing the clinical intervention, (4) implementation as the process of embedding and integration of the intervention in routine practice and its consistency of delivery and costs, and (5) maintenance as the institutionalization of the intervention in routine care [16,18-20]. Considering the current evidence-base for eMH and the increasing emphasis on comparative effectiveness research in testing clinical and cost-effectiveness of eMH [21], the RE-AIM framework might be a valuable tool to structure determinants of practices that are specific to eMH.

Research Question

Given the absence of a comprehensive overview of determinants of practices, we systematically reviewed the literature to develop a taxonomy relevant to the implementation of eMH. Knowledge on these determinants can inform the study of interventions that aim to improve the implementation of eMH in routine practice. The following research question guided the research: "What determinants of practice are identified as relevant to implementing eMH interventions for mood disorders in routine practice?" A broad view on eMH and care practice settings, including clinical and community practices, was adopted to provide a comprehensive taxonomy of determinants of mental health practice relevant to implementing eMH.

Methods

Study Design

A systematic review of scientific literature was conducted. RE-AIM was used to structure the review. Various implementation studies in the area of mental health care using RE-AIM substantiate the utility of this framework, including

evaluations of the implementation of behavior mental health assessment tools [22]; smoking cessation interventions in people with mental illnesses [23]; mental health, substance abuse, and health behavior interventions into specific primary care behavior health programs [24]; tele-mental health consultation program in pediatric primary care in rural settings [25]; and assessing a therapist's role in eMH for patients with depressive disorders [26].

Search Strategy

Due to the novelty of the topics concerned (ie, eMH and implementation), a broad search strategy was developed with high sensitivity to four key terms (as opposed to a focused strategy with higher specificity [27]): "implementation," "mental health care practice," "mood disorder," and "eMental-health." No time frame was applied. On the basis of literature, benchmark definitions for these concepts were developed, and a total of 408 synonyms were formulated for the search strings. A trained librarian guided the formulation of the search strings. The benchmark definitions and search strings are included in Multimedia Appendix 1. The search was conducted in July 2015 in the three main bibliographical databases (PubMed, PsycINFO, and EMBASE). All identified papers were examined for eligibility by two researchers (CV and MM) independently. Disagreements were solved by discussion and, where necessary, moderated by a third researcher (AK) to reach consensus.

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria are shown in Textboxes 1 and 2.

Data Extraction

A systematic qualitative narrative approach was applied for the data extraction, analyses, and synthesis of the results [28-30]. A field guide was developed to extract relevant data from the retained articles. Items included the study aim, methods, the psychotherapeutic intervention, eMH technology applied, type of mood disorder, implementation intervention (eg, training of professionals, or a focused marketing campaign to raise awareness of eMH among patients), settings, sample(s), recruitment procedures, results, and findings in terms of determinants of practice. The data were tabulated and categorized in accordance with four of the five RE-AIM dimensions: reach, adoption, implementation, and maintenance. Table 1 presents definitions and adaptations to the RE-AIM dimensions that we applied for the purpose of this study. Effectiveness was not addressed in this review as ample reviews on the clinical effectiveness of eMH for mood disorders are available [1-3]. The implementation dimension was broadened to also include the purposive implementation interventions that might have been employed to achieve better implementation outcomes.

Analyses and Synthesis

Thematic analysis was applied to identify the recurrent and most important determinants to implementing eMH in routine practice (ie, themes) arising in the included literature. Thematic analysis is a common method for identifying, grouping, and summarizing findings from included studies in narrative review [29]. The (groups of) determinants were developed inductively (ie, without a priori defined topics guiding the analysis). We did not apply a threshold for recurrence of certain themes in the data. Data were extracted by three researchers (CV, MM, and LB) independently. Data files were merged and discrepancies solved by discussion to reach consensus. Freely available reference management software (Mendely, Elsevier), a spreadsheet (Microsoft Excel, Microsoft Corporation), and qualitative analysis software (ATLAS.ti, Scientific Software Development GmbH) were used to organize and conduct the selection, data extraction, and data analysis.

Textbox 1. Inclusion criteria.

1. Reporting of empirical research such as observational studies using ethnographic methods or experimental studies following a pre-post or randomized controlled trial design
2. The psychotherapeutic intervention under study had an information and communication technology (ICT) component (eg, using videoconferencing, Web, or mobile technologies to deliver mental health care)
3. The psychotherapeutic intervention targeted a mood disorder.
4. The study targeted (1) an adult population, (2) mental health care professionals (HCPs) or, (3) other persons or organizations involved in implementation of eMH.
5. The study took place in routine mental health care settings.

Textbox 2. Exclusion criteria.

1. Studies were reporting clinical effectiveness data only.
2. The full-text article was not available through Open Access or library loaning services.
3. The full-text article was not available in the English language.

Table 1. Dimensions of reach, effectiveness, adoption, implementation, and maintenance (RE-AIM); their definitions; and its focus.

Dimension	Definitions [16]	Comment
Reach	Participation ratio of patients and their characteristics	
Effectiveness	Impact of the (clinical) intervention on patients' health, quality of life, and economic outcomes	Not addressed in this study
Adoption	Proportion and representativeness of staff and organizations delivering the services	
Implementation	(Clinical) interventions' fidelity and (implementation) costs	Added: deliberate and purposive actions to implement eMH[a] [31]
Maintenance	Extent to which the intervention is and remains to be part of routine care practice	

[a]eMH: electronic mental health interventions, or eMental health.

Results

Study Selection

The searches resulted in 16,718 records. After removing the duplicates, 13,417 unique titles remained and were screened for eligibility against the inclusion and exclusion criteria. In total, 13,159 articles were excluded on the basis of the information in titles and abstracts. A total of 258 articles were retained, and after examining the full-text articles, a total of 48 studies were included in the analysis. Figure 1 provides an overview of the inclusion and exclusion of studies in the different phases of the systematic review.

General Study Characteristics

Table 2 provides an overview of the main characteristics of the studies, including the RE-AIM dimension(s) addressed, target disorder, therapeutic principles, technology applied, guidance modalities, and study design.

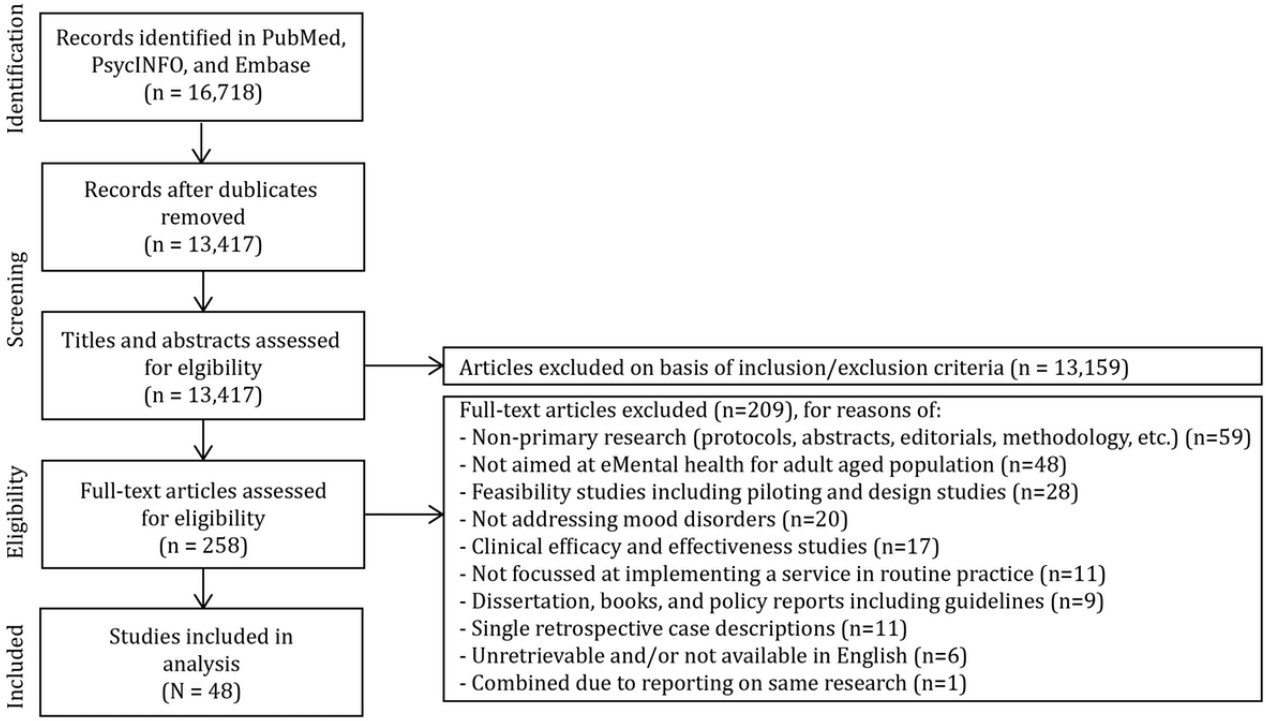
Most studies investigated reach (n=33), followed by adoption (n=19), implementation (n=6), and maintenance (n=4). The specific type of the target disorder was often described in broad terms such as common mental disorders or mood disorders (n=20), or in exemplary disorders such as depression or anxiety (n=17). Most studies (n=39) did not explicitly report the therapeutic principles of the clinical intervention that was implemented. More than half of the studies investigated the provision of mental health services for mood disorders through videoconferencing technologies (n=26), most often by using videoconferencing for support and consultations. The remainder of the studies focused on Internet-based interventions (n=20). Three studies looked at purely self-help interventions (through Web and mobile technologies), and 10 studies did report on a specific eMH intervention but did not report the guidance modality. Eighteen studies specified the eMH intervention and described the guidance modality. The majority (n=44) of the studies were of an observational, that is, descriptive nature. Most of these (n=20) applied mixed-methods (eg, a survey and semistructured interviews), followed by a large proportion (n=16) of studies that applied qualitative methods such as ethnography or consensus-seeking methods using focus-group discussions. Five studies were of an experimental design, applying either quantitative or mixed-methods. More information about the specific studies' aims, designs, settings, participants, and clinical and implementation-related interventions are reported in Multimedia Appendix 2.

Determinants of Practice

In total, 37 specific determinants of practices relevant to implementing eMH in routine care were identified. The 37 determinants were clustered resulting in a taxonomy of six groups: (1) acceptance of eMH by patients and service delivery staff, (2) appropriateness or clinical relevance of eMH, (3) engagement of participants in implementing and delivering eMH, (4) resources for implementing and delivering eMH, (5) work processes in delivering eMH, and (6) leadership in implementing and delivering eMH. Group definitions are provided in Table 3. The spider diagram in Figure 2 shows that the majority of studies reported determinants in the domain reach that were related to acceptance (n=34) and appropriateness (n=23). When categorized under RE-AIM, reach and the domain adoption were studied most often, addressing determinants related to acceptance (n=17), appropriateness (n=11), and engagement (n=10). Least investigated were the domains of implementation and maintenance.

A detailed list of the determinants is included in Table 4, including their definitions, main perspective, RE-AIM dimensions, and references to the source articles. The following subsections detail the determinants for each of the four RE-AIM domains. The perspective from which become apparent are included, differentiating between (1) patients, (2) staff (individuals and groups) involved in delivering mental health services, (3) organizations as the functional and administrative structures aimed to deliver mental health care, and (4) the system perspective as the human and material resources and organizational arrangements on a community level aimed at to preserve, protect, and restore peoples' health [32]. More detailed information, including the related excerpts of texts retrieved from the articles, are in Multimedia Appendix 2.

Figure 1. Information flow through the different phases of the systematic review.



Reach

The domain reach includes determinants of practices that are related to patients' participation in eMH and their characteristics. Of the 33 studies that were categorized under reach, most investigated patients' and mental HCPs perceptions and attitudes of patients and professionals (n=20), or the actual use (n=9) of eMH in a routine care setting. Most studies were of an observational nature (n=31). Two studies used an experimental design for testing interventions aimed at increasing access and use of eMH.

From the perspective of patients, two main groups of factors appeared to be relevant in implementing eMH in routine care: acceptance and appropriateness. Determinants grouped under acceptance concern the perceived and actual feasibility of interacting with eMH. For example, knowledge about the existence of eMH (awareness, n=13) and technological aspects of the treatment (eg, usability and stability, n=10) were most often reported in the included literature.

Determinants categorized under appropriateness refers to the patients' perceived fit, relevance, or compatibility of eMH in addressing his or her mental disorder. Within this group, the professional-patient relationship was reported most often by both care providers and patients to be an important aspect that requires consideration when implementing eMH. For example, the perceived importance of interaction and verbal communication was highlighted by van der Vaart, et al [58], showing that the lack in nonverbal communication in Web-based treatments can pose limits to discussing more difficult issues with patients.

From the perspective of staff, engagement emerged as a group of factors next to the determinants grouped under acceptance and appropriateness. Engagement relates to the sustained and effective involvement of staff in implementing and delivering eMH for mood disorders in routine care. Most notably, engagement seem to be related to the organizing structures, policies, and procedures within an organization (n=4), as well as the availability and stability of the required information and communication technology (ICT; n=4). For example, in a qualitative study on expectations of both patients and health professionals in commencing in Internet-based psychotherapy, Montero-Marin et al [48] noted the importance of standardizing Web-based interventions in an integrated service delivery model.

From the perspective of mental health service providing organizations, resources in terms of available and stability of facilitating infrastructure was mentioned (n=2) as an important determinant. In addition, the modus operandi in service delivery both in terms of primary care processes (eg, referral pathways, n=2) as well as facilitating processes (eg, administrative and ICT support and billing processes, n=1) require consideration when implementing eMH in routine practice. Additionally, leadership in terms of existing cultures, strategies, and priorities emerged from the included articles as a determinant of practice (n=1). Regarding the primary care processes, Buist et al [43] showed that considering eMH as a valid service option can influence actual application. Differences in actual use might be caused by differing levels of interest and experience in the eMH service of the service managers.

At health care system level, there were three aspects reported to be of importance, namely policy-making processes (n=2), the availability of appropriate resources including qualified staff (n=2), and collaboration and cooperation within the system and across disciplines (n=1).

Table 2. Overview of studies categorized per reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) domain; technology applied; target disorder; therapeutic principles; and study design.

Characteristic	Reach (n=33)	Adoption (n=19)	Implementation (n=6)	Maintenance (n=4)	n[a]
Target disorder					
Depressive disorder	8	3	2	—[b]	10
Mood disorders[c]	16	9	—	2	20
Not specified[d]	8	7	4	2	17
Therapeutic principles [e]					
Cognitive behavior therapy	5	3	2	—	8
Other (eg, mindfulness)	1	—	—	—	1
General psychotherapy	27	16	4	4	39
Technology applied					
Internet-based (unguided)	2	—	—	—	2
Internet-based (guided[f])	3	3	1	—	5
Internet-based (minimal guidance)	1	—	—	—	1
Internet-based (therapist guided)	1	—	—	—	1
Internet-based (blended)	1	1	—	—	1
Internet-based (not specified[g])	8	2	1	—	10
Computer-based	1	1	—	—	1
mobile health (unguided)	1	—	—	—	1
Videoconferencing	15	12	4	4	26
Study design					
Experimental—quantitative methods	2	—	—	—	2
Experimental—mixed-methods	—	2	1	—	3
Observational—qualitative methods	10	9	2	1	15
Observational—quantitative methods	6	1	—	1	8
Observational—mixed-methods	15	7	2	2	20

[a]The n in this column are unique references. Some studies were categorized under more than one RE-AIM dimension.

[b]Refers to no studies categorized under that condition.

[c]Mood disorders including depressive disorder and/or in combination with other mental health disorders.

[d]Refers to the studies that described the target disorder in exemplary wordings without becoming specific. The generic wordings related to mood disorders.

[e]Not all studies specifically discussed the target disorder or psychotherapeutic principles of the service as studies focused, for example, on perceptions of the delivery method relevant to implementation and not on the specific treatment itself.

[f]Some form of guidance; guidance modality and intensity was not specified.

[g]Not specified if it was a guided intervention or self-help.

Table 3. Identified groups of determinants of practice and their definitions.

Group	Definition	Determinants
Acceptance	The perception among patients, providers, organizations, and systems that eMH[a] is agreeable, congenial, or satisfactory.	Access to treatment; expectations and preferences; observability and experience; evidence base; convenience; technology; awareness; skills and competences; privacy; clinical cultures; education; costs; policy; health care system structures
Appropriateness	The perceived fit, relevance, or compatibility of eMH for the patient in addressing his or her mental disorder.	Professional-patient interaction; effectiveness; personal need; flexibility; negative effects; safety; patient characteristics
Engagement	Continuing implementing, delivering, and receiving eMH and remain doing so in the context of concrete treatment plans.	Organizational structures and procedures; leadership; staffing and roles; access and reliability of ICT[b]; time; collaboration
Resources	The availability and appropriateness of resources required in implementing and delivering eMH, including human resources, equipment, funding, and other infrastructural aspects.	Personnel; funds; infrastructure
Work processes	The course of action (modus of operandi) in service delivery and all other tasks and responsibilities mental health care service organizations have.	Primary process; facilitating processes
Leadership	Directing and controlling the working processes and organizing activities that enable implementation and delivery of eMH.	Culture; communication; management; strategies and priorities; external relations

[a]eMH: electronic mental health interventions, or eMental health.

[b]ICT: information and communication technology.

Figure 2. Spider diagram of the spread of the number of studies (n=48) categorized under the RE-AIM dimensions and the six main groups of determinants we identified in literature: acceptance, appropriateness, engagement, resources, work processes, and leadership. RE-AIM: reach, effectiveness, adoption, implementation, and maintenance.

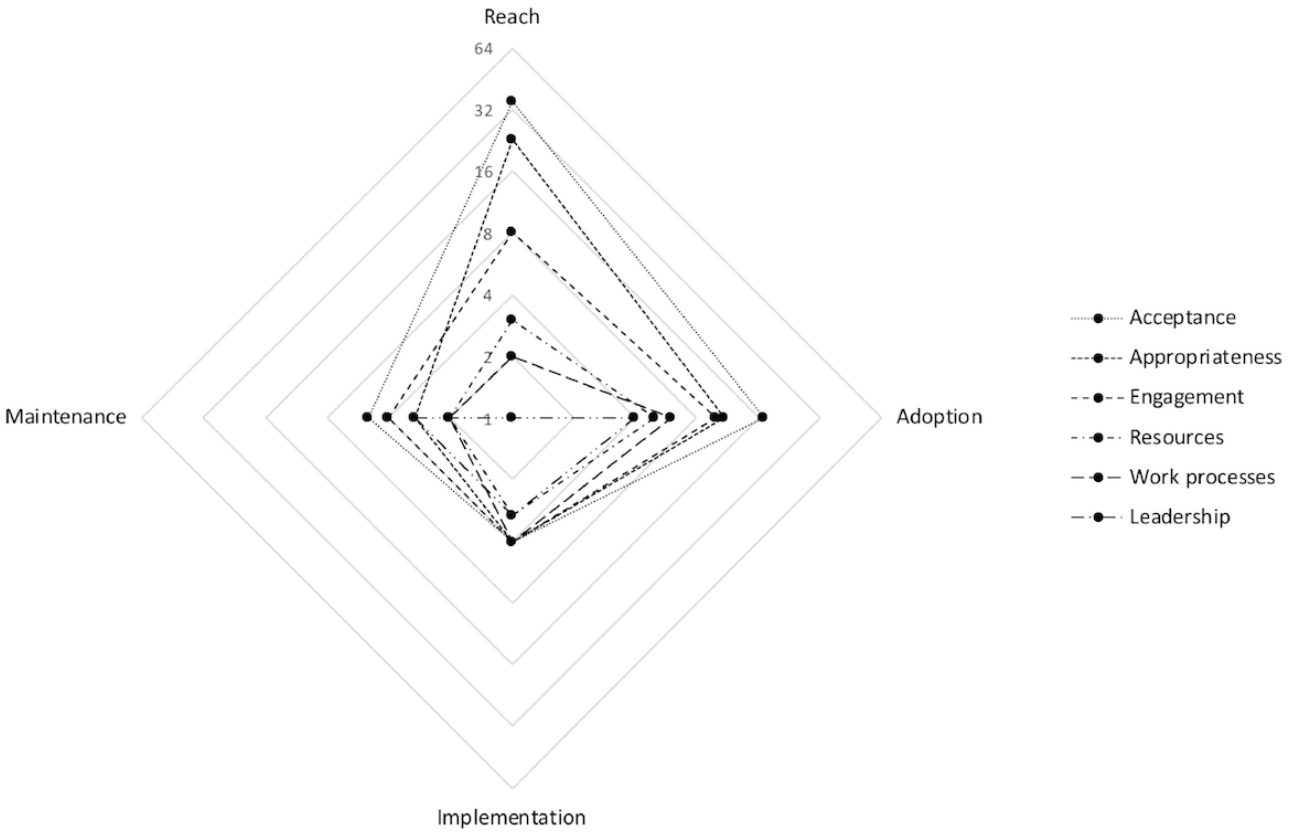


Table 4. Determinants of practice identified in the literature mapped on each reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) dimension, including their proposed definitions, main perspective, and references. Indented are determinants grouped within a group of determinants.

Cluster/Determinant	Perspective	RE-AIM[a]	n	References
Acceptance: the perception among patients and providers that using eMH[b] is agreeable, congenial, or satisfactory				
Access to treatment: the state of accessibility and the act of accessing mental health services.	Patient	R, A	9	[33-41]
Expectations and preferences: individual and collective attitudes, expectations, and preexisting preferences about receiving and providing mental health care in general and eMH specifically.	Patient	R, A, I	12	[34,37,41-50]
Expectations and preferences: individual and collective attitudes, expectations, and preexisting preferences about receiving and providing mental health care in general and eMH specifically.	Staff	R, A, I, M	13	[43,48,51-61]
Observability and experience: the possibility and actual of observations in use (seeing or hearing about the treatment) and experiences of staff in the process of accepting eMH as a valid treatment option.	Staff	R, A, I	7	[43,51-53,59,62,63]
Evidence-base: the scientific evidence of the feasibility and effectiveness of eMH.	Staff	R, A, I	3	[46,52,61]
Convenience: the comfort experienced by patients in accessing and receiving mental health care, including overcoming geographical distances, time constraints, and availability of treatment materials.	Patient	R, A, I, M	14	[33,34,39-42,47,59,60,62,64-67]
Technology: the technical aspects of eMH, including availability of and familiarity with ICT, complexity, usability, and working procedures.	Patient	R, A, M	11	[34,35,37,42,48,49,51,54,55,66,68]
Convenience: the comfort experienced by patients in accessing and receiving mental health care, including overcoming geographical distances, time constraints, and availability of treatment materials.	Staff	R, A, I, M	8	[43,51-57]
Technology: the technical aspects of eMH, including availability of and familiarity with ICT, complexity, usability, and working procedures.	Patient	R, A, M	14	[34,37,44-46,48-51,59,60,69-71]
Technology: the technical aspects of eMH, including availability of and familiarity with ICT, complexity, usability, and working procedures.	Staff	R, A, I, M	8	[43,46,51,53,62,63,71,72]
Skills and competences: specific personal capacities and means required for receiving (patients) or providing (staff) eMH.	Patient	R, A	7	[33,39,48,51,54,59,73]
Skills and competences: specific personal capacities and means required for receiving (patients) or providing (staff) eMH.	Staff	R, A, I, M	5	[48,54,55,61,66]
Privacy: respecting patients' and providers' freedom from unauthorized intrusion, including discretion and confidentiality.	Patient	R, A	4	[35,48,49,73]
Privacy: respecting patients' and providers' freedom from unauthorized intrusion, including discretion and confidentiality.	Staff	R, A	1	[48]
Clinical culture: socially defined and agreed "ways of doing," including norms, habits, and roles.	Staff	R, A, I, M	6	[43,53,60,61,65,67]
Education: training of staff in providing eMH in routine care, including technical and therapeutic training, formal education, credentialing, peer-group learning, and supervision.	Staff	R, A, I	13	[43,46,51-53,58,61-63,67,71,72,74]
Costs: the expenditures made to receive or provide eMH.	Patient	R, A, M	3	[40,66,67]
Appropriateness: the perceived fit, relevance, or compatibility of eMH for the patient in addressing his or her mental disorder				
Professional-patient relationship: the professional interaction between (mental) health care provider and patient, including the aspects such as trust, comfort, and therapeutic interaction.	Patient	R, A, I	18	[33,35,39,40,42,46,48,50,54,55,59,68-70,73,75-77]
Professional-patient relationship: the professional interaction between (mental) health care provider and patient, including the aspects such as trust, comfort, and therapeutic interaction.	Staff	R, A, I	10	[46,52,54,55,57-59,61,71,77]
Effectiveness: patients' mental health care needs, including information needs and specific (mental) health conditions.	Patient	R	3	[33,35,40]

Cluster/Determinant	Perspective	RE-AIM[a]	n	References
Personal need: individual mental health care needs, including information needs and specific (mental) health conditions.	Patients	R, A, M	8	[33,35,42,58,59,65,69,75]
Flexibility: the extent to which care providers can alter or adapt the eMH to the (perceived) needs of the patient or care provider.	Staff	R, A, I, M	6	[46,58,61,67,69,72]
Negative effects: the perceived and actual negative (clinical) outcomes of receiving eMH.	Patient	R, A	3	[33,46,78]
Safety: the physical and mental safety of patients receiving eMH.	Patient	R	3	[35,55,78]
Safety: the physical and mental safety of patients receiving eMH.	Staff	R, A	3	[52,55,59,69]
Patient characteristics: individual patient characteristics, including age, gender, clinical history, social economic status, and clinical symptoms relevant to eMH.	Patient	R, A	7	[37,48,69,70,73,78,79]
Patient characteristics: individual patient characteristics, including age, gender, clinical history, social economic status, and clinical symptoms relevant to eMH.	Staff	R, A, I	4	[43,52,59,61]
Engagement: continuing implementing, delivering, and receiving eMH and remain doing so in the context of concrete treatment plans				
Organizational structures and procedures: the organizing structures, policies, and procedures for delivery of eMH, including standards and clinical guidelines, administrative support, technical support, and other facilitating services.	Staff	R, A, I	8	[43,48,52,55,59,61,62,72]
Leadership: the managerial capacity and operationalization of an organization, including leadership, goal setting, strategies, and supportive measures	Staff	R, A, I	4	[55,58,62,72]
Staffing and roles: the availability of staff necessary in delivering eMH, including qualifications, roles, and responsibilities	Staff	R, A, I, M	7	[35,48,53,59,60,62,72]
Access and reliability of ICT[c]: the availability, stability, and reliability of required technology, including interoperability with other existing technology (eg, electronic patient record).	Staff	R, A, I	10	[43,48,52,53,56,59,62,63,71,72]
Time: the time constraints in providing mental health care in general and eMH specifically.	Staff	I	1	[61]
Collaboration: the possibility and actual act of parties involved in delivery of eMH willingly work together, including sharing of information and expertise.	Staff	R, A, I	3	[61,72,77]
Resources: the availability and appropriateness of resources required in implementing and delivering eMH, including human resources, equipment, funding, and other infrastructural aspects				
Personnel: the availability, capacity, and capabilities of persons necessary in the delivering eMH.	Organization	A, I	2	[62,80]
Funds: the availability and sources of pecuniary resources necessary for delivering eMH and its impact on existing (care) budgets	Organization	A, I, M	3	[66,67,72,80]
Infrastructure: availability, quality, and stability of facilitating structures required for delivering eMH, including offices and equipment.	Organization	R, A, I, M	7	[43,52,53,60,62,67,72]
Processes: the course of action (modus of operandi) in service delivery and all other tasks and responsibilities mental health care service organizations have				
Primary process: a series of actions conducing to the primary objectives of a mental health care organization such as referral processes, establishing diagnosis, and providing treatment.	Organization	R, A, I, M	7	[43,48,53,60,62,67,80]
Facilitating processes: the facilitating activities required for primary processes to deliver mental health care services. Facilitating processes do not directly add value to service delivery but are necessary to provide the services.	Organization	R, A, I, M	7	[43,52,60,62,67,72,80]
Leadership: directing and controlling the working processes and organizing activities that enable implementation and delivery of eMH				
Culture: socially defined and agreed "ways of doing," including norms, habits, and roles relevant to delivering eMH.	Organization	R, A, I, M	2	[43,67]

Cluster/Determinant	Perspective	RE-AIM[a]	n	References
Communication: the mechanisms, means, and contents of disseminating information across the mental health care organization.	Organization	A, I	1	[62]
Management: the managerial capacity and operationalization of an organization delivering eMH, including leadership, goal setting, strategies, and supportive measures.	Organization	A, I, M	3	[60,62,80]
Strategies and priorities: the operationalization of and operationalized objectives into feasible working plans, including vision, mission, priorities, and work plans.	Organization	R, A, I, M	2	[43,67]
External relations: cooperation and collaboration of various external parties involved and/or affected by delivery of eMH, including sharing knowledge.	Organization	A, I, M	3	[65,67]
Health care system: the organization of people, institutions, and resources that deliver mental health care services to meet the health needs of target populations				
Policy: the plans or courses of actions intended to influence and determine decisions and actions relevant to delivery of eMH.	Setting	R, A, I, M	2	[43,60]
Resources: the availability and appropriateness of resources required in delivering eMH, including HCPs[d], ICT and standardization, funding, and other infrastructural aspects.	Setting	R, M	4	[60,65,70,71]
Community acceptance: the shared perception among the community that eMH is agreeable, palatable, or satisfactory.	Setting	M	2	[65,66]
Collaboration: cooperation and collaboration of various parties involved in delivery of eMH, including knowledge sharing.	Setting	R, A, I	1	[43]
Structure: the organizing and organized plan of health services in a given (geographical) context and relevant to the implementation and delivery of eMH.	Setting	M	1	[60]

[a]RE-AIM: reach, effectiveness, adoption, implementation, and maintenance. Please refer to Table 1 for the specific definitions of the RE-AIM framework. The following abbreviations are used in this column: R: reach; A: adoption; I: implementation; and M: maintenance.

[b]eMH: electronic mental health interventions. or eMental health.

[c]ICT: information and communication technology.

[d]HCPs: health care professionals.

Adoption

Adoption mirrors the decision of staff and organizations involved in delivering the eMH services and the extent to which they actually use and deploy the services to their patients. Of the 19 studies that were characterized under adoption, 16 studies investigated adoption-related perceptions and attitudes toward eMH (n=9), or actual use (n=7) of eMH in routine care settings showing adoption. Three studies investigated and tested an adoption-enhancing intervention aimed at increasing the number of staff involved in the delivery of eMH.

Seen from the perspective of staff delivering the services, a frequently mentioned determinant grouped under acceptance was patients' awareness and knowledge of the existence of eMH (n=5). Similarly, the awareness of eMH as a viable treatment option among staff was also identified as a relevant determinant in staff adopting eMH (n=6). Adoption can be facilitated by allowing clinicians to gain experience with eMH and the observability of eMH (n=7). In terms of appropriateness of eMH, the studies indicated that patient-professional relationship is an important determinant to consider when designing interventions aimed at improving adoption rates (n=7). To illustrate, May et al [54] reported on the use of videoconferencing technology in delivering psychotherapy, indicating that the therapist-patient relation should include strategies that appropriately addresses the disorder for which verbal interaction might be essential. Furthermore, the availability and stability of the technical aspects, including infrastructure and interoperability of related ICT (n=8), can be an influential factor in facilitating the engagement of professionals in continuing to offer and apply eMH to their patients.

From the organizations' perspective, the determinants addressing adoption related mostly to the availability of infrastructural resources (n=5) and the primary care process (n=5). Infrastructural resources included the availability, quality, and stability of facilitating structures such as office rooms and ICT equipment. Determinants related to the primary care processes included issues with referral procedures, diagnostic procedures, and therapy guidelines and manuals. For instance, Jameson et al [53] highlighted that clinical policies and procedures for initiating a referral and coordinating between the various partners involved in service delivery are necessary for successful and sustainable use of eMH.

One article reported determinants from a health care system perspective. Buist et al [43] reported on the importance of mechanisms that enable collaboration, sharing of information, and policies supporting better use of these mechanisms.

Implementation

Determinants categorized under implementation relate to the extent to which eMH is used in real-world settings as intended (ie, fidelity of use), implementation costs, or deliberate and purposive actions to implement eMH. Of the 6 studies identified under implementation, 2 investigated an implementation-related intervention focusing on training mental health providers to use eMH in daily practice. The other 4 studies performed a process evaluation (n=1) and investigated use and utilization of eMH (n=3).

The most frequently reported determinants from the perspective of staff were related to acceptance. These concerned raising staffs' awareness about the existence of eMH (n=3) and providing education to staff (n-4) in applying eMH in routine care. Specific determinants included references to technical and therapeutic training, formal education and credentialing, and peer-group learning and supervision. For example, Willhelmsen et al [61] showed the importance of training of general practitioners (GPs) in increasing patients' acceptance of eMH, which might strengthen the perceived credibility of eMH.

Furthermore, from the perspective of staff, engagement was found to be influenced by the availability of support and facilitating services (n=4). For example, Avey et al [72] reported in a qualitative study on implementation processes that coordination and collaboration between the various persons involved in the service delivery should be facilitated effectively and that a dedicated program coordinator was valued highly among the participating hospitals.

From the viewpoint of an organization, the availability of resources such as staffing (n=2), funding (n=2), and infrastructural facilities (n=2) were reported as relevant determinants. In addition, various factors emerged from the literature related to the primary modes operandi (n=3). For example, Reifels et al [80] discussed that successful implementation might depend on the existence or establishment of effective primary processes in the service delivery structures. Similarly, implementation outcomes can be determined by factors facilitating and supporting the primary processes in delivering mental health care services (n=4). Examples include issues with office space, availability of equipment, and administrative support as Adler et al [62] highlighted. Besides the organizational structures and processes, leadership and management (n=3) need to be considered when implementing eMH. This includes scheduling problems, lack of a clear goals, and managerial support to address issues with existing clinical demands.

From the perspective of health care systems, less rich information was found in the included studies. However, Buist et al [43] did report on determinants of practices relating to the availability of policy measures (n=1) and possibilities to collaborate and share knowledge within and across disciplines and settings (n=1).

Maintenance

Under maintenance, determinants were categorized that relate to keeping the eMH as a normal part of routine care practices. All 4 maintenance studies were of a descriptive nature aiming to establish usage and utility figures of videoconferencing-delivered mental health services (n=2), capture end-user perceptions (n=1), or describe potential success factors (n=1) of programs that remained in practice after their implementation phase.

From the patients' viewpoint, the convenience of eMH was seen as an important determinant in maintaining the service in practice (n=4). In an evaluation of patients' perceptions of a routine tele-psychiatry service in central Alberta, Simpson et al [66] highlighted the importance of reducing waiting times and travel time and that this in the long term might outweigh preferences for face-to-face consultations.

From the perspective of mental health staff, the clinical culture in terms of socially defined and agreed ways of doing (n=2), including norms, habits, and roles, are considered to be important in maintaining the services in routine practice. Hailey et al [65] showed that traditional patterns might keep staff from changing their practice, even if the service is in operation for a considerable time.

At the organizational level, various determinants were reported, including availability of funds (n=2) and infrastructure (n=2), the primary modes of operation (n=2), supporting structures and activities (n=2), and leadership and management (n=3). Regarding the latter, Whitten et al [67] showed in a study comparing tele-psychiatry programs that are in routine care for some time that the different business approaches these programs took might have contributed to their success.

From the perspective of the health care system, besides the importance of policy (n=1), community acceptance (n=2), and organizing and organized plans of health services (ie, structure; n=1), the availability and appropriateness of resources required in maintaining eMH in practice were mentioned (n=2).

Discussion

Principal Findings

We developed a taxonomy of 37 determinants of mental health care practices known in the literature as relevant to successfully implement eMH for mood disorders. The determinants of practices clustered in six groups are expressed at (a combination of) patient, staff, organization, and setting levels and address one or more RE-AIM dimensions (see Table 3). Three determinants were reported most frequently: (1) acceptance of eMH in terms of the expectations and preferences of patients and professionals; (2) appropriateness of eMH in addressing the mental health disorder, and specifically, the therapeutic interactions mediated by eMH; and (3) the availability, stability, and reliability of required technologies, including successful interoperability with other existing technologies.

Strengths and Limitations

The search strategy in this review aimed to capture as much relevant scientific literature as possible. For this reason, broadly defined search terms were used. By applying a standardized integrative approach (RE-AIM in combination with qualitative thematic analysis), we were able to search for commonalities in the concepts and underlying study characteristics while

preserving the heterogeneous nature of the data retrieved from the studies. However, and although we searched three important bibliographic databases, it is likely that important work from social scientist generalist databases was excluded.

The evidence supporting the determinants identified in this study is mostly of a descriptive nature obtained from observational studies. Due to the limited empirical evidence verifying causality of specific determinants of practices and implementation successes, the findings of this work should be interpreted with care. In an attempt to substantiate this, we conducted a quality appraisal analysis. We included a wide variety of studies ranging from observational case studies using qualitative ethnographic methods to randomized controlled trials quantitatively testing specific implementation interventions. However, because of the heterogeneity of these studies and the absence of validated instruments to assess quality, it proved impossible to come to sensible conclusions about the quality of the evidence. An elaborate approach as done by Greenhalgh et al [81,82], meta-narrative approach in developing a model of diffusion of innovations by including the research traditions from which the included studies emerged might be a fruitful approach but was beyond the scope of this review.

Comparison With Other Work

Drozd et al [83] conducted a scoping review of 164 publications (including gray literature). The investigators applied the Active Implementation Framework (AIF) to identify implementation-related factors [84]. The AIF describes the components of an implementation practice, including aspects of staff and patient selection, training, supervision, performance assessment, decision support, administrative support, system intervention, and leadership. Drozd and colleagues found in their review factors similar to those that emerged from our analysis of the literature, including certain competences of patients and professionals and organizational drivers. Regarding the latter, the authors did not find empirical support for determinants such as leadership. The authors conclude that not finding empirical evidence for organizational drivers merely indicates a gap in the implementation-related research. Despite the low numbers (n=4), our study shows that leadership indeed is found in empirical research to be a relevant determinant in implementing eMH. This difference can perhaps be explained by the methodological choices that were made for reviewing the literature. Where Drozd and colleagues choose to follow a top-down approach (the AIF), our review followed a quantitative inductive process in identifying the topics related to implementing eMH that emerged from the included articles. Furthermore, the search strategy and data sources in light of their quality and comparability most likely influenced the results.

Similarly, Ross et al [85] updated a systematic review (of reviews, n=44) and looked at qualitative accounts of factors that influence implementation of eHealth interventions in a broader context, including somatic care. Factors identified by these researchers are comparable with the ones presented here, including complexity factors and adaptability, adding to the users' perception of the acceptability of eHealth interventions. However, it should be noted that the concept of eHealth used by the authors included a variety of ICT-mediated health care services in four main categories: management systems, communication systems, clinical decision support systems, and information systems. In this respect, the authors did not address eHealth to contain purposed intrinsic therapeutic content aimed at improving health conditions as we did. This raises the question of whether generic eHealth both in terms of care setting (health care in general vs mental health care for mood disorders) and purpose (information sharing, support systems vs therapeutic interventions focusing on care and cure) give rise to (partial) different taxonomies of determinants of practice.

Recommendations for Implementation Practice

Implementation practitioners might benefit in implementing eMH in routine care practices by taking into account the barriers and facilitators that are identified in this systematic review. Specific implementation activities can be designed and applied on the basis of these factors to achieve better implementation outcomes.

One of the most frequently mentioned barriers emerging from the literature concerns the expectations and preferences of patients and professionals about eMH services. Negative individual and collective attitudes, expectations, and existing preferences can prohibit successful implementation of eMH. Ebert et al [45] showed that providing information to patients can enhance their acceptance of eMH. In addressing expectations and preferences of mental health care staff, it is advisable to include service delivery staff in the early stages of decision making and strategy development to increase acceptance and inform concrete implementation activities aimed at the concerns of the end users.

A second important determinant of practice is related to the appropriateness of the eMH intervention in addressing the mental disorder. Within this cluster, the nature and quality of the interactions between the professional and the patient is thought to be highly influential in obtaining favorable clinical outcomes. This includes aspects such as building trust, comfort, and the quality of the therapeutic interactions. eMH interventions delivered through ICT are thought to influence these interactions negatively. Hadjistavropoulos et al [74,86] showed that specific training can change knowledge about, attitudes toward and confidence in delivering eMH. Careful development of training programs and (continuous) guidance of HCPs in applying the eMH intervention might lower barriers with perceived patient-professional interaction through eMH. In addition, innovative models of for integrating therapist support in eMH services might address issues with engagement and the patient-professional relationship [87].

Third, the availability and reliability of required technologies is considered an important determinant for mental HCPs to remain engaged in providing eMH to their patients in routine care. This includes the interoperability with other existing technologies such as electronic health records. It seems important to ensure that the user perspective, including that of the service delivery staff, is taken into account and that the eMH service seamlessly fits within existing technologies and work processes. Here, single-sign on technology and intelligent portal designs might be fruitful avenues to explore.

Future Research

To increase impact and added value of future research on implementation of eMH for mood disorders in routine practice, the following two topics should be taken into account: (1) identifying organization and system-level determinants and (2) empirical evidence on the effects of implementation strategies in addressing specific barriers and exploiting facilitating factors.

Until now, most implementation research was focused on practitioner and patient-level determinants. Service delivery takes place in a social context at micro (individuals, teams), mesa (organizations), and macro (systems) level. Knowledge about how these different contexts influence implementation efforts can facilitate further scaling up of eMH. Research on systems level might focus on the possible policy measures that enhance implementation of eMH at service deliverer level. For example, what resources at organization or health care system-level are required to deliver eMH? This can include processes of task shifting, curricula and certification of mental health staff, ICT and standardization, funding, and other infrastructural aspects. Or, what role does community acceptance have in implementing eMH in routine practice, and how can the shared perception of community as a whole be changed? Detailed knowledge of organization and setting level factors might be more likely to come from a combination of clinical psychology, social sciences, organizational psychology, and policy research. Here, the MasterMind project [88] might provide inspiration for further research on determinants of practices of eMH.

Furthermore, the field would benefit from well-performed experiments designed to test implementation interventions addressing specific determinants of practices. As shown in this review, there is limited evidence on the causal relationship between determinants and implementation outcomes. Well-designed experiments studying the effects of to the local context–tailored implementation strategies might contribute to the understanding of mechanisms of implementation processes. Do, for example, educational meetings (and in what formats) contribute in raising awareness among GPs about which patient might benefit most from which eMH intervention? Or can championing an Internet-based cognitive behavioral therapy service increase the adoption of other therapists in mental health care team while maintaining the flexibility therapists need to adapt parts of the treatments to the patients' needs? Fusing implementation practices and research into natural implementation laboratories might be a valuable approach to engage in comparative effectiveness studies of implementation interventions. In these types of studies, experimental implementation interventions can be compared with usual implementation activities for their effects on the degree of normalization of a clinical intervention in real-world service delivery settings. The ImpleMentAll project (project position paper and study protocol forthcoming) might be a good example of this approach. This type of future research might lead to a shift from practice-based and evidence-informed to evidence-based implementation of clinically effective and relevant eMH interventions.

Conclusions

This study systematically reviewed scientific literature and developed an evidence-informed taxonomy of six clusters of 37 determinants of practices we found in literature: (1) acceptance of eMH interventions among patients, providers, organizations, and health care settings; (2) appropriateness of eMH interventions in addressing the disorder; (3) engagement in implementing, delivering, and receiving eMH interventions and remain doing so; (4) the availability and appropriateness of resources for implementing and delivering eMH interventions; (5) processes relating to the modus of operandi in delivering eMH interventions; and (6) leadership directing and controlling processes and organizing activities enabling implementation and delivery of eMH interventions. On the basis of these determinants of practices, implementation-enhancing interventions can be designed, tested, and applied to achieve better implementation outcomes. Suggestions for implementation practice are discussed, such as in-depth training of professionals, careful selection, and continuous development of the eMH technology used. In addition, focal points for future research are provided, including implementation-related factors on organization and system level, as well as (quasi) experimental research to test the effectiveness of specific implementation interventions in attaining better implementation outcomes for eMH service provision.

Acknowledgments

The authors would like to thank Dr C. Planting of the VU Medical Centre/GGZ InGeest for providing expert advice and help in operationalizing the search strategy for this systematic review. Furthermore, the authors would like to express gratitude to the MasterMind and the ImpleMentAll project for supporting this work. The MasterMind project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the Competitiveness and Innovation Framework Programme (CIP) by the European Community (Grant Agreement number: 621000). The ImpleMentAll project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733025. These funding bodies had no influence in the design, execution, analysis, or interpretation of the results of this study.

Authors' Contributions

HR, JS, and CV originated the idea for conducting this systematic review. CV, MM, AK, and HR designed the study protocol. CV, MM, and LB executed the search strategy and extracted the data. CV authored the study. All authors provided feedback and suggestions for this manuscript and read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Benchmark definitions, definitions of RE-AIM, and the actual search strings that were applied in the search and analysis strategy.

[PDF File (Adobe PDF File), 85KB - mental_v5i1e20_app1.pdf]

Multimedia Appendix 2

Data file with two sheets. Sheet 1 contains the aims, designs, settings, participants, and clinical and implementation-related interventions of the studies that were included in this review. Sheet 2 lists the determinants and supporting excerpts of texts retrieved from the articles that were included in the thematic analysis.

[XLSX File (Microsoft Excel File), 104KB - mental_v5i1e20_app2.xlsx]

References

1. Lindefors N, Andersson G. In: Lindefors N, Andersson G, editors. Guided Internet-Based Treatments in Psychiatry. Cham: Springer; 2016.
2. Andersson G, Cuijpers P, Carlbring P, Riper H, Hedman E. Guided Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis. World Psychiatry 2014 Oct;13(3):288-295 [FREE Full text] [doi: 10.1002/wps.20151] [Medline: 25273302]
3. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clin Psychol Rev 2012 Jun;32(4):329-342. [doi: 10.1016/j.cpr.2012.02.004] [Medline: 22466510]
4. Riper H, Andersson G, Christensen H, Cuijpers P, Lange A, Eysenbach G. Theme issue on e-mental health: a growing field in internet research. J Med Internet Res 2010;12(5):e74 [FREE Full text] [doi: 10.2196/jmir.1713] [Medline: 21169177]
5. May CR, Johnson M, Finch T. Implementation, context and complexity. Implement Sci 2016 Dec 19;11(1):141 [FREE Full text] [doi: 10.1186/s13012-016-0506-3] [Medline: 27756414]
6. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. Adm Policy Ment Health 2009 Jan;36(1):24-34 [FREE Full text] [doi: 10.1007/s10488-008-0197-4] [Medline: 19104929]
7. Topooco N, Riper H, Araya R, Berking M, Brunn M, Chevreul K, et al. Attitudes towards digital treatment for depression: a European stakeholder survey. Internet Interv 2017 Jun;8:1-9. [doi: 10.1016/j.invent.2017.01.001]
8. Wensing M, Oxman A, Baker R, Godycki-Cwirko M, Flottorp S, Szecsenyi J, et al. Tailored Implementation For Chronic Diseases (TICD): a project protocol. Implement Sci 2011 Sep 07;6:103 [FREE Full text] [doi: 10.1186/1748-5908-6-103] [Medline: 21899753]
9. Krause J, Agarwal S, Bodicoat DH, Ring A, Shepherd D, Rogers S, et al. Evaluation of a tailored intervention to improve management of overweight and obesity in primary care: study protocol of a cluster randomised controlled trial. Trials 2014 Mar 19;15:82 [FREE Full text] [doi: 10.1186/1745-6215-15-82] [Medline: 24641767]
10. Aarons GA, Sommerfeld DH. Leadership, innovation climate, and attitudes toward evidence-based practice during a statewide implementation. J Am Acad Child Adolesc Psychiatry 2012 Apr;51(4):423-431 [FREE Full text] [doi: 10.1016/j.jaac.2012.01.018] [Medline: 22449648]
11. Fleuren MA, Paulussen TG, Van Dommelen DP, Van Buuren BS. Towards a measurement instrument for determinants of innovations. Int J Qual Health Care 2014 Oct;26(5):501-510 [FREE Full text] [doi: 10.1093/intqhc/mzu060] [Medline: 24951511]
12. Wensing M, Huntink E, van Lieshout LJ, Godycki-Cwirko M, Kowalczyk A, Jäger C, et al. Tailored implementation of evidence-based practice for patients with chronic diseases. PLoS One 2014;9(7):e101981 [FREE Full text] [doi: 10.1371/journal.pone.0101981] [Medline: 25003371]
13. Wozney L, Newton AS, Gehring ND, Bennett K, Huguet A, Hartling L, et al. Implementation of eMental Health care: viewpoints from key informants from organizations and agencies with eHealth mandates. BMC Med Inform Decis Mak 2017 Jun 2;17(1):1. [doi: 10.1186/s12911-017-0474-9]
14. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. Am J Prev Med 2012 Sep;43(3):337-350 [FREE Full text] [doi: 10.1016/j.amepre.2012.05.024] [Medline: 22898128]
15. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015;10:53 [FREE Full text] [doi: 10.1186/s13012-015-0242-0] [Medline: 25895742]
16. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999 Sep;89(9):1322-1327. [doi: 10.2105/AJPH.89.9.1322] [Medline: 10474547]

17. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. Health Educ Res 2006 Oct;21(5):688-694 [FREE Full text] [doi: 10.1093/her/cyl081] [Medline: 16945984]
18. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. Am J Public Health 2013 Jun;103(6):e38-e46. [doi: 10.2105/AJPH.2013.301299] [Medline: 23597377]
19. Belza B, Toobert DJ, Glasgow RE. RE-AIM for Program Planning: Overview and Applications. In: National Council on Aging. Washington: National Council on Aging; 2014:1-14.
20. Jilcott S, Ammerman A, Sommers J, Glasgow RE. Applying the RE-AIM framework to assess the public health impact of policy change. Ann Behav Med 2007 Oct;34(2):105-114. [doi: 10.1080/08836610701564055] [Medline: 17927550]
21. Kleiboer A, Smit J, Bosmans J, Ruwaard J, Andersson G, Topooco N, et al. European COMPARative Effectiveness research on blended Depression treatment versus treatment-as-usual (E-COMPARED): study protocol for a randomized controlled, non-inferiority trial in eight European countries. Trials 2016 Dec 03;17(1):387 [FREE Full text] [doi: 10.1186/s13063-016-1511-1] [Medline: 27488181]
22. Krist AH, Phillips SM, Sabo RT, Balasubramanian BA, Heurtin-Roberts S, Ory MG, MOHR Study Group. Adoption, reach, implementation, and maintenance of a behavioral and mental health assessment in primary care. Ann Fam Med 2014;12(6):525-533 [FREE Full text] [doi: 10.1370/afm.1710] [Medline: 25384814]
23. Saw A, Kim J, Lim J, Powell C, Tong EK. Smoking cessation counseling for Asian immigrants with serious mental illness: using RE-AIM to understand challenges and lessons learned in primary care-behavioral health integration. Health Promot Pract 2013 Sep;14(5 Suppl):70S-79S [FREE Full text] [doi: 10.1177/1524839913483141] [Medline: 23667056]
24. Young J, Gilwee J, Holman M, Messier R, Kelly M, Kessler R. Mental health, substance abuse, and health behavior intervention as part of the patient-centered medical home: a case study. Behav Med Pract Policy Res 2012 Jun 20;2(3):345-354. [doi: 10.1007/s13142-012-0148-1]
25. Arora PG, Connors EH, Blizzard A, Coble K, Gloff N, Pruitt D. Dissemination and implementation science in program evaluation: A telemental health clinical consultation case example. Eval Program Plann 2017 Dec;60:56-63. [doi: 10.1016/j.evalprogplan.2016.09.003] [Medline: 27685163]
26. Mol M, Dozeman E, van Schaik DJ, Vis CP, Riper H, Smit JH. The therapist's role in the implementation of internet-based cognitive behavioural therapy for patients with depression: study protocol. BMC Psychiatry 2016 Sep 30;16(1):338 [FREE Full text] [doi: 10.1186/s12888-016-1045-9] [Medline: 27716108]
27. Green S, Higgins J. Preparing a Cochrane review. In: Cochrane Handbook for Systematic Reviews of Interventions. Chichester, UK: John Wiley & Sons, Ltd; Sep 26, 2008:11-30.
28. Arai L, Britten N, Popay J, Roberts H, Petticrew M, Rodgers M, et al. Testing methodological developments in the conduct of narrative synthesis: a demonstration review of research on the implementation of smoke alarm interventions. Evid Policy J Res Debate Pract 2007 Aug 01;3(3):361-383. [doi: 10.1332/174426407781738029]
29. Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy-making in the health field. J Health Serv Res Policy 2005 Jul;10 Suppl 1:6-20. [doi: 10.1258/1355819054308576] [Medline: 16053580]
30. Popay J, Roberts H, Snowden A, Petticrew M, Arai L, Rodgers M, et al. Lancaster.ac.uk. 2006 Apr. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A Product from the ESRC Methods Programme URL: http://www.lancaster.ac.uk/shm/research/nssr/research/dissemination/publications/NS_Synthesis_Guidance_v1.pdf [accessed 2018-03-09] [WebCite Cache ID 6xmbUdrz8]
31. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar;38(2):65-76 [FREE Full text] [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
32. Porta M. A Dictionary of Epidemiology, Sixth edition. New York: Oxford University Press; 2014.
33. Beattie A, Shaw A, Kaur S, Kessler D. Primary-care patients' expectations and experiences of online cognitive behavioural therapy for depression: a qualitative study. Health Expect 2009 Mar;12(1):45-59 Included in the review [FREE Full text] [doi: 10.1111/j.1369-7625.2008.00531.x] [Medline: 19250152]
34. De Las Cuevas C, Artiles J, De La Fuente J, Serrano P. Telepsychiatry in the Canary Islands: user acceptance and satisfaction. J Telemed Telecare 2003;9(4):221-224 Included in the review. [doi: 10.1258/135763303322225553] [Medline: 12952693]
35. Gibson KL, Coulson H, Miles R, Kakekakekung C, Daniels E, O'Donnell S. Conversations on telemental health: listening to remote and rural First Nations communities. Rural Remote Health 2011;11(2):1656 Included in the review [FREE Full text] [Medline: 21553998]
36. Graham C, Franses A, Kenwright M, Marks I. Psychotherapy by computer: a postal survey of responders to a teletext article. Psychiatr bull 2018 Jan 2;24(09):331-332 Included in the review. [doi: 10.1192/pb.24.9.331]
37. Handley TE, Kay-Lambkin FJ, Inder KJ, Attia JR, Lewin TJ, Kelly BJ. Feasibility of internet-delivered mental health treatments for rural populations. Soc Psychiatry Psychiatr Epidemiol 2014 Feb;49(2):275-282 Included in the review. [doi: 10.1007/s00127-013-0708-9] [Medline: 23689825]

38. Hilty DM, Nesbitt TS, Kuenneth CA, Cruz GM, Hales RE. Rural versus suburban primary care needs, utilization, and satisfaction with telepsychiatric consultation. J Rural Health 2007;23(2):163-165 Included in the review. [doi: 10.1111/j.1748-0361.2007.00084.x] [Medline: 17397373]
39. Mucic D. International telepsychiatry: a study of patient acceptability. J Telemed Telecare 2008 Jul;14(5):241-243 Included in the review. [doi: 10.1258/jtt.2008.080301]
40. Musiat P, Goldstone P, Tarrier N. Understanding the acceptability of e-mental health--attitudes and expectations towards computerised self-help treatments for mental health problems. BMC Psychiatry 2014 Apr 11;14(1):109 Included in the review [FREE Full text] [doi: 10.1186/1471-244X-14-109] [Medline: 24725765]
41. Saurman E, Lyle D, Perkins D, Roberts R. Successful provision of emergency mental health care to rural and remote New South Wales: an evaluation of the Mental Health Emergency Care-Rural Access Program. Aust Health Rev 2014 Feb;38(1):58-64 Included in the review. [doi: 10.1071/AH13050] [Medline: 24331157]
42. Boggs JM, Beck A, Felder JN, Dimidjian S, Metcalf CA, Segal ZV. Web-based intervention in mindfulness meditation for reducing residual depressive symptoms and relapse prophylaxis: a qualitative study. J Med Internet Res 2014 Mar 24;16(3):e87 Included in the review [FREE Full text] [doi: 10.2196/jmir.3129] [Medline: 24662625]
43. Buist A, Coman G, Silvas A, Burrows G. An evaluation of the telepsychiatry programme in Victoria, Australia. J Telemed Telecare 2000;6(4):216-221 Included in the review. [doi: 10.1258/1357633001935383] [Medline: 11027122]
44. Casey LM, Joy A, Clough BA. The impact of information on attitudes toward e-mental health services. Cyberpsychol Behav Soc Netw 2013 Aug;16(8):593-598 Included in the review. [doi: 10.1089/cyber.2012.0515] [Medline: 23679567]
45. Ebert DD, Berking M, Cuijpers P, Lehr D, Pörtner M, Baumeister H. Increasing the acceptance of internet-based mental health interventions in primary care patients with depressive symptoms. A randomized controlled trial. J Affect Disord 2015 May 01;176:9-17 Included in the review. [doi: 10.1016/j.jad.2015.01.056] [Medline: 25682378]
46. Jones RB, Ashurst EJ. Online anonymous discussion between service users and health professionals to ascertain stakeholder concerns in using e-health services in mental health. Health Informatics J 2013 Dec;19(4):281-299 Included in the review. [doi: 10.1177/1460458212474908] [Medline: 24255052]
47. Mohr DC, Siddique J, Ho J, Duffecy J, Jin L, Fokuo JK. Interest in behavioral and psychological treatments delivered face-to-face, by telephone, and by internet. Ann Behav Med 2010 Aug;40(1):89-98 Included in the review [FREE Full text] [doi: 10.1007/s12160-010-9203-7] [Medline: 20652466]
48. Montero-Marín J, Prado-Abril J, Botella C, Mayoral-Cleries F, Baños R, Herrera-Mercadal P, et al. Expectations among patients and health professionals regarding Web-based interventions for depression in primary care: a qualitative study. J Med Internet Res 2015 Mar 10;17(3):e67 Included in the review [FREE Full text] [doi: 10.2196/jmir.3985] [Medline: 25757358]
49. Proudfoot J, Parker G, Hadzi PD, Manicavasagar V, Adler E, Whitton A. Community attitudes to the appropriation of mobile phones for monitoring and managing depression, anxiety, and stress. J Med Internet Res 2010 Dec 19;12(5):e64 Included in the review [FREE Full text] [doi: 10.2196/jmir.1475] [Medline: 21169174]
50. Werner P. Willingness to use telemedicine for psychiatric care. Telemed J E Health 2004;10(3):286-293 Included in the review. [doi: 10.1089/tmj.2004.10.286] [Medline: 15650523]
51. Carper MM, McHugh RK, Barlow DH. The dissemination of computer-based psychological treatment: a preliminary analysis of patient and clinician perceptions. Adm Policy Ment Health 2011 Oct 15;40(2):87-95 Included in the review. [doi: 10.1007/s10488-011-0377-5]
52. Gibson K, O'Donnell S, Coulson H, Kakepetum-Schultz T. Mental health professionals' perspectives of telemental health with remote and rural First Nations communities. J Telemed Telecare 2011;17(5):263-267 Included in the review. [doi: 10.1258/jtt.2011.101011] [Medline: 21824967]
53. Jameson JP, Farmer MS, Head KJ, Fortney J, Teal CR. VA community mental health service providers' utilization of and attitudes toward telemental health care: the gatekeeper's perspective. J Rural Health 2011;27(4):425-432 Included in the review. [doi: 10.1111/j.1748-0361.2011.00364.x] [Medline: 21967387]
54. May CR, Ellis NT, Atkinson T, Gask L, Mair F, Smith C. Psychiatry by videophone: a trial service in north west England. Stud Health Technol Inform 1999;68:207-210 Included in the review. [Medline: 10724871]
55. May C, Gask L, Atkinson T, Ellis N, Mair F, Esmail A. Resisting and promoting new technologies in clinical practice: the case of telepsychiatry. Soc Sci Med 2001 Jun;52(12):1889-1901 Included in the review. [doi: 10.1016/s0277-9536(00)00305-1]
56. Monthuy-Blanc J, Bouchard S, Maïano C, Séguin M. Factors influencing mental health providers' intention to use telepsychotherapy in First Nations communities. Transcult Psychiatry 2013 Apr;50(2):323-343 Included in the review. [doi: 10.1177/1363461513487665] [Medline: 23666941]
57. Sinclair C, Holloway K, Riley G, Auret K. Online mental health resources in rural Australia: clinician perceptions of acceptability. J Med Internet Res 2013 Sep 05;15(9):e193 Included in the review [FREE Full text] [doi: 10.2196/jmir.2772] [Medline: 24007949]
58. van der Vaart R, Witting M, Riper H, Kooistra L, Bohlmeijer ET, van Gemert-Pijnen LJ. Blending online therapy into regular face-to-face therapy for depression: content, ratio and preconditions according to patients and therapists using a

Delphi study. BMC Psychiatry 2014 Dec 14;14(1):355 Included in the review [FREE Full text] [doi: 10.1186/s12888-014-0355-z] [Medline: 25496393]
59. Whitten P, Kuwahara E. A multi-phase telepsychiatry programme in Michigan: organizational factors affecting utilization and user perceptions. J Telemed Telecare 2004;10(5):254-261 Included in the review. [doi: 10.1258/1357633042026378] [Medline: 15494082]
60. Ohinmaa A, Roine R, Hailey D, Kuusimäki ML, Winblad I. The use of videoconferencing for mental health services in Finland. J Telemed Telecare 2008;14(5):266-270 Included in the review. [doi: 10.1258/jtt.2008.071212] [Medline: 18633003]
61. Wilhelmsen M, Høifødt RS, Kolstrup N, Waterloo K, Eisemann M, Chenhall R, et al. Norwegian general practitioners' perspectives on implementation of a guided web-based cognitive behavioral therapy for depression: a qualitative study. J Med Internet Res 2014 Sep 10;16(9):e208 Included in the review [FREE Full text] [doi: 10.2196/jmir.3556] [Medline: 25208886]
62. Adler G, Pritchett LR, Kauth MR, Nadorff D. A pilot project to improve access to telepsychotherapy at rural clinics. Telemed J E Health 2014 Jan;20(1):83-85 Included in the review [FREE Full text] [doi: 10.1089/tmj.2013.0085] [Medline: 24168721]
63. Austen S, McGrath M. Telemental health technology in deaf and general mental-health services: access and use. Am Ann Deaf 2006;151(3):311-317 Included in the review. [doi: 10.1353/aad.2006.0033]
64. Casey LM, Wright MA, Clough BA. Comparison of perceived barriers and treatment preferences associated with internet-based and face-to-face psychological treatment of depression. Int J Cyber Behav Psychol Learn 2014 Oct;4(4):16-22 Included in the review. [doi: 10.4018/ijcbpl.2014100102]
65. Hailey D, Ohinmaa A, Roine R, Bulger T. Uptake of telemental health services in Alberta: a success, but not in all regions. J Telemed Telecare 2016 Dec 02;13(3_suppl):42-44 Included in the review. [doi: 10.1258/135763307783247329]
66. Simpson J, Doze S, Urness D, Hailey D, Jacobs P. Telepsychiatry as a routine service--the perspective of the patient. J Telemed Telecare 2001;7(3):155-160 Included in the review. [doi: 10.1258/1357633011936318] [Medline: 11346475]
67. Whitten P, Do C, Kingsley C. An analysis of telepsychiatry programs from an organizational perspective. Cyberpsychol Behav 2000 Dec;3(6):911-916 Included in the review. [doi: 10.1089/109493100452165]
68. Greenwood J, Chamberlain C, Parker G. Evaluation of a rural telepsychiatry service. Australas Psychiatry 2004 Sep;12(3):268-272 Included in the review. [doi: 10.1080/j.1039-8562.2004.02097.x] [Medline: 15715789]
69. Morrison C, Walker G, Ruggeri K, Hughes JM. An implementation pilot of the MindBalance web-based intervention for depression in three IAPT services. tCBT 2014 Nov 14;7:e15 Included in the review. [doi: 10.1017/S1754470X14000221]
70. Rowe N, Gibson S, Morley S, Krupinski EA. Ten-year experience of a private nonprofit telepsychiatry service. Telemed J E Health 2008 Dec;14(10):1078-1086 Included in the review. [doi: 10.1089/tmj.2008.0037] [Medline: 19119830]
71. Simpson J, Doze S, Urness D, Hailey D, Jacobs P. Evaluation of a routine telepsychiatry service. J Telemed Telecare 2001;7(2):90-98 Included in the review. [doi: 10.1258/1357633011936219] [Medline: 11331046]
72. Avey JP, Hobbs RL. Dial in: fostering the use of telebehavioral health services in frontier Alaska. Psychol Serv 2013 Aug;10(3):289-297 Included in the review. [doi: 10.1037/a0028231] [Medline: 22924798]
73. Rohland BM, Saleh SS, Rohrer JE, Romitti PA. Acceptability of telepsychiatry to a rural population. Psychiatr Serv 2000 May;51(5):672-674 Included in the review. [doi: 10.1176/appi.ps.51.5.672] [Medline: 10783191]
74. Hadjistavropoulos HD, Thompson MJ, Klein B, Austin DW. Dissemination of therapist-assisted internet cognitive behaviour therapy: development and open pilot study of a workshop. Cogn Behav Ther 2012;41(3):230-240 Included in the review. [doi: 10.1080/16506073.2011.645550] [Medline: 22428582]
75. Callahan EJ, Hilty DM, Nesbitt TS. Patient satisfaction with telemedicine consultation in primary care: comparison of ratings of medical and mental health applications. Telemed J 1998;4(4):363-369 Included in the review. [doi: 10.1089/tmj.1.1998.4.363] [Medline: 10220477]
76. Fortney JC, Pyne JM, Mouden SB, Mittal D, Hudson TJ, Schroeder GW, et al. Practice-based versus telemedicine-based collaborative care for depression in rural federally qualified health centers: a pragmatic randomized comparative effectiveness trial. Am J Psychiatry 2013 Apr;170(4):414-425 Included in the review [FREE Full text] [doi: 10.1176/appi.ajp.2012.12050696] [Medline: 23429924]
77. Swinton JJ, Robinson WD, Bischoff RJ. Telehealth and rural depression: physician and patient perspectives. Fam Syst Health 2009 Jun;27(2):172-182 Included in the review. [doi: 10.1037/a0016014] [Medline: 19630458]
78. DeAndrea DC. Testing the proclaimed affordances of online support groups in a nationally representative sample of adults seeking mental health assistance. J Health Commun 2015;20(2):147-156 Included in the review. [doi: 10.1080/10810730.2014.914606] [Medline: 25116383]
79. Titov N, Andrews G, Kemp A, Robinson E. Characteristics of adults with anxiety or depression treated at an internet clinic: comparison with a national survey and an outpatient clinic. PLoS One 2010 May 28;5(5):e10885 Included in the review [FREE Full text] [doi: 10.1371/journal.pone.0010885] [Medline: 20526371]
80. Reifels L, Bassilios B, King KE, Fletcher JR, Blashki G, Pirkis JE. Innovations in primary mental healthcare. Aust Health Rev 2013 Jun;37(3):312-317 Included in the review. [doi: 10.1071/AH12203] [Medline: 23601705]
81. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q 2004;82(4):581-629 [FREE Full text] [doi: 10.1111/j.0887-378X.2004.00325.x] [Medline: 15595944]

82. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O, Peacock R. Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review. Soc Sci Med 2005 Jul;61(2):417-430. [doi: 10.1016/j.socscimed.2004.12.001] [Medline: 15893056]
83. Drozd F, Vaskinn L, Bergsund HB, Haga SM, Slinning K, Bjørkli CA. The implementation of internet interventions for depression: a scoping review. J Med Internet Res 2016 Sep 08;18(9):e236 [FREE Full text] [doi: 10.2196/jmir.5670] [Medline: 27608548]
84. Fixsen DL, Naoom SF, Blase KA, Friedman RM, Wallace F. Implementation Research: A Synthesis of the Literature. Tampa, Florida, USA: National Implementation Research Network, FMHI Publication #231; 2005:1-119.
85. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci 2016 Dec 26;11(1):146 [FREE Full text] [doi: 10.1186/s13012-016-0510-7] [Medline: 27782832]
86. Hadjistavropoulos HD, Pugh NE, Nugent MM, Hesser H, Andersson G, Ivanov M, et al. Therapist-assisted internet-delivered cognitive behavior therapy for depression and anxiety: translating evidence into clinical practice. J Anxiety Disord 2014 Dec;28(8):884-893 [FREE Full text] [doi: 10.1016/j.janxdis.2014.09.018] [Medline: 25445078]
87. Schueller SM, Tomasino KN, Mohr DC. Integrating human support into behavioral intervention technologies: the efficiency model of support. Clin Psychol Sci Pract 2016 Nov 17;24(1):27-45. [doi: 10.1111/cpsp.12173]
88. Vis C, Kleiboer A, Prior R, Bønes E, Cavallo M, Clark SA, et al. Implementing and up-scaling evidence-based eMental health in Europe: the study protocol for the MasterMind project. Internet Interv 2015 Nov;2(4):399-409. [doi: 10.1016/j.invent.2015.10.002]

Abbreviations

AIF: Active Implementation Framework
eMH: electronic mental health interventions or eMental health
GP: general practitioner
HCPs: health care professionals
ICT: information and communication technology
RE-AIM: reach, effectiveness, adoption, implementation, and maintenance

Edited by J Torous; submitted 04.01.18; peer-reviewed by P Chow, G Strudwick; comments to author 23.01.18; revised version received 07.02.18; accepted 08.02.18; published 16.03.18.

Please cite as:
Vis C, Mol M, Kleiboer A, Bührmann L, Finch T, Smit J, Riper H
Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors
JMIR Ment Health 2018;5(1):e20
URL: http://mental.jmir.org/2018/1/e20/
doi:10.2196/mental.9769
PMID:29549072

Original Paper

Open Notes in Swedish Psychiatric Care (Part 1): Survey Among Psychiatric Care Professionals

Lena Petersson[1], MSc; Gudbjörg Erlingsdóttir[1], PhD

Faculty of Engineering, Department of Design Sciences, Lund University, Lund, Sweden

Corresponding Author:
Lena Petersson, MSc
Faculty of Engineering
Department of Design Sciences
Lund University
Box 118
Lund, SE-22100
Sweden
Phone: 46 462220533
Fax: 46 462224431
Email: Lena.Petersson@design.lth.se

Abstract

Background: When the Swedish version of Open Notes, an electronic health record (EHR) service that allows patients online access, was introduced in hospitals, primary care, and specialized care in 2012, psychiatric care was exempt. This was because psychiatric notes were considered too sensitive for patient access. However, as the first region in Sweden, Region Skåne added adult psychiatry to its Open Notes service in 2015. This made it possible to carry out a unique baseline study to investigate how different health care professionals (HCPs) in adult psychiatric care in the region expect Open Notes to impact their patients and their practice. This is the first of two papers about the implementation of Open Notes in adult psychiatric care in Region Skåne.

Objective: The objective of this study was to describe, compare, and discuss how different HCPs in adult psychiatric care in Region Skåne expect Open Notes to impact their patients and their own practice.

Methods: A full population Web-based questionnaire was distributed to psychiatric care professionals in Region Skåne in late 2015. The response rate was 28.86% (871/3017). Analyses show that the respondents were representative of the staff as a whole. A statistical analysis examined the relationships between different professionals and attitudes to the Open Notes service.

Results: The results show that the psychiatric HCPs are generally of the opinion that the service would affect their own practice and their patients negatively. The most striking result was that more than 60% of both doctors (80/132, 60.6%) and psychologists (55/90, 61%) were concerned that they would be less candid in their documentation in the future.

Conclusions: Open Notes can increase the transparency between patients and psychiatric HCPs because patients are able to access their EHRs online without delay and thus, can read notes that have not yet been approved by the responsible HCP. This may be one explanation as to why HCPs are concerned that the service will affect both their own work and their patients.

(JMIR Ment Health 2018;5(1):e11) doi:10.2196/mental.9140

KEYWORDS

electronic health record; eHealth; baseline survey; mental health; open notes; psychiatry; health professionals

Introduction

The Development of Open Notes

A discussion has surfaced recently about the effects of patients having online access to their electronic health records (EHRs; here referred to as Open Notes) in psychiatric care [1,2] and whether patients and health care professionals (HCPs) would be put at risk by the service [3]. However, not many psychiatric care clinics have implemented such a service. According to Open Notes Mental Health (toolkit), there are 21 implementations to date in the United States and Canada, apart from the seven regions that have implemented the service in psychiatry in Sweden. As all these implementations are recent, little is known about the perceptions of HCPs to the service in this context.

Open Notes is one of the most important civic electronic health (eHealth) services in Sweden. All citizens in the country are able to access their EHRs from care online and can thus read clinical notes through the Internet. The initial implementation of the service in hospitals, primary care, and specialized care had previously raised both questions and resistance among the HCPs [4-6]. However, no baseline studies were conducted at that time that can be compared with the one presented in this paper. When the service was launched in 2012 in Sweden, some medical specialties, where patient digital access was considered sensitive, were exempt. One of these was psychiatry. In 2015, Region Skåne, the county board of the southernmost county in Sweden was the first in the country to add adult psychiatry to Open Notes. Through the service, patients in adult psychiatric care in Region Skåne were able to access entries in their EHRs from September 5, 2015 online. This development is in line with the reasoning of the OpenNotes Project in the United States—that patients in psychiatric care should not be treated differently than other groups of patients [1,3,7]. The introduction of Open Notes in psychiatry provided an opportunity for us to carry out a unique baseline study by conducting a full population survey of the employees in adult psychiatry in Region Skåne before the service became available to patients.

The Technical Prerequisite

In Region Skåne, in contrast to the OpenNotes Project and the system used by the US Department of Veterans Affairs (VA), patients can access their EHRs as soon as they are entered into the system and can thus, read their clinical notes in many cases before the responsible HCP has signed off on them. This means that the notes have not yet been approved by the responsible HCP when they are made available for the patient to read online. On the other hand, a signed note means that the responsible HCP has decided that the information is correct. HCPs can neither opt out from participating nor can they choose which patients can access the service. This is because the service has been implemented in the entire public health care system in the region and thus, includes all inpatients and outpatients.

The Open Notes service in Sweden is accessible by logging into a secure online patient portal. In certain cases, information is withheld from patients, such as information that could pose risks to the patient or relatives. To ensure the ability to enter such information in the health record, there is a special template for this purpose called specific information. This information is only digitally accessible to the HCPs, but patients can access it by requesting a paper copy of their EHRs. In Region Skåne, inpatients in adult psychiatric care (approximately 5% of the patients) are exempted from immediate access to the service but can access their EHRs 4 weeks after hospitalization. The rationale for this decision is the risk that inpatients will read their Open Notes at a critical stage in their treatment and that this could harm them. There is also the risk that inpatients would compare their notes with those of other inpatients, become upset, and agitate each other when they find differences in the treatment. Outpatients in psychiatric care can read their entries right away, just as patients in non-Psychiatric care in Region Skåne have been able to do since the service was first introduced.

The aim of this study was to describe, compare, and discuss how different HCPs in adult psychiatric care in Region Skåne expect Open Notes to impact their patients and their own practice. This is the first of two papers about the implementation of Open Notes in adult psychiatric care in Region Skåne. The second one (in preparation) will report on the actual experiences of the HCPs.

Methods

Survey Design

The material presented is the product of a baseline survey in psychiatric care. This is a substudy in a research project (the EPSA Project, financed by AFA Insurance in Sweden) on how the work and work environment of HCPs are affected by civic eHealth services such as Open Notes.

The baseline survey used in this study is based on one developed and implemented by the OpenNotes Project in the United States [8-10]. In line with the original survey [8,11], the Swedish version covers three areas: *The impact on the patients*, *The impact on the practice*, and *About me*. First, the original OpenNotes survey was translated and adjusted to fit the Swedish context. Second, the researchers conducted four multiprofessional focus groups with employees. The purpose was to validate the areas of interest in the questionnaire in the Swedish context. Third, a Web survey was designed concerning online patient access to their EHRs and the work environment of the HCPs who meet the patients. Previous surveys on the implementation of online patient access to their EHRs in Sweden have been directed to either doctors or nurses [5]. The survey consisted of 34 fixed-choice questions (mostly 4-point scale answers) and three open-ended questions and was designed so that the respondents could choose not to answer all the questions.

Setting and Population

The Division of Psychiatric Care in Region Skåne consists of three subdivisions: adult, children and youth, and forensic. It was decided that only patients in adult psychiatry would be offered online access to their EHRs to begin with. The adult psychiatry subdivision employs roughly 3000 people. In 2013, there were 436,000 outpatient visits and 6600 inpatients in adult psychiatric care in the region. Online access to the EHR service for all adult psychiatric care patients opened on October 5, 2015.

The entire population of HCPs (n=3017) in adult psychiatry in Region Skåne who meet patients were invited to participate in this study. This included assistant nurses, doctors, medical secretaries, nurses, occupational therapists, physical therapists, psychologists, and social workers. The rationale for not taking a sample was that it is a heterogeneous population where some of the professional groups are large and others are small. In addition, the employees in Region Skåne were the first in psychiatric care in Sweden whose patients would be able to read their notes online, and thus, it was important that everyone in the population had the opportunity to answer the survey.

Survey Administration

We used the Web survey tool, *Sunet Survey*. The emails were sent from Lund University. On September 17, 2015, a

prenotification email was sent to the study population, and on September 18, the survey was sent electronically to the institutional email addresses of the professionals with a cover letter and a link to the survey. Both the prenotification email and cover letter informed the recipients that participation was voluntary, that the computer files with the results were confidential, respondents could terminate their participation at any time, and tracking of individual responses was not possible. We did not offer any survey incentives. We sent four reminders, and the survey closed on October 2, 3 days before patients were given online access to their EHRs. All the material in the baseline study was thus collected before the implementation.

Data Analysis

We present descriptive information for each fixed-choice question and chi-square tests to examine the relationships between professionals and attitudes to the Open Notes service. Due to the small number of respondents, occupational therapists, physical therapists, social workers, and all others (as one group) were grouped together for the chi-square tests. All reported *P* values were two-sided. $P<.05$ was considered statistically significant. Due to the answer options, we did not conduct chi-square tests on five of the questions. The survey data was imported and analyzed in Statistical Package for the Social Sciences (SPSS) version 23 (IBM Corp). The analysis of the open-ended questions is not included in this paper.

Ethics

The researchers followed the guidelines on research ethics issued by the Swedish Research Council [12]. This study does not cover any sensitive information and does not require ethical approval according to the Swedish regulations on research ethics.

Results

The Respondents

The response rate to the Web survey was 28.86% (871/3017). The distribution between the different professions corresponds well with the overall percentage of employees in each profession in the region. The questionnaire was distributed to both permanent and temporary employees, which may have influenced the response rate negatively. Table 1 presents the demographics of the survey respondents. For statements that evaluated attitudes, we combined the alternatives somewhat agree and agree, indicating that the respondent agreed to some level. Tables 2 and 3 provide more information about this process.

Expected Impact on Patients

Table 2 presents the percentages of respondents who somewhat agree or agree with questions about the impact of the service on the patients. They are generally pessimistic about the future impact of Open Notes on patients. Almost 58.0% (488/840) believe that their patients will worry more after reading their notes, and only 11.2% (93/833) believe that the service will inspire their patients to take better care of themselves. More than 63.2% (529/837) expect that their patients will disagree with the content in their notes, and half of the respondents (436/832) expect their patients to request changes in the notes. Only 27.4% (227/830) of the respondents believe that Open Notes will increase the patients' trust for them as professionals.

The chi-square tests show that there are differences in opinions among the different groups of professionals, especially regarding whether patients will be satisfied with the content in their notes and if Open Notes will increase the patients' trust for the HCPs. Medical secretaries (55/72, 76%) and assistant nurses (126/172, 73.3%) agree to a larger degree with the statement, A majority of patients will disagree with what is written in their notes, than doctors (82/131, 62.6%) and psychologists (44/89, 49%). Medical secretaries (46/68, 68%) agree to a larger degree with the statement, A majority of patients will request changes to the content of notes, compared with doctors (77/128, 60.2%) and psychologists (35/89, 39%). Doctors (24/130, 18.5%) and psychologists (16/89, 18%), in turn, agree with the statement, A majority of patients will trust me more as their caregiver, to a lesser degree than nurses (59/217, 27.2%) and assistant nurses (58/178, 32.6%).

Table 1. Demographic characteristics of the respondents in percentage and number (n). A total of 853 of the 871 respondents answered the professional affiliation question; 851 answered the gender question.

Professional affiliation and gender	Survey respondents, n (%)
Nurse	228 (26.7)
Assistant nurse	182 (21.3)
Doctor	133 (15.6)
Psychologist	91 (10.7)
Medical secretary	76 (8.9)
Social Worker	57 (6.7)
Other	53 (6.2)
Occupational therapist	17 (1.9)
Physical therapist	16 (1.9)
Gender	
Female	628 (73.8)
Male	223 (26.2)

Table 2. Psychiatric professionals' views on how patient online access to EHRs in adult psychiatric care will affect the patients: proportion of respondents who *somewhat agree* to *agree* and the results of the chi-square test for these items. The number of total responses for each item ranged from 830 to 840.

Survey item	n (%)	*P* value
Among my patients who read their electronic health record from psychiatry online		
A majority of patients will better understand their health and medical conditions.	252 (30.1)	.36
A majority of patients will worry more.	488 (58.1)	.32
A majority of patients will better remember the plan for their care.	402 (48.2)	.63
A majority of patients will disagree with what is written in their notes.	529 (63.2)	<.001
A majority of patients will request changes to the content of notes.	436 (52.4)	.001
A majority of patients will take better care of themselves.	93 (11.2)	.15
A majority of patients will be more likely to take medications as prescribed.	154 (18.5)	.13
A majority of patients will find significant errors in the notes.	351 (41.9)	.03
A majority of patients will feel more in control of their health care.	372 (44.4)	.53
A majority of patients will be better prepared for visits.	261 (31.1)	.02
A majority of patients will trust me more as their caregiver.	227 (27.4)	.001
A majority of patients will contact me or my practice with questions about their notes.	570 (68.7)	.002
A majority of patients will find the notes to be more confusing than helpful.	438 (52.7)	.03

[a]Represents the number and percent of respondents who indicated *somewhat agree* to *agree* on a 4-point scale with the following response options: *disagree*, *somewhat disagree*, *somewhat agree*, and *agree*.

Expected Impact on Practice

Table 3 shows how the respondents expect Open Notes to affect their practice, way of documenting, and care delivery. Approximately 40% of the respondents believe that visits will take longer (299/852), that they will have to take care of patients' questions in addition to the visits (343/845), and that patients will be offended when they read their notes online (376/844). Forty percent (342/845) expect to become less candid in their documentation and that they will spend significantly more time writing, dictating, or editing notes. Only 21.2% (177/838) believe that care delivery will become more efficient. Approximately one-third expect (305/839) an increase in patient safety. Seventeen percent (147/850) think that the service will contribute to care on equal terms for all patients to a large or very large extent. Thirty-six percent (302/849) believe that the relationship between their profession and the patient will change, but only 20.6% (174/845) think that relationships between different professions in adult psychiatric will change. Nearly half of the respondents (386/846) believe that the implementation of Open Notes increases the risk for threat and violence. Very few of the respondents (75/851, 8.8%) often meet patients who have read their health record on paper. Approximately one-third (231/835) of the respondents agreed that Open Notes in adult psychiatric care is generally a good idea.

The chi-square test results in Table 3 show that there are differences among the professional groups, especially on the items that are about clinical documentation and the general idea of Open Notes. Doctors (63/133, 47.4%) and medical secretaries (31/71, 44%) are more worried that visits will take more time compared with nurses (71/228, 31.1%) and psychologists (21/90, 23%). The results show the same pattern when it comes to the statement I will spend significantly more time addressing patient questions outside of visits. Approximately half of the doctors (73/132, 55.3%) and medical secretaries (34/69, 49%) claim that they are moderately concerned, very concerned, or so concerned that they do not want Open Notes to be implemented in psychiatric care at all compared with nurses (86/227, 37.9%) and psychologists (32/89, 36%).

Medical secretaries (42/69, 61%) and doctors (73/132, 55.3%) are also more worried about patients being offended when reading their notes online than are assistant nurses (82/178, 46.1%), nurses (94/227, 41.4%), and psychologists (36/90, 40%). Sixty one percent of both doctors (80/132) and psychologists (55/90) are worried that they will be less candid in their documentation. More than half of the doctors (76/133, 57.1%) and psychologists (46/90, 51%) and 45% (31/69) of the medical secretaries are worried that they will have to spend significantly more time writing, dictating, or editing notes. Finally, doctors (25/132, 18.9%) and psychologists (17/87, 20%) are less likely to agree with the statement Patient online access to their EHRs in adult psychiatry is generally a good idea than medical secretaries (19/72, 26%), nurses (60/223, 26.9%), and assistant nurses (51/175, 29.1%).

In summary, the results show that the HCPs were of the opinion that the service will negatively impact their work in different ways. The statistical analysis also shows that people in different professional groups vary concerning their misgivings about how the service will affect their own work: doctors, psychologists, and medical secretaries in many cases are more negative to the service than the other professional groups.

Table 3. Psychiatric professionals' views on patients' online access to electronic health records (EHRs) in adult psychiatric care: expectations of how practice and clinical documentation will be affected and the results of the chi-square test for these items. The number of total responses for each item ranged from 835 to 852.

Survey item	n (%)	*P* value
Visits will take significantly longer[a]	299 (35.09)	<.001
I will spend significantly more time addressing patient questions outside of visits[a]	343 (40.6)	<.001
Patients who read their notes will be offended[a]	376 (44.5)	<.001
I will be less candid in my documentation[a]	342 (40.5)	<.001
I will spend significantly more time writing or dictating or editing notes[a]	352 (41.5)	<.001
Medical care will be delivered more efficiently (yes response)[b]	177 (21.1)	.008
Patient satisfaction will improve (yes response)[b]	247 (29.5)	.06
Patient care will be safer (yes response)[b]	305 (36.3)	.01
Patient online access to their EHRs[c]will contribute to health care on equal terms for all patients (large or very large extent)[d]	147 (17.3)	.01
Patient online access to their EHRs in adult psychiatry will affect the relationship between the different professionals working there (large or very large extent)[d]	174 (20.6)	.006
Patient online access to their EHRs in adult psychiatry will affect the relationship between the patient and your profession (large or very large extent)[d]	302 (35.6)	.02
Patient online access to their EHRs in adult psychiatry will affect the risk for me to be subjected to threat and violence (will increase)[e]	386 (45.6)	
Patient online access to their EHRs in adult psychiatry will affect the risk for me to be reported to the Patients Advisory Committee (will increase)[e]	356 (42.2)	
Patient online access to their EHRs in adult psychiatry will affect the risk for me to be reported to Health and Social Care Inspection (will increase)[e]	273 (32.2)	
How often do you meet patients who have read their health record on paper? (to a large or a very large extent)?[f]	75 (8.8)	
How many of your patients do you think will read their EHRs online? [g]		
0-10 (%)	121 (14.4)	
11-25 (%)	214 (25.4)	
26-50 (%)	250 (29.7)	
51-75 (%)	196 (23.3)	
76-100 (%)	60 (7.1)	
Patient online access to their EHRs in adult psychiatry is generally a good idea (somewhat agree to agree)[h]	231 (27.7)	<.001

[a]Number and percentage of employees responding that they were *moderately concerned*, *very concerned*, or *so concerned that I do not want patient online access to my EHR in psychiatric care at all*. It was also possible to choose the options *minimally concerned* and *not concerned*.

[b]Number and percentage of employees responding *yes*. It was also possible to answer *no*.

[c]EHR: electronic health record.

[d]Number and percentage of employees responding that they to *a large extent* or *a very large extent* agree. It was also possible to choose the options to *a little extent* or *not at all*.

[e]Number and percentage of employees responding that *the risk will increase*. It was also possible to answer *the risk will not change*, *the risk will decrease*, and *not relevant*. Due to the answer options, we did not conduct a chi-square test on these questions.

[f]Number and percentage of employees responding that they to *a large extent* or *a very large extent* agree. It was also possible to choose the options to *a little extent*, *not at all*, or *not relevant*. Due to the answer options, we did not conduct a chi-square test on this question.

[g]Due to the answer options, we did not conduct a chi-square test on this question.

[h]Represents the number and percent of respondents who indicated *somewhat agree* to *agree* on a 4-point scale with the following response options: *disagree*, *somewhat disagree*, *somewhat agree*, and *agree*.

Discussion

Principal Findings

To our knowledge, this is the first baseline study that examines how HCPs working in adult psychiatric care in public care expect Open Notes to affect their work and how these expectations vary between different professions. Generally though, the respondents in this study are more negative to Open Notes than the respondents in previous baseline studies in non-Psychiatric settings in the United States [3,8]. As the service is obligatory in Sweden, HCPs cannot opt out from participating, and it is not possible to exclude patients. In the US OpenNotes Project, doctors were enrolled on a voluntary basis and could exclude patients they thought were less apt to handle the service. This might account for some of the differences. Another explanation may be that transparency in psychiatric care can be more problematic as the content in the notes may worry patients and could influence the patient-doctor relationship [13].

An important difference, compared with similar services in the United States [11,14], is that Region Skåne clinical notes are accessible to outpatients without delay. This has been one of the most debated features of the Open Notes service in Sweden, even in non-Psychiatric settings, because it allows patients to read entries in their EHRs before they are signed [4]. This may explain why approximately 60% of both doctors and psychologists are worried that they will be less candid in their documentation in the future. The OpenNotes Project in the United States has also expressed concerns that increased transparency may *water down* the content of the records [2]. Furthermore, in a recent study of Open Notes at the VA System in the United States, mental health clinicians claim that they are more careful about what they write to protect the patients and themselves [15].

Many of the respondents are pessimistic in their expectations of the impact of Open Notes on their patients in adult psychiatry. There is a need for more knowledge about the effects of the service on patients in general [16]; in psychiatric care, it may be particularly important to gain a greater understanding of how the service affects patient groups with different diagnoses.

This is the first study where medical secretaries are asked about their expectations regarding the implementation of Open Notes. Medical secretaries work with administrative tasks such as transcribing dictated notes, talking to patients on the telephone, and meeting them at the reception. To our surprise, the chi-square tests show that in some cases, medical secretaries are as negative as the doctors. Seventy-six percent believe that a majority of the patients will disagree with the content of their records, and over 60% answered that they were worried that patients who read their notes online will be offended by the entries. The medical secretaries may be concerned that because they are working on the front line, they will be the ones who will first encounter the disappointed and perhaps upset patients.

Region Skåne has been informed about the results from the baseline survey and is aware of the possible implications of the deployment of the Open Notes service. It will consider taking actions when the results from the follow-up survey are fully analyzed in the spring of 2018. The results of this baseline study are being used to influence the planned implementation of Open Notes in children and youth psychiatry and forensic psychiatry in Region Skåne.

Limitations

This study has a number of limitations. First, the response rate to the Web questionnaire was 28.86%. One explanation may be that this is a full population study, and some employees did not work during the time when it was possible to answer the survey. Still, the group distribution among the respondents corresponds well with the percentage of employees in each profession, which indicates that we have good representation of all professional groups. Second, the topic of a Web survey can affect the response rate among respondents [17]. On the one hand, a topic of high interest to respondents can increase the response rate; on the other, topics of a sensitive nature may result in a lower response rate [17]. The rhetoric put forth by key actors in Sweden is that Open Notes is a civic service and a technical solution aimed at the patient. Thus, any significant impact that it may have on the work or work environment of HCPs has not been taken into consideration. However, we know from our previous studies in non-Psychiatric settings that Open Notes has raised both questions and resistance among HCPs in Sweden [4]. Thus, the topic of the questionnaire is sensitive, and this may have affected the response rate negatively. Third, the results are limited to only one out of 20 regions in Sweden. Region Skåne, however, is one of the three largest regions in Sweden and was the first to implement the Open Notes service in psychiatric care, which made the study possible.

Conclusions

Over 40 years ago, Shenkin and Warner presented the iconoclastic idea of patient access to their records on a regular basis [18]. The vision of the authors was that this would enhance the quality of care. For less than a decade now, digitalization in health care has made it technically possible to provide patients with online access to their records, and the reactions to the service may not be fully as positive as Shenkin and Warner anticipated. The results of this study show that the HCPs in psychiatric care in Region Skåne expect the implementation of patient access to their EHRs to have mainly a negative impact on their patients and on their own working life. The main concern seems to be linked to the enhanced transparency that the service offers to the patients. The fact that roughly 60% of the doctors and psychologists state that they will change their entries as a result of the implementation is alarming. Not only does this indicate that the Open Notes service will affect the working life of the doctors and psychologists but also that the service may not meet the intentions of the implementers, that is, to provide patients with full information about their health conditions. Many questions about the factual impact of the service in psychiatric care still remain unanswered. During the spring of 2017, we distributed a follow-up survey to the employees in adult psychiatric in Region Skåne. We hope to be able to answer some of these questions in the next paper by comparing the results from the baseline study presented here with the results from the follow-up survey. Thus, the second paper will report on the actual experiences of the HCPs.

Acknowledgments

The research presented in this paper is funded by AFA Insurance in Sweden via the project eHealth Services' Impact on the Working Environment of Health Professionals (EPSA). The authors are grateful to Jan Walker and the OpenNotes team at Harvard Medical School for letting them use the OpenNotes survey in their study.

Conflicts of Interest

None declared.

References

1. Kahn MW, Bell SK, Walker J, Delbanco T. A piece of my mind. Let's show patients their mental health records. J Am Med Assoc 2014 Apr 02;311(13):1291-1292. [doi: 10.1001/jama.2014.1824] [Medline: 24691603]
2. Walker J, Darer JD, Elmore JG, Delbanco T. The road toward fully transparent medical records. N Engl J Med 2014 Jan 02;370(1):6-8. [doi: 10.1056/NEJMp1310132] [Medline: 24304001]
3. Dobscha SK, Denneson LM, Jacobson LE, Williams HB, Cromer R, Woods S. VA mental health clinician experiences and attitudes toward OpenNotes. Gen Hosp Psychiatry 2016;38:89-93. [doi: 10.1016/j.genhosppsych.2015.08.001] [Medline: 26380876]
4. Erlingsdóttir G, Lindholm C. When patient empowerment encounters professional autonomy: the conflict and negotiation process of inscribing an eHealth service. Scand J Public Adm 2015;19(2):27-48 [FREE Full text]
5. Scandurra I, Jansson A, Forsberg-Fransson M, Ålander T. Is 'patient's online access to health records' a good reform? – opinions from Swedish healthcare professionals differ. Procedia Comput Sci 2015 Apr;64(4):964-968 [FREE Full text] [doi: 10.1016/j.procs.2015.08.614]
6. Grünloh C, Cajander Å, Myreteg G. 'The Record is our work tool!'-Physicians' framing of a patient portal in Sweden. J Med Internet Res 2016 Jun 27;18(6):e167 [FREE Full text] [doi: 10.2196/jmir.5705] [Medline: 27349531]
7. Walker J, Kahn MW, Delbanco T. Transparency in the delivery of mental health care--reply. J Am Med Assoc 2014 Aug 13;312(6):650-651. [doi: 10.1001/jama.2014.7610] [Medline: 25117139]
8. Walker J, Leveille SG, Ngo L, Vodicka E, Darer JD, Dhanireddy S, et al. Inviting patients to read their doctors' notes: patients and doctors look ahead: patient and physician surveys. Ann Intern Med 2011 Dec 20;155(12):811-819 [FREE Full text] [doi: 10.7326/0003-4819-155-12-201112200-00003] [Medline: 22184688]
9. Delbanco T, Walker J, Darer JD, Elmore JG, Feldman HJ, Leveille SG, et al. Open notes: doctors and patients signing on. Ann Intern Med 2010 Jul 20;153(2):121-125. [doi: 10.7326/0003-4819-153-2-201007200-00008] [Medline: 20643992]
10. Walker J, Delbanco T. Interval examination: moving toward open notes. J Gen Intern Med 2013 Jul;28(7):965-969 [FREE Full text] [doi: 10.1007/s11606-013-2407-3] [Medline: 23620188]
11. Leveille SG, Walker J, Ralston JD, Ross SE, Elmore JG, Delbanco T. Evaluating the impact of patients' online access to doctors' visit notes: designing and executing the OpenNotes project. BMC Med Inform Decis Mak 2012 Apr 13;12:32 [FREE Full text] [doi: 10.1186/1472-6947-12-32] [Medline: 22500560]
12. Swedish Research Council. Good Research Practice. Stockholm: Swedish Research Council; 2017.
13. Farrell HM. Transparency in psychiatric care. Asian J Psychiatr 2012 Sep;5(3):273-274. [doi: 10.1016/j.ajp.2012.07.011] [Medline: 22981058]
14. Nazi KM, Turvey CL, Klein DM, Hogan TP, Woods SS. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. J Am Med Inform Assoc 2015 Mar;22(2):380-389. [doi: 10.1136/amiajnl-2014-003144] [Medline: 25352570]
15. Denneson LM, Cromer R, Williams HB, Pisciotta M, Dobscha SK. A qualitative analysis of how online access to mental health notes is changing clinician perceptions of power and the therapeutic relationship. J Med Internet Res 2017 Jun 14;19(6):e208 [FREE Full text] [doi: 10.2196/jmir.6915] [Medline: 28615152]
16. Woodman J, Sohal AH, Gilbert R, Feder G. Online access to medical records: finding ways to minimise harms. Br J Gen Pract 2015 Jun;65(635):280-281 [FREE Full text] [doi: 10.3399/bjgp15X685129] [Medline: 26009506]
17. Cunningham CT, Quan H, Hemmelgarn B, Noseworthy T, Beck CA, Dixon E, et al. Exploring physician specialist response rates to web-based surveys. BMC Med Res Methodol 2015;15:32 [FREE Full text] [doi: 10.1186/s12874-015-0016-z] [Medline: 25888346]
18. Shenkin BN, Warner DC. Sounding board. Giving the patient his medical record: a proposal to improve the system. N Engl J Med 1973 Sep 27;289(13):688-692. [doi: 10.1056/NEJM197309272891311] [Medline: 4727972]

Abbreviations

eHealth: electronic health
EHR: electronic health record

HCP: health care professional
VA: Veterans Affairs

Edited by J Torous; submitted 09.10.17; peer-reviewed by G Strudwick, T Fuller; comments to author 28.10.17; revised version received 20.12.17; accepted 08.01.18; published 02.02.18.

Please cite as:
Petersson L, Erlingsdóttir G
Open Notes in Swedish Psychiatric Care (Part 1): Survey Among Psychiatric Care Professionals
JMIR Ment Health 2018;5(1):e11
URL: http://mental.jmir.org/2018/1/e11/
doi:10.2196/mental.9140
PMID:29396386

Original Paper

Employees' Perspectives on the Facilitators and Barriers to Engaging With Digital Mental Health Interventions in the Workplace: Qualitative Study

Stephany Carolan[1], MSc; Richard O de Visser[1], PhD

School of Psychology, University of Sussex, Brighton, United Kingdom

Corresponding Author:
Stephany Carolan, MSc
School of Psychology
University of Sussex
Falmer
Brighton, BN1 9QH
United Kingdom
Phone: 44 1273876638
Fax: 44 1273678058
Email: sc587@sussex.ac.uk

Abstract

Background: Prevalence rates of work-related stress, depression, and anxiety are high, resulting in reduced productivity and increased absenteeism. There is evidence that these conditions can be successfully treated in the workplace, but take-up of psychological treatments among workers is low. Digital mental health interventions delivered in the workplace may be one way to address this imbalance, but although there is evidence that digital mental health is effective at treating stress, depression, and anxiety in the workplace, uptake of and engagement with these interventions remains a concern. Additionally, there is little research on the appropriateness of the workplace for delivering these interventions or on what the facilitators and barriers to engagement with digital mental health interventions in an occupational setting might be.

Objective: The aim of this research was to get a better understanding of the facilitators and barriers to engaging with digital mental health interventions in the workplace.

Methods: Semistructured interviews were held with 18 participants who had access to an occupational digital mental health intervention as part of a randomized controlled trial. The interviews were transcribed, and thematic analysis was used to develop an understanding of the data.

Results: Digital mental health interventions were described by interviewees as convenient, flexible, and anonymous; these attributes were seen as being both facilitators and barriers to engagement in a workplace setting. Convenience and flexibility could increase the opportunities to engage with digital mental health, but in a workplace setting they could also result in difficulty in prioritizing time and ensuring a temporal and spatial separation between work and therapy. The anonymity of the Internet could encourage use, but that benefit may be lost for people who work in open-plan offices. Other facilitators to engagement included interactive and interesting content and design features such as progress trackers and reminders to log in. The main barrier to engagement was the lack of time. The perfect digital mental health intervention was described as a website that combined a short interactive course that was accessed alongside time-unlimited information and advice that was regularly updated and could be dipped in and out of. Participants also wanted access to e-coaching support.

Conclusions: Occupational digital mental health interventions may have an important role in delivering health care support to employees. Although the advantages of digital mental health interventions are clear, they do not always fully translate to interventions delivered in an occupational setting and further work is required to identify ways of minimizing potential barriers to access and engagement.

Trial Registration: ClinicalTrials.gov: NCT02729987; https://clinicaltrials.gov/ct2/show/NCT02729987?term=NCT02729987&rank=1 (Archived at WebCite at http://www.webcitation.org/6wZJge9rt)

(JMIR Ment Health 2018;5(1):e8) doi:10.2196/mental.9146

KEYWORDS

anxiety; depression; eHealth; Internet; mental health; mHealth; occupational; online; stress; workplace

Introduction

Background

Nearly 1 in 3 workers in Europe report that they are affected by work-related stress, which is estimated to cost between 3% and 4% of gross national product [1]. Along with a societal and individual cost, common mental health problems such as stress, depression, and anxiety have a cost to organizations. They are associated with reduced productivity [2-5], early retirement [6], increased sickness absence [7-8], presenteeism (not working at capacity while at work) [9], and staff turnover through health-related job loss [10]. There is evidence that these conditions can be successfully prevented and treated in the workplace [11-14], but take-up of psychological treatments among workers is low, resulting in many workers going untreated [2,15,16]. One way of increasing workers' access to psychological treatments might be through the use of digital mental health interventions in the workplace. A recent meta-analysis found that these interventions are effective in increasing psychological well-being and workplace effectiveness but that the mean intervention completion (the extent to which participants adhered to the intervention) was 45%, with a range of 3% to 95% [17]. Although there are examples of occupational digital mental health interventions that have achieved good adherence [18-21], uptake of and engagement with these interventions in the workplace clearly remains a pressing concern.

Researchers cite a number of advantages to digital health interventions compared with traditional face-to-face interventions: these are often described as the anonymity and accessibility of the Internet with clients being able to access treatment at a time, a place, and at a pace that is convenient to them [22-24]. These advantages have led digital health interventions to being described as being well suited for the workplace [25], but with occupational digital mental health interventions still being in their infancy, little research has been done to see if these perceived advantages translate to an occupational setting; furthermore, little research has been done on the barriers and facilitators to take up and engagement with digital health interventions in a workplace setting.

The study reported here used qualitative interviews to increase understanding of the experiences of participants using an occupational digital mental health intervention as part of a randomized controlled trial (RCT). Combining quantitative and qualitative data is recommended as an effective means of getting a better understanding of new and innovative technologies [26] and other interventions [27].

The RCT compared access to a Web-based stress management intervention (WorkGuru) with and without access to an online facilitated discussion group. Full details of the trial are reported elsewhere [28,29]. WorkGuru is an 8-week modular program that is based on the principles of cognitive behavioral therapy (CBT), positive psychology, mindfulness, and problem solving. The intervention can be accessed on a secure platform on a computer or smartphone. There are 7 core modules and 3 optional modules. People completed the modules in the order and at a pace that they chose. The modules consisted of educational reading, interactive exercises, a stress and a thought diary, audio, and short animations. Participants could choose to share their work with an e-coach and could contact the coach for information or advice. The coach responded within 24 hours. The e-coach contacted each participant 3 times during the course of the 8-week program with reminders to login. Participants could also choose to opt-in to automated reminders (sent at a time and frequency that they chose) and a motivational message sent every Monday (the Monday morning message). Both reminders were sent by email. Along with the modules, participants could complete 8 self-monitoring standardized questionnaires.

The original trial population was recruited from 6 UK-based organizations: 2 local authorities, 2 universities, 1 third sector (not for profit) organization, and 1 telecommunication organization. Participants in the trial were randomized to 1 of 3 groups: the minimal support group (accessing the intervention with minimal support from an e-coach), the discussion group (access to the intervention with minimal support from an e-coach plus an online facilitated learning group), or the control group (access to the intervention after follow-up). Eligibility criteria for the RCT were as follows: (1) aged 18 years or over, (2) employed by a participating organization, (3) willing to engage with a digital CBT-based stress management intervention, (4) access to the Internet, (5) access to a tablet or computer, and (6) an elevated level of stress as demonstrated by a score of ≥20 on the ten-item Perceived Stress Scale (PSS-10) [30].

Research Questions

The research questions for this study were as follows: (1) What did participants see as the positives and the negatives of occupational digital mental health? (2) What helped and what hindered engagement with occupational digital mental health? (3) What more could be done to help participants engage with occupational digital mental health? (4) What did participants think a perfect digital mental health intervention would look like?

Methods

Participants

All participants (n=82) recruited to the RCT were invited via email to take part in this study. Four emails were sent over a 3-week period, inviting participation in telephone interviews. Further information about the study was given. The emails emphasized that we were keen to interview participants whether or not they had logged on to the program. The final email re-emphasized our wish to interview participants who had not engaged with the program. Participants were invited to contact the first author for more information and to arrange a time for the interview. Informed consent forms were distributed and

returned before the interview. Ethical approval was granted by the host university's ethics committee.

Data Collection

A total of 18 semistructured telephone interviews were conducted by the first author in May 2017. Each interview lasted between 20 and 50 min. The interview questions were informed by previous literature, experience from the RCT, and the study aims. The final question used a solutions focus approach (see [31]) to invite participants to imagine a perfect occupational digital mental health intervention. Participants received and were asked to read a participant information sheet informing them about the study, and they were asked to sign and return a consent form or give audio-recorded informed consent before the interview takes place. Interview recordings were transcribed verbatim and anonymized.

Data Analysis

Thematic analysis as described by Braun and Clarke [32] was used to develop an understanding of the data. The 6 phases of thematic analysis described by Braun and Clarke [32] are as follows: (1) familiarize yourself with the data, (2) generate initial codes, (3) search for themes, (4) review themes, (5) define and name themes, and (6) produce the report. Microsoft Excel (2011) was used to organize and manage the data. Both authors independently reviewed and coded a subset of the transcripts and discussed and resolved any inconsistencies to arrive at a shared interpretation of the data. The first author coded the remaining transcripts, which were reviewed by the second author for inconsistencies. Identifier pseudonyms were used.

Results

Recruitment and Participants

A comparison between the study participants and the original trial participants is given in Table 1. All participants were white. The sample was, on average, older (45 years compared with 41 years) and included less female participants (78% compared with 85%) than the original study. Recruitment from the universities and the telecommunication organization was broadly similar, but more participants were recruited from the third sector organization, and we were not able to recruit any participants from the 2 local authorities. The number of people in this study who recalled being randomized to the control group was representative of the original study, but the number that recalled that they had been randomized to the minimal support group was higher, and to the discussion group lower. Of the 18 participants in this study, 14 respondents (78%) reported that their work was predominantly office based; the remaining 4 (22%) reported a mixture of office and client work.

When participants were asked whether they thought they had engaged well with the intervention, 7 (39%) said they had engaged well, 8 said no or not very well (44%), and 3 had never logged into the intervention (17%). Participants were also asked to recall how many times they had logged into the program. The mean number of logins recalled by participants who said that they had engaged well with the intervention was 15.0 (range 4-30); the mean number for those who recalled that they had not engaged well was 9.8 (range 5-20).

All participants who accessed WorkGuru did so during working hours (including their lunch break), with only 2 saying that they also accessed it outside working hours. The initial trigger for accessing the intervention was described as current experience of stress, with a number of participants saying that the opportunity to use it arose at the right time. Participants said that they were looking for tools to help them cope with their stress. Moreover, 14 (78%) of the people interviewed for this study said that they had never used a digital health intervention before using WorkGuru. Of the remaining 4 participants, 3 had used a pedometer, 1 used a mood tracker, 1 monitored his or her sleep, and 1 participant accessed YouTube videos designed to help people sleep.

A total of 6 key themes were derived from the analysis: the positives and negatives of digital mental health; the facilitators and barriers to engagement; the role of the e-coach; and what made a perfect occupational digital health intervention.

Table 1. Comparison of participants in this study and the original trial. RCT: randomized control trial.

Comparison variable	Participants in this study (N=18)	Participants in RCT (N=82)
Mean age (SD)	45 (10.8)	41 (10.2)
Female, n (%)	14 (78)	70 (85)
Organization, n (%)		
Third sector	7 (39)	17 (21)
Universities	10 (56)	48 (58)
Telecommunications	1 (5)	3 (4)
Local authority	0 (0)	14 (17)
Allocated group, n (%)		
Discussion group	4 (22)	26 (32)
Minimal support group	8 (44)	28 (34)
Wait list control	6 (33)	28 (34)

The Positives of Digital Mental Health Interventions

Participants described digital mental health interventions as being convenient both in terms of accessing it at a time that is convenient for them and at a place that is convenient for them. The quote below reflects participants' appreciation of these characteristics:

> *Whenever I need something I can just straight away go there without waiting for someone, waiting for an appointment or like. I can get help as soon as possible and I can get it anywhere because it's online on the Internet.* [Sara, 31 years, university one]

Another aspect of this convenience identified by participants was the ability to work at a time that was convenient to them. Natalie [40 years, third sector] noted that the intervention gave "flexibility to access the intervention at a time that you can fit into your work diary." This meant that they could fit sessions in when they had time rather than having to fit with the timetable of a (potentially busy) therapist. Robert also appreciated the flexibility of access and talked about the importance of being able to work at his own pace:

> *It's incredibly accessible both in terms that I could choose when I was engaging with it, and it allowed me therefore to kind of pace myself and reflect on things and then go back to things when I wanted to rather than saying: "Well you've got a session, it's at 2 o'clock on a Friday and that's it, that's your only window". So I think it made it in some senses more live for me rather than an event that you go to.* [Robert, 46 years, university one]

Participants identified the stigma of mental illness as still being an issue in the workplace. One participant said:

> *I wouldn't tell it to anyone in my workplace.* [Sara, 31 years, university one]

Another participant described how she would not talk to her employer about the elements of work that contributed to her stress as:

> *I would then be forever seen as someone who doesn't cope well and then wouldn't get much career progression* [Sue, 43 years, university two]

Participants suggested that the discreteness and anonymity of digital mental health interventions helped them to overcome their fear of the stigma:

> *I think also it's very discreet. If you have to shuffle off and actually see somebody you know face to face, it's a bit more public, people are more likely to know about it.* [Fiona, 62 years, third sector]

The privacy of the Internet allowed participants to access support without work colleagues knowing. For example, Simon [48 years, university two] noted that the intervention allowed him to "get the support without necessarily drawing attention to myself at work. " Anonymity was also given by not having to call someone to make an appointment:

> *Personally it was easier to say, "I'm doing something to help myself," but without actually having to speak to someone. You know it's quite daunting if you've got a worry to actually pick up the phone and speak to someone.* [Anna, 47 years, third sector]

Anna found it easier to start the digital intervention because she did not have to speak to someone to make an appointment; other participants shared this view and suggested that by having access to a Web-based intervention they were able to access treatment, which they might not have done if they had to speak face-to-face with someone:

> *I felt quite positive about starting it off when it's not something I would've done if I'd had to go and physically speak to somebody about it.* [Tony, 56 years, third sector]

Some participants valued being able to access the intervention in the workplace. This feature enabled them take time out of stressful events at work to focus on themselves:

> *To be able to in a workplace setting after dealing with a particularly stressful case, being able to remove yourself and do something just for you with permission from your employer, was really an empowering tool that they gave us.* [Jane, 28 years, third sector]

Jane valued being able to access the intervention in the workplace, but other participants identified a number of barriers to accessing digital mental health interventions at work; these are described in the next section.

The Negatives of Digital Mental Health Interventions

Participants identified a number of negatives to accessing digital interventions in the workplace. These included not having a defined time in which to use the intervention. Although participants appreciated the flexibility of digital mental health interventions, a number of them also felt that they needed more self-discipline to remain engaged with a digital intervention compared with a face-to-face intervention where they had an appointment in their diary and an office or clinic to visit:

> *It's good not to have to do things in a certain time but it's also not good because you can often think "Actually I'll do it later," and never get round to it. [...] If it's online it's down to the individual themselves to go and do what they are required to do.* [Simon, 48 years, university two]

Other participants struggled with not having a private space to access the intervention:

> *And the other problem is sitting in an open plan, hot-desking space. In our room each desk runs into the next desk, there are no privacy screens between them. So I don't know if there's a sense of feeling that other colleagues can see what you're working on, they can see the screen of your computer.* [Natalie, 40 years, third sector]

For some participants, accessing the intervention at their desks meant that they might have benefited less from it, because existing ongoing work concerns that may have been the *cause* of stress were present in the therapeutic environment:

> *If you go somewhere else to an appointment, I think on the whole you're going to get more out of it than if you're fitting it in but you're still at your desk and you can see the invoices that need approving and your to-do list.* [Katy, 63 years, university one]

In addition to the lack of a *spatial* separation between work and therapy, there was also no *temporal* separation between work and therapy. For example, one interviewee noted that accessing the digital intervention at her desk meant that she did not have the journey back to work to help her switch back to work mode:

> *You're doing something very reflective and personal that might make you feel uncomfortable feelings, and then to go back into work mode immediately. I guess I think even if you go to a counselling session you have that physical journey back to work which helps switch modes back and so you've got time to kind of leave those feelings behind.* [Sue, 43 years, university two]

Another issue was that the workplace is often a place in which we are invested in appearing strong and capable. For example, one participant described how, although she was able to present herself positively to work colleagues, reflecting on her mental health in the workplace left her feeling exposed:

> *I was struggling. At work people probably wouldn't really have picked up that much was going on for me, I was quite happy to keep that going in front of people so then I'm at work and I'm...it starts you having to think about the other stuff that's affecting you internally but you're managing to put on a pretty OK persona when you're at work so then it just felt like I was having to...I didn't want to expose myself too much I suppose.* [Anna, 47 years, third sector]

Several participants said that one of the problems for them with completing a minimally guided digital intervention was the lack of human interaction. Although not having to speak to someone was a positive for some people (see above), it also meant that it was easier to disengage from the intervention:

> *It does allow you to maybe explore these things without having to open up directly to a person. But then the downside to that is that it also allows you to walk away from it more easily.* [Tony, 56 years, third sector]

Some participants noted that not having a one-to-one interaction meant that they might choose the "easier" elements of the intervention, and therefore not obtain the benefits of more comprehensive engagement. For example, John [33 years, university two] noted that it was possible to avoid the more challenging elements that "probably had more growth behind it . " The lack of face-to-face contact also meant that participants could be left feeling isolated and feeling that they had not made an emotional connection and that they were not " *sharing* ":

> *I guess it's the isolation, with doing everything anonymously and just taking time out on your own to do it there's no real sharing involved in it* [Jane, 28 years, third sector]

Facilitators to Engagement

In addition to the convenience, flexibility, and anonymity mentioned above, the main factors that participants identified as helping them to engage with the digital intervention were program content and design. Interesting content was one reason given for engaging with the program. For example, 1 participant said:

> *The content I think was what kept me going back into it because it was interesting. It had interesting content.* [John, 33 years, university two]

Participants liked that the program was interactive and they liked the way it was presented. The positive experience motivated them to continue:

> *It was in nice bite size chunks. It was well presented. It was quite enjoyable. Yeah, it was quite enjoyable to do. It was good taking yourself out of the work situation for a bit, before going back in again. So I mean it was just a very positive experience so I think that just encouraged me to carry on with it.* [Claire, 57 years, university one]

Each module gave an estimation of the amount of time it would take to complete, which enabled users to plan their engagement. Participants also appreciated that the intervention tracked their progress through the program; for example, 1 participant described how being able to see what modules she had completed motivated her to compete other modules:

> *You can see on screen you've done this and you've done this and you've done this, but you still need to do this. It was almost like playing an online game.* [Katy, 63 years, university one]

Other features that helped participants to engage with the intervention were reminders to log in that were built into the system. These included self-timed opt-in automated emails and the opt-in Monday morning message. This was an email message sent every Monday morning that included a motivational message and information on keeping yourself psychologically well at work. It was intended as a reinforcement of the key messages in the program and a reminder to log in. Personalized reminders were also provided by the e-coach who contacted each participant to remind them to log in to the program and to contact her if they needed any support. One participant suggested that email reminders from the e-coach were more helpful than the automated reminders:

> *I think when I got the emails from the work coach themselves, because it was a person enquiring that was much more of a prompt to look in and go: "Oh yeah, gosh, I do need to focus in on this and make some time for it," but when it was just an automated response it kind of felt, it kind of made me feel guilty about logging in.* [Jane, 28 years, third sector]

In addition to using the different reminders within the intervention, some participants described setting their own reminders by putting tasks in their work calendar. They noted that this helped them to engage with the program:

> *If you just think you've got forever to do it, it would have been easier to put it off whereas you know I wanted to do it so I set myself reminders and built it into my calendar.* [Claire, 57 years, university one]

A number of participants identified the importance of organizations and line managers in promoting the use of interventions such as WorkGuru and encouraging the staff to use them. Natalie described how support to use the intervention from a manager could make a big difference:

> *If you get a message from the manager that that's ok and that they encourage and support you to do that, that can make a big difference.* [Natalie, 40 years, third sector]

Promotion by the employer gave the intervention legitimacy and gave the staff explicit permission to use it:

> *I think probably the fact that this was circulated by the university, it probably added a bit of...almost legitimacy about it, I guess. This was something that was supported by the university, which is probably a little bit silly but when you're in a stressed situation it is just the knowledge that yeah well the university said this is an ok thing to do, it's ok for me to take time to be working through this and it's to their benefit because if I'm working more effectively then they benefit as well.* [Claire, 57 years, university one]

Barriers to Engagement

Over half of the interviewees identified the pressure of time or excessive workload as being the main reasons for not engaging with the intervention:

> *Although it was something that I wanted to do, getting [the prompt to logon] was just kind of a: "Oh god, have I really got time to do this today? Am I going to feel guilty for leaving my colleagues?"* [Jane, 28 years, third sector]

Similarly, Anna [47 years, third sector] noted that engaging with the intervention "*became almost a luxury*", and that when work pressures were mounting *"I couldn't devote the time to do it."*

In addition to time pressure, the symptoms of mental health problems were identified as potential barriers to engagement. For example, Chloe noted that effective engagement required levels of motivation that may not be possessed by people with depression:

> *Probably at the time, um I was very low, very depressed. [...] I suppose time would've been a bit of an issue, coupled with depression. I didn't have any motivation at all.* [Chloe, 44 years, telecommunication]

The Role of the E-Coach

Participants gave mixed reports on their use, appreciation, and expectation of the e-coach. A number of participants did not engage with the e-coach; some were unclear about what the role of the e-coach was or how they could use her support:

> *I thought it really helped when I did some of these exercises and like sitting and writing down the feelings that could happen or triggers. I did it a couple of times and it really helped me a lot so I don't know how to tell it to the coach. Can the coach help with this stuff or not? Also in the exercises they are there and what else can the coach help with?* [Sara, 31 years, university one]

One participant said that the communication from the e-coach felt automated:

> *Yeah it just, it seemed like an automated thing. I didn't really, I mean obviously I thought if you sent them an email it would get through to someone but um it just didn't feel very personal I guess.* [Rose, 38 years, university one]

However, another participant had a more positive experience:

> *I actually found the initial contact, really really, almost like validating. I was an individual I wasn't just a number, which I kind of really, really...really impressed me.* [Robert, 46 years, university one]

Participants were also divided about how proactive they wanted the e-coach to be. Some participants were happy that the e-coach was there if they wanted to ask any questions or *"if I've got a specific query"* [Claire, 57 years, university one].

Other participants wanted more contact with the e-coach:

> *I think it would be useful to have something a bit more proactive near the front just to try and ensure people really were comfortable with what they were doing.* [Tony, 56 years, third sector]

What Would a Perfect Digital Intervention Look Like?

When asked to describe what a perfect occupational digital mental health intervention might look like, almost half of the interviewees said that they would want to be able to access it only on a computer, the same number said on both a computer and a smartphone, and 2 said they would like to access the intervention only on a smartphone.

Participants wanted an intervention that would be anonymous and confidential and that could be tailored or adapted so that it could meet the needs of different people:

> *It's just remembering that everyone is different and everyone's moods has ups and downs, and depressions and joys are addressed in different ways and I guess a single program that takes everyone through a singular route probably doesn't hit the nail on the head.* [Tony, 56 years, third sector]

Nearly all participants described their perfect intervention as combining a short course that they could work through independently with a website that had regularly updated information and personalized advice that they could make use of as required over an indefinite period:

> *It would be sort of as I described, a short, fairly intensive course that you were checked up on whether you'd done it or not which would really help followed by the availability continuously after that, um, just*

> *for dipping into or for necessarily contacting somebody in person if possible.* [Rachel, 55 years, university one]

Interviewees said that the structure and layout of the short course should be simple, especially those who were less confident using information technology:

> *Yeah and it has got to be something very simple because I'm really not very technical. I am a bit of a, yeah a technology dinosaur to be honest so it would have to be very simple and accessible.* [Natalie, 40 years, third sector]

They also suggested that the content of the course should be interactive and consist of a mixture of reading and listening:

> *It's got to be something like this [WorkGuru] ...for me anyway, something that is interactive...because that's how I engage with stuff, it can't be just reading. I like that this was a mixture of reading, listening and actually doing stuff because I think it would be very easy not to take it in if it was just reading from a screen.* [Claire, 57 years, university one]

Participants were equally split between those wanting peer support as part of the time-unlimited resource and those who did not. One participant suggested that if peer support was available, she would want a small group:

> *If it was going to be something that I use regularly then I would probably want a smaller peer group, as in the sort of size that was in the discussion group that was active with WorkGuru rather than it being a kind of Facebook type thing where anybody can get involved because I think that floods it, and it becomes too much to actually digest and get involved with.* [Jill, 31 years, third sector]

In contrast, Rose stated that she would not use a support group for the following reason:

> *I'm not good with groups of people really so that's not something I'd make much use of myself.* [Rose, 38 years, university one]

A number of participants suggested that monitoring, including self-report tracking of stress symptoms, would be useful but emphasized that this information should not be made available to their employer.

The majority of participants wanted to be able to contact a coach if needed. For some, that support could be asynchronistic, but others wanted live chat either through video (eg, Skype) or instant messaging. A participant said:

> *You kind of sense the difference between someone who is physically there the whole time and yeah they're there, they're writing an answer but it's like an email conversation.* [John, 33 years, university two]

Discussion

Engagement With the Intervention

Only 4 interviewees said that they had used a digital health intervention before using WorkGuru. This suggests that despite the growing number of apps and websites, digital health is still a very underutilized resource. The trigger for initially accessing the intervention in this study was described by participants as a current experience of stress. This may suggest that perceived personal relevance is an important factor in initiating engagement with digital health interventions [33].

Positives and Negatives of Digital Mental Health in the Workplace

Participants in this study described contradictions between aspects of occupational digital mental health interventions, viewing the same aspects as both advantages and disadvantages. Convenience and flexibility could increase engagement with digital mental health by increasing the opportunities to access the intervention, but within a work environment, these advantages could also be experienced as disadvantages, resulting in difficulties in prioritizing time and a lack of spatial and temporal separation between work and therapy, which left some people feeling that they had competing priorities, or left them feeling exposed as they struggled to move from therapy mode to work mode. Knowles et al [34,35] identified similar contradictions in users' experience of digital therapies in nonwork settings. They identified contradictions in users' experience of flexibility, support, autonomy, connectedness, and anonymity in computerized therapy for depression and anxiety delivered predominantly in primary care.

In this study, the anonymity of digital health interventions was hard to maintain within an open-plan environment. Anonymity was important because it enabled participants to access help without fear of stigma and for some people it gave them the confidence to use the intervention, which they may not have done if they had to attend a face-to-face appointment or speak to their general practitioner (GP). However, other participants suggested that anonymity made it easier to disengage from the intervention. It could be argued that by removing some of the barriers to accessing face-to-face interventions such as inconvenient locations, inability to get an appointment, high cost, lack of transport, delay in access, and the fear of stigma, digital mental health may increase the number of people that take up therapy [36], but one of the effects of easing access to interventions may be increased dropout [37]. We can draw on the Prochaska and DiClemente's [38] stages of change model to illustrate this further. Prochaska and DiClemente ([38]; see also [39]) described 5 stages of behavioral change: (1) precontemplation (where there is no intention to change a behavior), (2) contemplation (where people are thinking about changing a behavior), (3) preparation (where people are intending to take action and may be taking small steps toward it), (4) action (where people are taking action), and (5) maintenance (where people work to prevent relapse). People who have made an appointment to attend a face-to-face intervention are more likely to be in the action stages of change, whereas people accessing digital interventions may also be in

the contemplation and preparation stages of change. They may be accessing the intervention out of curiosity—a wish to explore the possibility without making a commitment. This means that they may move back to the contemplation or preparation stages of the change model and may wish to access the digital intervention or another form of psychological intervention at a later date. In widening access to therapies, digital mental health interventions may be the first step in someone's therapeutic journey, and as such, disengagement should not necessarily be seen as a failure but as part of a process of seeking help. Our current data do not allow us to identify which users of digital mental health interventions are in which stage of the change model; future research may wish to explore this further to gain a better understanding of the role digital mental health interventions play in enabling people to access support and to change behaviors.

Along with being able to disengage from the intervention more easily, one of the other potential disadvantages of the lack of face-to-face contact in minimally supported digital mental health interventions identified by participants was the lack of emotional connection. Even when guidance is available, it is often voluntary, and users can choose not to engage with the e-coach. Some participants described feelings of isolation. An important component of traditional therapy is the therapeutic alliance, which is defined as the collaborative bond between therapist and patient [40]. Despite feelings of isolation expressed by some participants, there is evidence that a positive therapeutic alliance can develop in fully automated digital mental health interventions [41]. Clarke et al [41] found that the therapeutic alliance in a digital environment was not associated with treatment gains (in contrast to face-to-face psychotherapies), but that it was correlated with levels of engagement; perceived emotional engagement correlated positively with program use.

Facilitators and Barriers to Engagement

Along with the convenience, flexibility, and anonymity of digital mental health interventions, participants in this study identified program content and design as a facilitator to engagement. They liked that the program was interactive and that it was presented well. Intrinsic motivation (finding the content interesting) has been shown to be an important factor in treatment adherence to digital health interventions [42], as is design and appearance [33,43,44]. If people like an intervention they are more likely to continue with it [44]. Design features appreciated by participants included estimation of time to complete each module, a progress tracker, and reminders to log in and use the intervention. There is evidence that reminders increase engagement with digital interventions [45-47] and that people who choose to receive reminders to log in and choose to receive motivational emails show greater symptom reduction [48]. There is also evidence, however, that these email prompts could be easily ignored (and even resented) in a workplace context as a consequence of a full inbox [49]. There was some evidence of this in this study, but almost half of the participants mentioned receiving and appreciating the Monday morning message; this suggests that when reminders have an additional value (ie, motivational quotes and well-being information and advice), they are more likely to stand out in a busy email inbox.

The role of the organization and line managers was identified as an important facilitator to engagement with the digital mental health intervention. It was important to many of the participants that their use of the intervention was confidential; stigma about mental illness was still something that was perceived as being prevalent in the workplace, with some participants saying that knowledge about their mental health problems could be career limiting. Research supports this perspective with evidence that the stigma associated with mental ill health can result in lower wages [50], underemployment, and precarious employment [51]. However, although participants did not necessarily want their employer to know that they were accessing the intervention, they did think that it was important for organizations and line managers to circulate information about the intervention and to encourage its use. Organizational support gave the intervention legitimacy and signaled to the employees that they could use it. By circulating this information, organizations would be showing explicit concern for employee well-being, which has been shown to result in higher levels of employee commitment to the organization [52]. Further research is needed to get a better understanding about the role of organizations in promoting take-up and engagement with occupational digital mental health interventions.

Participants identified the lack of time as the main barrier to engaging with digital mental health interventions in the workplace. The lack of time has been identified by other studies on digital health interventions delivered in the workplace as a reason given by participants for disengaging from interventions [53-56]. Future research could explore further the role of employers in helping employees to prioritize accessing digital mental health interventions in the workplace.

The Role of the E-Coach

The intervention used in this research provided minimal guided support from an e-coach. In line with other minimal guided interventions (see [57]), the e-coach provided adherence support (log-in reminders) and feedback on request. Interviewees were divided by their experience of the e-coach and by how proactive they wanted the coaching to be. This division suggests that the type of support people want is a personal preference and might be best negotiated with the individual at the start of the program.

The Perfect Web-Based Intervention

When describing their perfect digital mental health intervention, interviewees described a simple, interactive, and easy-to-navigate website that could be accessed via a computer or a smartphone. There are advantages to delivering interventions via mobile devices such as smartphones (eg, the ability to employ ecological momentary assessments and to deliver interventions at moments of high need), but research in this area still remains in its infancy [45,58]. It was important to interviewees that the perfect intervention was anonymous and confidential and that it could be personalized (ie, tailored to their needs). Tailored interventions have been shown to be more effective than standardized approach to delivering digital interventions [59]. The intervention would combine a short course that users could work through independently with regularly updated, time-unlimited information and advice that they could dip in and out of over a longer period. The short

course described by interviewees reflects features identified in a systematic review as increasing engagement with occupational digital mental health interventions [17]; these include providing guidance, delivering in a short time frame (6-7 weeks), tailoring, and self-monitoring. Regularly updated content has been identified as an inducement to revisiting digital interventions [43]. To our knowledge, no other study on digital mental health interventions has identified the desire to access time-unlimited information and advice.

Interviewees reported that they wanted support from an e-coach but were divided about whether the support should be asynchronistic or synchronistic. Digital interventions that provide human guidance have been shown to be superior to unguided interventions [24,47,60-63], but currently there is no research comparing asynchronistic guidance with synchronistic guidance in digital mental health interventions.

A number of interviewees suggested incorporating self-monitoring, including self-report of stress symptoms. Self-monitoring is a core feature of many behavioral and psychological therapies [64] and has been recommended as an important component in the delivery of digital mental health [45]. Interviewees were divided about the use of peer support with some people saying they would like it and others saying they would not use it. There is currently little evidence to support the use of online peer support groups for people experiencing depression [65,66] or for young people experiencing mental health problems [67].

Implications for the Workplace

The findings from this study suggest that the role of organizations and line managers is crucial to promoting the use of digital mental health interventions in the workplace. For some employees, digital mental health interventions were an important means of accessing convenient and flexible support, and it formed an important component of a broader health and well-being strategy. To encourage uptake and engagement with these interventions, organizations and line managers must actively promote the interventions, and while maintaining confidentiality, support the staff to prioritize time during working hours and identify a private space to access the intervention and to reflect on the content.

Limitations

One of the limitations identified in the original study was that the participants recruited to the study (predominantly well-educated women working in social care or the knowledge industry in senior manager or administrative roles) were not representative of the general workforce. This limitation is evident in this study. Moreover, the majority of participants recruited in this study reported that their work was predominantly office based and all participants described having some autonomy over their work schedule. It is highly likely that the facilitators and barriers to the use of digital mental health interventions among other working groups (eg, employees working in blue-collar roles or in the service industries) will be different to those experienced by autonomous, office-based workers. There is a strong need for research into the use of occupational digital mental health interventions to be conducted in occupations and industries that are traditionally underrepresented (or wholly absent) in current studies.

Although this study was successful in engaging participants who did not perceive themselves as having engaged well with the intervention, participants were from a self-selecting group of employees who volunteered for the original trial and, therefore, did have some interest in engaging with digital mental health interventions. Therefore, we were unable to study the views of employees who may be less open to engaging with digital health interventions.

Another limitation to this study is the 1-year gap between participants being recruited to the original trial and being interviewed for this study. This meant that the study relied on participants' recollection of their experience, which may be flawed.

Conclusions

Occupational digital mental health interventions have an important role in delivering health care support to employees in the workplace and should form part of a broader health and well-being package. For some people, digital mental health interventions delivered in the workplace may help them to access help, which they may not have done if they had to access face-to-face therapies or speak to their GP. The convenience, flexibility, and anonymity of digital mental health interventions was experienced as both positives and as negatives, helping people to engage with occupational digital mental health, but also acting as barriers to engagement. It is important that developers of digital interventions and employers work with employees to overcome these challenges.

Conflicts of Interest

SC is the founder of WorkGuru and continues to have a commercial interest in the company.

References

1. Leka S, Jain A. Apps.who.int. Geneva: World Health Organisation; 2010. Health Impact of Psychosocial Hazards at Work: An Overview URL: http://apps.who.int/iris/bitstream/10665/44428/1/9789241500272_eng.pdf [accessed 2018-01-02] [WebCite Cache ID 6wAfhvXFt]
2. Birnbaum HG, Kessler RC, Kelley D, Ben-Hamadi R, Joish VN, Greenberg PE. Employer burden of mild, moderate, and severe major depressive disorder: mental health services utilization and costs, and work performance. Depress Anxiety 2010;27(1):78-89. [doi: 10.1002/da.20580] [Medline: 19569060]

3. Dewa CS, Thompson AH, Jacobs P. The association of treatment of depressive episodes and work productivity. Can J Psychiatry 2011 Dec;56(12):743-750. [doi: 10.1177/070674371105601206] [Medline: 22152643]
4. Gutman DA, Nemeroff CB. Stress and depression. In: Contrada R, Baum A, editors. The Handbook of Stress Science: Biology, Psychology, and Health. New York: Springer Publishing Company; 2011:345-357.
5. Waghorn G, Chant D, White P, Whiteford H. Disability, employment and work performance among people with ICD-10 anxiety disorders. Aust N Z J Psychiatry 2005;39(1-2):55-66. [doi: 10.1111/j.1440-1614.2005.01510.x] [Medline: 15660706]
6. Karpansalo M, Kauhanen J, Lakka TA, Manninen P, Kaplan GA, Salonen JT. Depression and early retirement: prospective population based study in middle aged men. J Epidemiol Community Health 2005 Jan;59(1):70-74 [FREE Full text] [doi: 10.1136/jech.2003.010702] [Medline: 15598730]
7. Bültmann U, Rugulies R, Lund T, Christensen KB, Labriola M, Burr H. Depressive symptoms and the risk of long-term sickness absence: a prospective study among 4747 employees in Denmark. Soc Psychiatry Psychiatr Epidemiol 2006 Nov;41(11):875-880. [doi: 10.1007/s00127-006-0110-y] [Medline: 16951921]
8. Henderson M, Glozier N, Holland EK. Long term sickness absence. Br Med J 2005 Apr 9;330(7495):802-803 [FREE Full text] [doi: 10.1136/bmj.330.7495.802] [Medline: 15817531]
9. Harvey SB, Glozier N, Henderson M, Allaway S, Litchfield P, Holland-Elliott K, et al. Depression and work performance: an ecological study using web-based screening. Occup Med (Lond) 2011 May;61(3):209-211. [doi: 10.1093/occmed/kqr020] [Medline: 21525074]
10. Solomon C, Poole J, Palmer KT, Coggon D. Health-related job loss: findings from a community-based survey. Occup Environ Med 2007 Mar;64(3):144-149 [FREE Full text] [doi: 10.1136/oem.2005.024257] [Medline: 17095549]
11. Bhui KS, Dinos S, Stansfeld SA, White PD. A synthesis of the evidence for managing stress at work: a review of the reviews reporting on anxiety, depression, and absenteeism. J Environ Public Health 2012;2012:515874 [FREE Full text] [doi: 10.1155/2012/515874] [Medline: 22496705]
12. Corbière M, Shen J, Rouleau M, Dewa CS. A systematic review of preventive interventions regarding mental health issues in organizations. Work 2009;33(1):81-116. [doi: 10.3233/WOR-2009-0846] [Medline: 19597288]
13. Joyce S, Modini M, Christensen H, Mykletun A, Bryant R, Mitchell PB, et al. Workplace interventions for common mental disorders: a systematic meta-review. Psychol Med 2016 Mar;46(4):683-697. [doi: 10.1017/S0033291715002408] [Medline: 26620157]
14. Vanhove AJ, Herian MN, Perez AL, Harms PD, Lester PB. Can resilience be developed at work? A meta-analytic review of resilience-building programme effectiveness. J Occup Organ Psychol 2015 Apr 25;89(2):278-307. [doi: 10.1111/joop.12123]
15. Dewa CS, Hoch JS. Barriers to mental health service use among workers with depression and work productivity. J Occup Environ Med 2015 Jul;57(7):726-731 [FREE Full text] [doi: 10.1097/JOM.0000000000000472] [Medline: 26147540]
16. Lim D, Sanderson K, Andrews G. Lost productivity among full-time workers with mental disorders. J Ment Health Policy Econ 2000 Sep 01;3(3):139-146. [Medline: 11967449]
17. Carolan S, Harris P, Cavanagh K. Improving employee wellbeing and effectiveness: a systematic review and meta-analysis of workplace psychological interventions delivered online. J Med Internet Res 2017;19(7):e271 [FREE Full text] [doi: 10.2196/jmir.7583]
18. Ebert DD, Heber E, Berking M, Riper H, Cuijpers P, Funk B, et al. Self-guided internet-based and mobile-based stress management for employees: results of a randomised controlled trial. Occup Environ Med 2016 May;73(5):315-323. [doi: 10.1136/oemed-2015-103269] [Medline: 26884049]
19. Heber E, Lehr D, Ebert DD, Berking M, Riper H. Web-based and mobile stress management intervention for employees: a randomized controlled trial. J Med Internet Res 2016;18(1):e21 [FREE Full text] [doi: 10.2196/jmir.5112] [Medline: 26818683]
20. Thiart H, Lehr D, Ebert DD, Berking M, Riper H. Log in and breathe out: internet-based recovery training for sleepless employees with work-related strain - results of a randomized controlled trial. Scand J Work Environ Health 2015 Mar;41(2):164-174. [doi: 10.5271/sjweh.3478] [Medline: 25590336]
21. Umanodan R, Shimazu A, Minami M, Kawakami N. Effects of computer-based stress management training on psychological well-being and work performance in japanese employees: a cluster randomized controlled trial. Ind Health 2014;52(6):480-491 [FREE Full text] [Medline: 25055847]
22. Cavanagh K, Millings A. Increasing engagement with computerised cognitive behavioural therapies. ICST Trans Amb Sys 2013 Feb 22;13(2):e3 [FREE Full text] [doi: 10.4108/trans.amsys.01-06.2013.e3]
23. Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. J Med Internet Res 2006;8(2):e10 [FREE Full text] [doi: 10.2196/jmir.8.2.e10] [Medline: 16867965]
24. Spek V, Cuijpers P, Nyklícek I, Riper H, Keyzer J, Pop V. Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. Psychol Med 2007 Mar;37(3):319-328. [doi: 10.1017/S0033291706008944] [Medline: 17112400]

25. Junge M, Lehr D, Bockting C, Berking M, Riper H, Cuijpers P, et al. For whom are internet-based occupational mental health interventions effective? Moderators of internet-based problem-solving training outcome. Internet Interv 2015 Mar;2(1):39-47 [FREE Full text] [doi: 10.1016/j.invent.2014.11.007]
26. Waller R, Gilbody S. Barriers to the uptake of computerized cognitive behavioural therapy: a systematic review of the quantitative and qualitative evidence. Psychol Med 2009 May;39(5):705-712. [doi: 10.1017/S0033291708004224] [Medline: 18812006]
27. de Visser RO, Graber R, Hart A, Abraham C, Scanlon T, Watten P, et al. Using qualitative methods within a mixed-methods approach to developing and evaluating interventions to address harmful alcohol use among young people. Health Psychol 2015 Apr;34(4):349-360. [doi: 10.1037/hea0000163] [Medline: 25822051]
28. Carolan S, Harris PR, Greenwood K, Cavanagh K. Increasing engagement with, and effectiveness of, an online CBT-based stress management intervention for employees through the use of an online facilitated bulletin board: study protocol for a pilot randomised controlled trial. Trials 2016 Dec 15;17(1):598 [FREE Full text] [doi: 10.1186/s13063-016-1733-2] [Medline: 27978858]
29. Carolan S, Harris P, Greenwood K, Cavanagh K. Increasing engagement with an occupational digital stress management program through the use of an online facilitated discussion group: results of a pilot randomised controlled trial. Internet Interv 2017 Dec;10:1-11 [FREE Full text] [doi: 10.1016/j.invent.2017.08.001]
30. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [Medline: 6668417]
31. Jackson P, McKergow M. The Solutions Focus: The SIMPLE Way to Positive Change. London: Nicholas Brealey Publishing; 2002.
32. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101 [FREE Full text] [doi: 10.1191/1478088706qp063oa]
33. Brouwer W, Oenema A, Crutzen R, de Nooijer J, de Vries NK, Brug J. An exploration of factors related to dissemination of and exposure to internet-delivered behavior change interventions aimed at adults: a Delphi study approach. J Med Internet Res 2008;10(2):e10 [FREE Full text] [doi: 10.2196/jmir.956] [Medline: 18417443]
34. Knowles S, Toms G, Sanders C, Bee P, Lovell K, Rennick-Egglestone S, et al. Qualitative meta-synthesis of user experience of computerised therapy for depression and anxiety. PLoS One 2014;9(1):e84323 [FREE Full text] [doi: 10.1371/journal.pone.0084323] [Medline: 24465404]
35. Knowles SE, Lovell K, Bower P, Gilbody S, Littlewood E, Lester H. Patient experience of computerised therapy for depression in primary care. BMJ Open 2015 Nov 30;5(11):e008581. [doi: 10.1371/journal.pone.0084323]
36. Ebert DD, Lehr D, Boß L, Riper H, Cuijpers P, Andersson G, et al. Efficacy of an internet-based problem-solving training for teachers: results of a randomized controlled trial. Scand J Work Environ Health 2014 Nov;40(6):582-596. [doi: 10.5271/sjweh.3449] [Medline: 25121986]
37. Lehr D, Geraedts A, Persson Asplund R, Khadjesari Z, Heber E, de Bloom J, et al. Occupational e-Mental Health: Current Approaches and Promising Perspectives for Promoting Mental Health in Workers. In: Wiencke M, Cacace M, Fischer S, editors. Healthy at Work. Cham: Springer; 2016.
38. Prochaska J, DiClemente C. Transtheoretical therapy: toward a more integrative model of change. Psychotherapy 1982;19(3):276-288 [FREE Full text] [doi: 10.1037/h0088437]
39. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. Am Psychol 1992 Sep;47(9):1102-1114. [Medline: 1329589]
40. Krupnick JL, Sotsky SM, Simmens S, Moyer J, Elkin I, Watkins J, et al. The role of the therapeutic alliance in psychotherapy and pharmacotherapy outcome: findings in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. J Consult Clin Psychol 1996 Jun;64(3):532-539. [Medline: 8698947]
41. Clarke J, Proudfoot J, Whitton A, Birch M, Boyd M, Parker G, et al. Therapeutic alliance with a fully automated mobile phone and web-based intervention: secondary analysis of a randomized controlled trial. JMIR Ment Health 2016 Feb 25;3(1):e10 [FREE Full text] [doi: 10.2196/mental.4656] [Medline: 26917096]
42. Alfonsson S, Olsson E, Hursti T. Motivation and treatment credibility predicts dropout, treatment adherence, and clinical outcomes in an internet-based cognitive behavioral relaxation program: a randomized controlled trial. J Med Internet Res 2016;18(3):e52 [FREE Full text] [doi: 10.2196/jmir.5352] [Medline: 26957354]
43. Brouwer W, Oenema A, Crutzen R, de Nooijer J, de Vries N, Brug J. What makes people decide to visit and use an internet ‐ delivered behavior ‐ change intervention?: A qualitative study among adults. Health Educ 2009 Oct 16;109(6):460-473 [FREE Full text] [doi: 10.1108/09654280911001149]
44. Ludden GD, van Rompay TJ, Kelders SM, Van Gemert-Pijnen JE. How to increase reach and adherence of web-based interventions: a design research viewpoint. J Med Internet Res 2015;17(7):e172 [FREE Full text] [doi: 10.2196/jmir.4201] [Medline: 26163456]
45. Bakker D, Kazantzis N, Rickwood D, Rickard N. Mental health smartphone apps: review and evidence-based recommendations for future developments. JMIR Ment Health 2016;3(1):e7 [FREE Full text] [doi: 10.2196/mental.4984] [Medline: 26932350]

46. Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. J Med Internet Res 2009;11(2):e16 [FREE Full text] [doi: 10.2196/jmir.1138] [Medline: 19632970]
47. Hilvert-Bruce Z, Rossouw PJ, Wong N, Sunderland M, Andrews G. Adherence as a determinant of effectiveness of internet cognitive behavioural therapy for anxiety and depressive disorders. Behav Res Ther 2012 Aug;50(7-8):463-468. [doi: 10.1016/j.brat.2012.04.001] [Medline: 22659155]
48. Whitton AE, Proudfoot J, Clarke J, Birch M, Parker G, Manicavasagar V, et al. Breaking open the black box: isolating the most potent features of a web and mobile phone-based intervention for depression, anxiety, and stress. JMIR Ment Health 2015;2(1):e3 [FREE Full text] [doi: 10.2196/mental.3573] [Medline: 26543909]
49. Wahle F, Bollhalder L, Kowatsch T, Fleisch E. Toward the design of evidence-based mental health information systems for people with depression: a systematic literature review and meta-analysis. J Med Internet Res 2017 May 31;19(5):e191 [FREE Full text] [doi: 10.2196/jmir.7381] [Medline: 28566267]
50. Baldwin ML, Marcus SC. Labor market outcomes of persons with mental disorders. Ind Relat 2007 Jul;46(3):481-510. [doi: 10.1111/j.1468-232X.2007.00478.x]
51. Krupa T, Kirsh B, Cockburn L, Gewurtz R. Understanding the stigma of mental illness in employment. Work 2009;33(4):413-425. [doi: 10.3233/WOR-2009-0890] [Medline: 19923664]
52. Mearns K, Hope L, Ford MT, Tetrick LE. Investment in workforce health: exploring the implications for workforce safety climate and commitment. Accid Anal Prev 2010 Sep;42(5):1445-1454. [doi: 10.1016/j.aap.2009.08.009] [Medline: 20538100]
53. Abbott JM, Kaldo V, Klein B, Austin D, Hamilton C, Piterman L, et al. A cluster randomised trial of an internet-based intervention program for tinnitus distress in an industrial setting. Cogn Behav Ther 2009;38(3):162-173. [doi: 10.1080/16506070902763174] [Medline: 19675959]
54. Abbott J, Klein B, Hamilton C, Rosenthal AJ. The impact of online resilience training for sales managers on wellbeing and performance. E-JAP 2009 Jun 15;5(1):89-95. [doi: 10.7790/ejap.v5i1.145]
55. Persson AR, Dagöö J, Fjellström I, Niemi L, Hansson K, Zeraati F, et al. Internet-based stress management for distressed managers: results from a randomised controlled trial. Occup Environ Med 2017 Aug 30 Epub ahead of print(forthcoming) [FREE Full text] [doi: 10.1136/oemed-2017-104458] [Medline: 28855344]
56. Geraedts A, Kleiboer A, Wiezer N, Cuijpers P, van Mechelen W, Anema J. Feasibility of a worker-directed web-based intervention for employees with depressive symptoms. Internet Interv 2014 Jul;1(3):132-140 [FREE Full text] [doi: 10.1016/j.invent.2014.07.001]
57. Ebert DD, Lehr D, Smit F, Zarski A, Riper H, Heber E, et al. Efficacy and cost-effectiveness of minimal guided and unguided internet-based mobile supported stress-management in employees with occupational stress: a three-armed randomised controlled trial. BMC Public Health 2014;14:807 [FREE Full text] [doi: 10.1186/1471-2458-14-807] [Medline: 25099533]
58. Lui JH, Marcus DK, Barry CT. Evidence-based apps? A review of mental health mobile applications in a psychotherapy context. Prof Psychol Res Pr 2017;48(3):199-210. [doi: 10.1037/pro0000122]
59. Johansson R, Sjöberg E, Sjögren M, Johnsson E, Carlbring P, Andersson T, et al. Tailored vs. standardized internet-based cognitive behavior therapy for depression and comorbid symptoms: a randomized controlled trial. PLoS One 2012;7(5):e36905 [FREE Full text] [doi: 10.1371/journal.pone.0036905] [Medline: 22615841]
60. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. Cogn Behav Ther 2009;38(4):196-205 [FREE Full text] [doi: 10.1080/16506070903318960]
61. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clin Psychol Rev 2012 Jun;32(4):329-342. [doi: 10.1016/j.cpr.2012.02.004] [Medline: 22466510]
62. Heber E, Ebert DD, Lehr D, Cuijpers P, Berking M, Nobis S, et al. The benefits of web- and computer-based interventions for stress: a systematic review and meta-analysis. J Med Internet Res 2017 Feb 17;19(2):e32 [FREE Full text] [doi: 10.2196/jmir.5774] [Medline: 28213341]
63. Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on Internet-based mental health interventions — a systematic review. Internet Interv 2014 Oct;1(4):205-215 [FREE Full text] [doi: 10.1016/j.invent.2014.08.003]
64. Humphreys K, Marx B, Lexington J. Self Monitoring as a Treatment Vehicle. In: O'Donohue WT, Fisher JE, editors. General Principles and Empirically Supported Techniques of Cognitive Behaviour Therapy. New Jersey: Wiley & Sons; 2009:576-583.
65. Griffiths KM, Calear AL, Banfield M. Systematic review on Internet Support Groups (ISGs) and depression (1): do ISGs reduce depressive symptoms? J Med Internet Res 2009;11(3):e40 [FREE Full text] [doi: 10.2196/jmir.1270] [Medline: 19793719]
66. Melling B, Houguet-Pincham T. Online peer support for individuals with depression: a summary of current research and future considerations. Psychiatr Rehabil J 2011;34(3):252-254. [doi: 10.2975/34.3.2011.252.254] [Medline: 21208865]
67. Ali K, Farrer L, Gulliver A, Griffiths KM. Online peer-to-peer support for young people with mental health problems: a systematic review. JMIR Ment Health 2015;2(2):e19 [FREE Full text] [doi: 10.2196/mental.4418] [Medline: 26543923]

Abbreviations

CBT: cognitive behavioral therapy

GP: general practitioner
PSS: Perceived Stress Scale
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 09.10.17; peer-reviewed by N Bragazzi, S Aggarwal; comments to author 02.11.17; revised version received 20.11.17; accepted 22.11.17; published 19.01.18.

Please cite as:
Carolan S, de Visser RO
Employees' Perspectives on the Facilitators and Barriers to Engaging With Digital Mental Health Interventions in the Workplace: Qualitative Study
JMIR Ment Health 2018;5(1):e8
URL: http://mental.jmir.org/2018/1/e8/
doi:10.2196/mental.9146
PMID:29351900

Original Paper

Inducing Behavioral Change in Seekers of Pro-Anorexia Content Using Internet Advertisements: Randomized Controlled Trial

Elad Yom-Tov[1], PhD; Anat Brunstein-Klomek[2,3], PhD; Or Mandel[2], BSc; Arie Hadas[2], PhD; Silvana Fennig[2,4], MD

[1]Microsoft Research, Herzliya, Israel

[2]Department of Child and Adolescent Psychiatry, Schneider Children's Medical Center of Israel, Petach Tikvah, Israel

[3]School of Psychology, Interdisciplinary Center, Herzliya, Israel

[4]Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel

Corresponding Author:
Elad Yom-Tov, PhD
Microsoft Research
13 Shenkar Street
Herzliya, 46875
Israel
Phone: 972 747111359
Fax: 972 747111359
Email: eladyt@yahoo.com

Abstract

Background: The influence of pro-anorexia (pro-ana) websites is debated, with studies indicating both negative and positive effects, as well as significant variation in the effects of different websites for those suffering from eating disorders (EDs) and the general population. Online advertising, known to induce behavioral change both online and in the physical world, has not been used so far to modify the search behavior of people seeking pro-ana content.

Objective: The objective of this randomized controlled trial (RCT) was to examine if online advertisements (ads) can change online search behaviors of users who are looking for online pro-ana content.

Methods: Using the Bing Ads system, we conducted an RCT to randomly expose the searchers for pro-ana content to 10 different ads referring people to one of the three websites: the National Eating Disorders Association, the National Institutes of Mental Health, and MyProAna. MyProAna is a pro-ana website that was found in a previous study to be associated with less pathological online behaviors than other pro-ana websites. We followed participants exposed and unexposed to the ads to explore their past and future online searches. The ads were shown 25,554 times and clicked on 217 times.

Results: Exposure to the ads was associated with a decrease in searches for pro-ana and self-harm content. Reductions were greatest among those referred to MyProAna (reduction of 34.0% [73/215] and 37.2% [80/215] for pro-ana and self-harm, respectively) compared with users who were referred elsewhere (reduction of 15.47% [410/2650] and 3.21% [85/2650], respectively), and with users who were not shown the ads, who increased their behaviors (increase of 57.12% [6462/11,314] and 4.07% [461/11,314], respectively). In addition, those referred to MyProAna increased their search for treatment, as did control users, who did so to a lesser extent. However, users referred elsewhere decreased their searches for this content.

Conclusions: We found that referring users interested in ED-related content to specific pro-ana communities might lessen their maladaptive online search behavior. This suggests that those who are preoccupied with EDs can be redirected to less pathological online searches through appropriate pathways.

Trial Registration: ClinicalTrials.gov NCT03439553; https://clinicaltrials.gov/show/NCT03439553 (Archived by WebCite at http://www.webcitation.org/6xNYnxYlw)

(JMIR Ment Health 2018;5(1):e6) doi:10.2196/mental.8212

KEYWORDS

anorexia nervosa; bulimia nervosa; eating disorders; online advertising; online behavior; Pro-ana

Introduction

Nowadays, individuals interested in extreme weight loss can find an extensive body of knowledge, as well as support, in their disordered eating through websites colloquially known as *pro-ana* sites. Some of these sites serve as online communities that promote an anorexic lifestyle, mainly by propagating positive viewpoints of anorexia as well as sharing practical tips on how to lose weight and conceal symptoms [1-3]. Daga et al [4] counted at least 300,000 websites promoting anorexic behaviors (257,000 "pro anorexia," 18,600 "pro-ana," 14,200 "thinspiration," and 577 "anorexic-nation"). Studies examining the effects of pro-ana websites have found negative outcomes on their visitors, such as lower self-esteem, higher perceived body weight, and increased likelihood of engaging in weight-restrictive practices [1,5-8]. Online behaviors of those interested in pro-ana sites may include online language usage (posts) and queries [9], as well as drug seeking, smoking, self-injury, and suicide [8].

On the other hand, some studies have suggested that pro-ana websites can also increase subjective feelings of social support, acceptance, and belongingness [10-12]. Therefore, it seems that these sites are not only harmful but may also offer their participants a potential benefit [13,14]. The exact influence of these sites is therefore still not clear, and there seems to be a difference between users who suffer from eating disorders (EDs) and the general population; students exposed to the pro-ana websites had greater negative affect, lower social self-esteem, and lower appearance self-efficacy [5]. *Recovery sites* are less numerous [4] and provide information about the disorder and how to reach treatment. They usually include posts about personal experiences, links to professional sites, forums, and other pages related to EDs. Like *pro-ana* users, pro-recovery visitors are characterized by a similar need of sharing and understanding; they often feel that the virtual forum is more supportive than traditional therapy [15]. Although it is important to provide information and support, the quality of Web-based treatment information at the recovery sites was found to be poor and deficient in accountability [16].

There are also a number of promising alternative Internet-based delivery systems for the treatment of ED patients, although most are still in an early phase of development [17,18]. A previous study, for example, has examined Internet-delivered, computer-assisted health education programs aimed at improving body satisfaction and decreasing the weight and shape concerns [19].

In a previous study, Yom Tov et al showed that there is variance between different pro-ana communities [9], and MyProAna website was found to be associated with the least harmful behaviors of those tested and the highest percentage of treatment seeking among its users. As this previous result was only based on an association rather than a causal relationship, in this study, we investigated how referring users to MyProAna community, using online advertisements (ads), would affect their online search behavior.

The effectiveness of Web advertising has long been investigated, especially due to their prominent role in the context of sales and marketing [20-22]. An important advantage of online advertising is the ability to perform behavioral targeting (BT), a widespread technology in which the ads are shown only to a specific audience to whom they are relevant [22]. Accumulating evidence indicates that online ads can be used to encourage the abandonment of unhealthy practices and, thus, to promote healthier lifestyles. Recently, Yom-Tov et al [23] used BT to present smokers, identified by their online behavior, with different antismoking ads. They then compared the smokers' searches before and after the intervention and found that the ads made a behavioral change in a gender-dependent manner. To the best of our knowledge, no previous studies have used such online ads to change users' search behavior in the context of EDs.

Here, we use search behavior to inform of user's behavior and its reflection of real-world behaviors. Online behavior may reflect offline behavior, including aspects of health, such as taking of prescription drugs, the conditions experienced by people [24], precursors to the development of disease [25], and symptoms indicative of certain cancers [26]. Thus, the ability to change online search behavior is expected to be advantageous in helping to modify behavior in the physical world.

In this study, we used an online randomized control trial (RCT) design [21] to redirect Web users interested in ED to a variety of ED-related websites, including MyProAna community, found to be associated with less harmful online behaviors [9]. First, we identified users interested in ED-related content. Then, we measured whether those users' online behavior was affected by the presentation of online ads that route the users either to the MyProAna community or to official health informational sites (which are all pro-recovery sites). These were chosen because they are official sites that promote information about EDs and professional treatments. However, in a study among undergraduate students, the authors did not find significant differences in terms of abnormal eating behaviors among people who visited pro-ana sites and those who visited professional EDs sites [6]. Our hypothesis was that participants redirected to the MyProAna community, which was associated with less pathological online behaviors, would show decreased search behavior for other pro-ana communities or to other sites associated with self-harm compared with participants not exposed to our ads or to prorecovery websites, such as the Centers for Disease Control and Prevention (CDC) website.

Methods

Overview

We conducted an RCT using the Bing search engine. Users of this search engine who were searching for pro-ana content were randomized into either being shown one of the 10 randomly chosen textual ads, referring people to one of the three randomly chosen websites, or not to be shown these ads. We then followed people, both those exposed to the ads and those not exposed to them, to explore their future searches online. The control intervention was "usual care," meaning users were served whatever ads the Bing Ads system would have otherwise served. The authors designed the textual ads. The ethical question in the Internet research field of EDs is complicated and remains

a continuing dilemma: do we stay passive observers of a social phenomenon that is impossible to control or can we study the field through the active anonymous participation of Internet users. We consider this study ethical as the criteria for the selection of the target population of our study was restricted to people already searching for the pro-ana websites. As the users were already searching for pro-ana content online, we assume they would have arrived at the MyProAna website or similar sites regardless of our intervention. These online communities were extensively studied in the past and were found to have some supportive effects on the users [8-10]. From all the pro-ana websites, we chose the one that was, as per our previous study, associated with the least harmful behaviors [9]. The Microsoft Institutional Review Board and the Interdisciplinary Center (IDC) Herzliya Review Board approved the study.

Advertisements

The ads contained text and took the form of a title, a body, and a link to a Uniform Resource Locator (URL) (shown to the users). As noted above, there were 10 different textual versions of the title and body, as shown in Table 1. The ads referred people to one of 3 sites, the names of which were visible to the user. The 3 sites were as follows: the National Eating Disorders Association (NEDA) [27], the National Institutes of Mental Health (NIMH) [28], and the MyProAna website [29].

A full factorial design was used such that all combinations of titlebody and URL were tested (a total of 30 combinations). The ads were shown only to the people who searched from computers located in the United States and who performed searches on the Bing search engine. According to recent estimates, we noted that 21.4% of the US Internet users use Bing [30]. As per the 2010 US Census, the correlation between the number of Bing users per county in the United States and the number of people in that county is R^2=.83 (P<.001). Thus, it is estimated that Bing users are a representative sample of the US population, at least in terms of their geographic distribution.

The ads were shown when the searches of users contained one or more of the following 6 keywords: Thinspiration, Thinspo, Proana/Pro Ana, Anorexia, or eating disorder (see [16] and references therein for the use of these keywords). Several advertisers can bid to show ads for the same keywords, and the Bing advertising system chooses which ads to show based on the monetary bids that the advertisers provide. In this experiment, as recommended by the Binge Ads system, the bids were set between zero and US $0.99 per keyword. If the Ads system chose to show one of the experimental ads, one of the 10 ads was randomly chosen with equal probability. The cost cited above is the cost that the investigators paid for each ad clicked by a user.

If one of the study ads were shown, they were displayed either directly underneath the search text (top of the page) or to the right of the search results (right of the page). Sometimes, the Ads system presented our ads in addition to other ads paid for by other advertisers. In those cases, a placement at location 1 meant that the ad was shown as the first ad in the list, and lower locations implied a lower order within the set of ads shown.

As noted above, the Bing Ads system randomly chose which of the 10 ads to show. Each of the 10 ads had the same probability of being displayed. Although it is likely that most users see the ads, only some users click on the ad. The ads were shown between April 19, 2016, and May 11, 2016.

Advertisement Categorization

We scored the ads according to their expression of the following six attributes: negativity, ambivalence, acceptability, sociality, treatment, and tips. A description of the attributes is given in Table 2. Categorization was used to generalize the ads in the statistical models below. The ads were categorized by 20 nonspecialist people from the crowdsourcing site *CrowdFlower*, who were asked to rate each ad on each attribute, according to the description provided for each category (Table 2), on a scale between 1 (lowest) and 7 (highest). The final score for each ad on each attribute was the average of the 20 scores. As a comparison between laypeople and professionals, 13 mental health multidisciplinary workers from a specialist EDs department also rated the ads on these attributes, so as to provide a view on how specialists view the ads.

Table 1. The titles and descriptions of the advertisements used in the study.

Title	Body
Diagnosed with ED[a]?	If you need a place to talk about it, you are welcome to our community
Eating Disorders info	Complete information about Anorexia, Bulimia and other Eating Disorders
Looking for help?	Learn how to deal with Eating Disorders
Sick of your weight?	Join us! Connect with those who completely understand!
Suffer from Anorexia?	Can't live with Anorexia anymore, but can’t live without? Click here!
Suffer from ED?	Click here to learn all about eating disorders
Suffer from ED?	Join our community and get all the support you need
Tired of your Anorexia?	Click here to get in touch with those who feel the same
Tired of your Anorexia?	If you want to stop being controlled by your anorexia, click here!
Want to be thinner?	Enter here if you are tired of not being understood

[a]ED: eating disorder.

Table 2. Advertisement attributes and their description.

Attributes	The description given to the crowdsourcing workers and to the specialists
Negativity	The ad[a] expresses a negative view of EDs[b] or of weight loss
Ambivalence	The ad expresses ambivalence toward EDs or toward losing weight
Acceptability	The ad implies that EDs and weight loss are acceptable practices
Sociality	The ad offers people to become part of a group
Treatment	The ad will appeal to people who want to get treatment
Tips	The ad would appeal to readers who seek weight loss tips

[a]Ad: advertisement.

[b]EDs: eating disorders.

Table 3. Keywords used to identify behaviors of interest.

Categories of users' interest	Keywords
Pro-anorexia/eating disorders	proana[a] (and its variations), anorexia, anorectic, EDNOS[b], bulimia, thinspiration, thinspo, ana buddy
MyProAna	MyProAna
Self-harm	cut my, hurt myself, self-harm, self-injury, self-poisoning, hair pulling
Substance abuse	smoke (and its variations), LSD[c], hash, vape, heroine, inject
Treatment	psychologist (and its variations), clinic, hospital
Depression	hopeless, helpless, depressed (and its variations)
Suicide	suicide, kill myself

[a]Pro-ana: pro-anorexia.

[b]EDNOS: eating disorder not otherwise specified.

[c]LSD: lysergic acid diethylamide.

Search Behaviors

On the basis of previous work [23,24], we tracked users' interest before and after the ad displays. Specifically, we extracted all search queries in the following 7 categories: pro-anorexia, MyProAna, self-harm, substance abuse, treatment, depression, and suicide (see Table 3). These behaviors were tracked from one month before the first ad was shown until a month after the last ad was shown for users who were logged into the system and could thus be tracked.

Analysis

We modeled the likelihood of a user to click an ad using a logistic regression model with the following independent attributes: time of display (date, hour), URL, ad position (top or right and order of display), device on which the ad was shown, and ad categories (as detailed above). We further tested the effect of individual ads on the change in behavior by modeling attributes of the ads and of the users who saw them using a linear regression model. The attributes used to model each ad display were as follows: user attributes (age, gender), whether the ad was clicked, ad location (position and rank), URL, ad text, number of previous ads that the user was shown, ad position (top or right, and order of display), and ad categories (as detailed above, using the scores of the crowdsourced workers).

Results

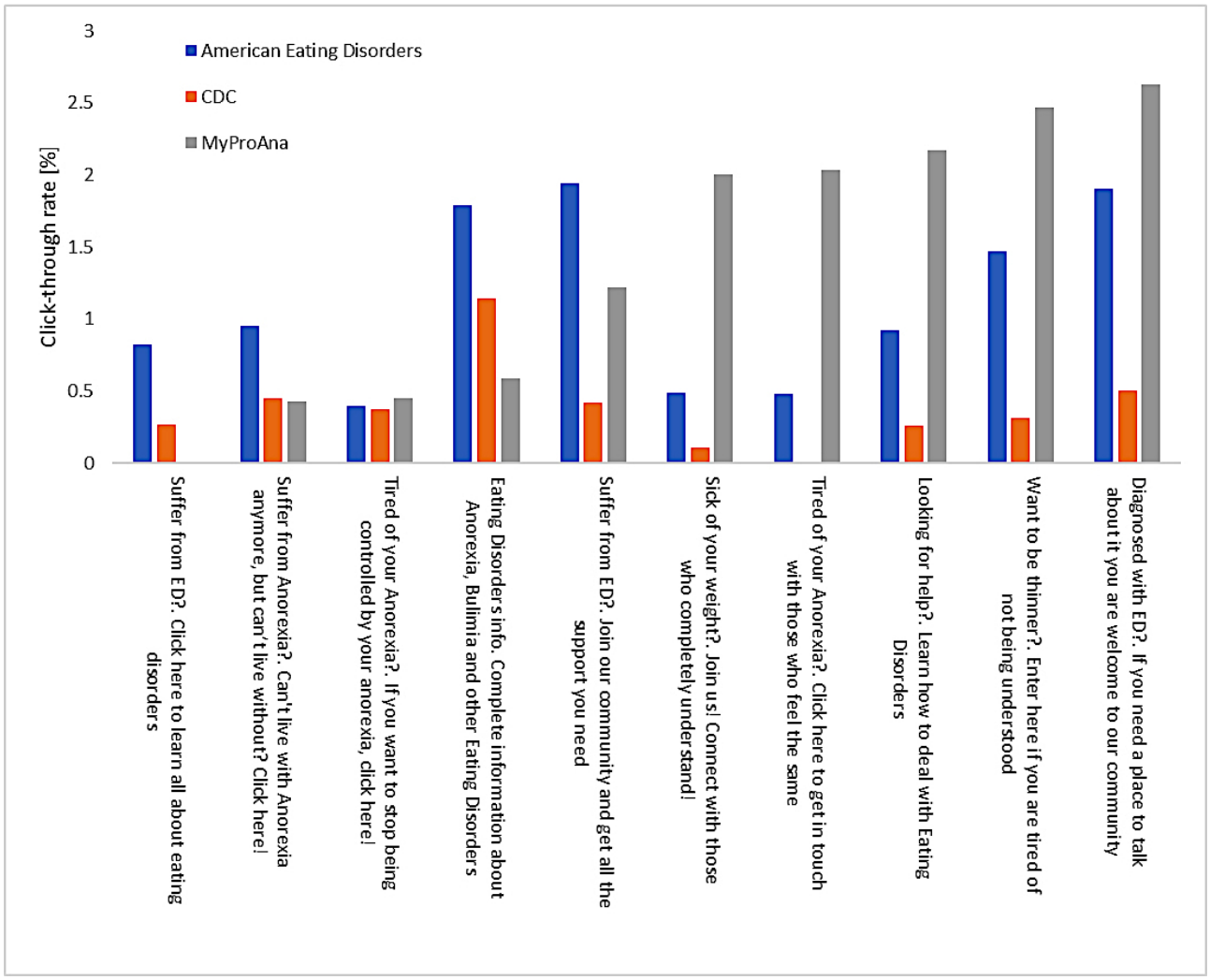
Agreement Between Experts and Laypeople on Advertisement Attributes

We calculated the Spearman correlation between the average score given by the specialist and the average score for each advertisement, as calculated from the scores given by crowdsourcing workers. Although the scores of both groups were highly correlated for acceptability [rho (ρ)=.66, P=.038], sociality (ρ=.92, P<.05), and reference to treatment (ρ=.82, P<.05), they were not highly correlated for how ads are interpreted on negativity (ρ=.61, P>.05), ambivalence (ρ=.25, P=.48), and tips (ρ=.30, P=.40).

Campaign Statistics

The ads were shown 25,554 times and clicked 217 times. Thus, the click-through rate (CTR) was 0.85%, in line with similar advertising campaigns [15]. The CTRs by ad text and the site referred are shown in Figure 1. As Figure 1 shows, CTRs varied considerably within ads—many ads were clicked only when they referred people to one of the 3 sites, but not others.

Figure 1. Click-through rates as a function of advertisement text and the site it referred users to. CDC: Centers for Disease Control and Prevention; ED: eating disorder.



Note that some people viewed multiple ads (if they made multiple queries), and thus, some of the analysis below is at the level of individual ads, whereas most are at the level of users, taking into account the number of times past advertising was displayed.

The Bing Ads system provides demographic information (age group and gender) for people who saw the ads and provided this information to the Ads system. Figure 2 shows the number of times that the ads were shown, which was contingent on the number of searches, and the CTR by age and gender. Note that some of the users saw multiple instances of the ads. Women were found to be the primary seekers of content using the proposed terms (80% of the ads were shown to women [n=20,443]), and the two age groups with most searches were 18-24 and 35-64 years. CTRs did not vary significantly by age group or gender and were all around 1% (Figure 2).

We modeled the likelihood of a user to click an ad using a logistic regression model with the following independent attributes: time of display (date, hour), URL, ad position (top or right and order of display), device on which the ad was shown, and ad categories (as detailed in the Methods section). Statistically significant (N=25,554) variables of this model were that the ad referred to NIMH (slope: −1.01, P<.001), ad positioned below other ads (slope: −0.35, P<.001), ads expressing a negative view of EDs (slope: −0.54, P<.001), and ads with a Windows operating system (implying, usually, desktop computers) (slope: 1.2, P<.001). Although the first 3 attributes made the ads less likely to be clicked, the last made them more likely to be clicked.

Change in Behaviors of Interest

On average, 407 people searched for each of the 7 behaviors of interest. These people made, on average, 2716 queries for each of these behaviors (excluding the queries that triggered the ad display).

We defined an increase in behavior as, *when a user began engaging in a behavior after the ad was shown to them, where this user did not engage in this behavior before the ad was shown, and a decrease as the ceasing search for a behavior after the ad was shown, when the user was searching for it before the ad was shown*. We note that our analysis in this part is based on exposure to the ads and not only for those ads that were clicked. We did it for 2 reasons.

Figure 2. (A) Number of times that advertisements were shown and (B) the click-through rates by age and gender.

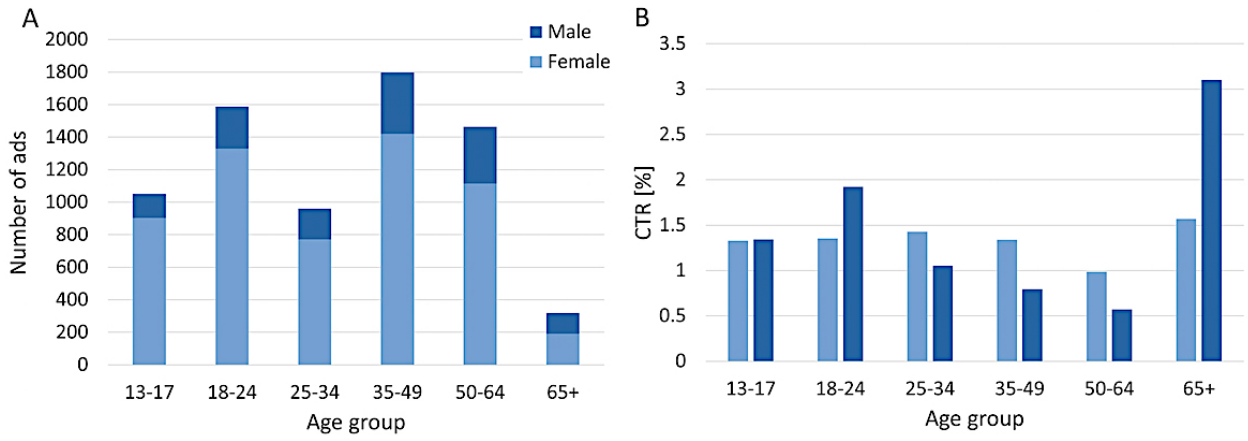
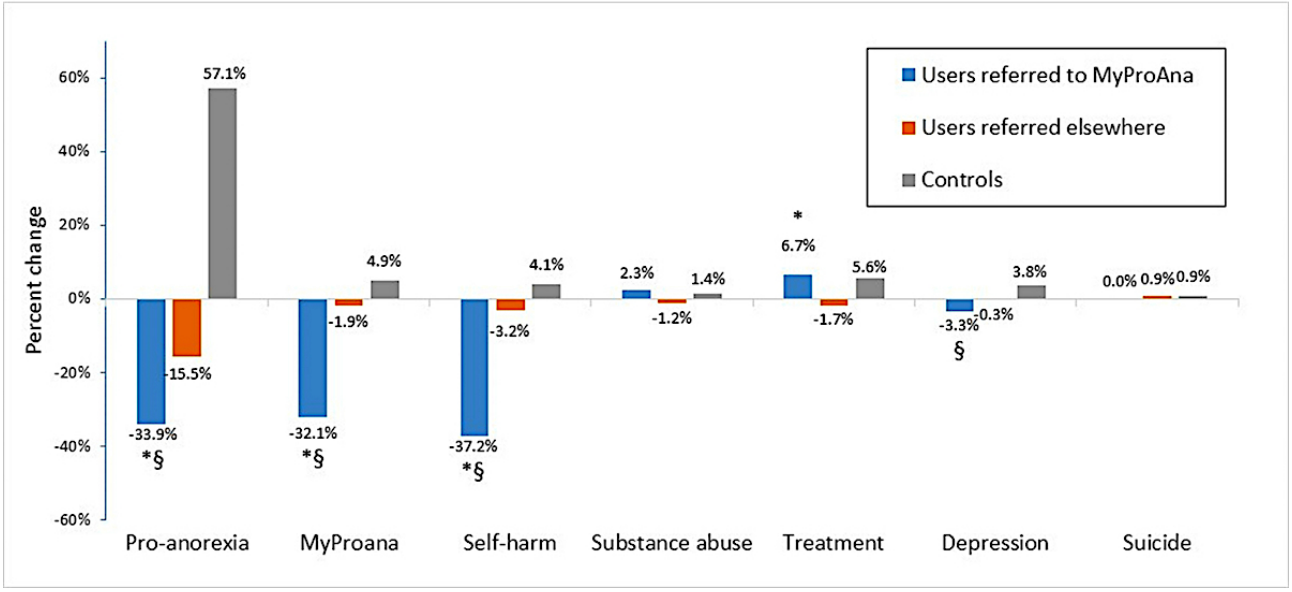


Figure 3. Change in behaviors following ads display. The "*" denotes that the difference between the users referred to MyProAna was statistically significantly different from users referred elsewhere at $P<.05$ (rank sum test). The "§" denotes that the difference between the users referred to MyProAna was statistically significantly different from the controls at $P<.05$ (rank sum test).



First, the number of people who were exposed to ads far exceeds the number of people who clicked on them. Second, previous work [23] has found that exposure is often sufficient to elicit behavioral change. Figure 3 shows the average change in behavior for 3 populations, which were as follows: (1) people who were shown ads referring them to the MyProAna site (n=87); (2) people who were shown ads referring them to one of the two other sites (n=1676), and (3) a random sample of people who made searches containing the same target keywords, but were not shown the ads (n=10,000). Note that no statistically significant difference was found when comparing the 3 populations by age and gender (chi-squared test, $P>.05$).

As Figure 3 shows, people who were referred to MyProAna reduced their search for this website (as can be expected, if they access the site later directly, and not via Bing), but also for pro-ana content and for self-harm content. These reductions were greater than the reductions for users who were referred elsewhere, who experienced the reduction to a smaller extent, and to the control users, who increased their behaviors. Users referred to MyProAna increased their search for treatment, as did control users, who did so to a lesser extent. Users referred elsewhere decreased their searches for this content. Only minor changes were found for the remaining 3 behaviors. Thus, our ads, when they referred people to the MyProAna website, reduced seeking of self-harm and pro-ana content and increased searches for treatment, compared with other populations. We cannot determine whether the individuals directed to MyProAna decreased their search behaviors for pro-ana content and self-harm content because they found their search goal at the MyProAna site or because they did not consume such content anymore. However, given that searches for treatment increased, it is more likely that the latter is true.

We further tested the effect of individual ads on the change in behavior by modeling the attributes of the ads and of the users who saw them using a linear regression model.

Table 4. Statistically significant attributes obtained for each behavior. Attributes in quotation marks refer to a specific ad by its title.

Attribute	Slope (SE[a])	*t* statistic	*P* value[b]
Pro-ana [c] (R^2=.09)			
Age	−0.004 (0.001)	−5.66	<.001
Ad position (rank)	−0.021 (0.010)	−2.03	.04
"Suffer from ED?"[d]	0.119 (0.039)	3.04	.002
"Want to be thinner?"	0.233 (0.090)	2.58	.01
Self-harm (R^2=.13)			
Age	0.002 (0.001)	2.40	.02
Number of previous ads	−0.005 (0.001)	−6.57	<.001
Substance abuse (R^2=.05)			
Referred to MyProAna	0.381 (0.157)	2.42	.02
"Want to be thinner?"	0.484 (0.209)	2.31	.02
Number of previous ads	−0.043 (0.012)	−3.44	.001
Negative view of ED	0.289 (0.098)	2.95	.003
Treatment	−0.189 (0.090)	−2.10	.04
Treatment (R^2=.01)			
"Want to be thinner?"	0.215 (0.105)	2.05	.04
Number of previous ads	0.032 (0.001)	3.98	<.001
Suicide (R^2=.03)			
Number of previous ads	0.126 (0.029)	4.28	<.001

[a]SE: standard error.

[b]Statistically significant (P<.05) attributes for predicting the change in behavior.

[c]Pro-ana: pro-anorexia.

[d]ED: eating disorder.

The attributes used to model each ad display were as follows: user attributes (age, gender), whether the ad was clicked, ad location (position and rank), URL, ad text, number of previous ads that the user was shown, ad position (top or right, and order of display), and ad categories (as detailed in the Methods section, using the scores of the crowdsourced workers). Statistically significant attributes (P<.05) as well as the total explanatory power of the model for each behavior (through the coefficient of determination, R^2) are shown in Table 4. Several observations can be made from Table 4. First, models for pro-ana searches, self-harm, and, to a lesser extent, substance abuse are most predictive, meaning that for those behaviors our models are most accurate in predicting behavioral change. Second, the number of previous ads plays an important role in several models, but not always in the same way; more exposure to our ads results in less self-harm and substance abuse, but more suicide search and treatment queries. Finally, for the pro-ana model, people of lower age were more likely to change their behavior following our ads. The most effective ads were those that either suggested a wish to be thinner or proposed that the person is suffering from their ED.

Discussion

This study's results indicate that ads may change the online search behavior of users looking for pro-ana content. Importantly, our study did not find that the ads caused any significant indications of additional harmful online behavior.

Indeed, high exposure to the proposed ads was associated with a decrease in self-harm and substance abuse and an increase in treatment searches. A small increase in suicide-related queries was observed when searchers were repeatedly exposed to ads, where the model explained a very small part of the variance, requiring additional research to validate this possible harm. These finding are in line with previous studies in other areas (eg, smoking cessation), indicating a possible behavioral change based on usage of online ads [31-33]. Interestingly, when an ad referred people to the MyProAna website, it had a beneficial influence, as observed by fewer harmful searches. Specifically, among those referred to MyProAna, there was a reduction in the searches for pro-anorectic content as well as self-harm content. This is especially impressive as the control group (which was not presented with the experiment ads) increased their behavior. This study suggests that self-harm online

behaviors could be changed using simple and cost-effective online ads.

One explanation for the decrease in pro-ana and self-harm queries might be that people referred to the pro-ana website found information on these topics within the website. However, this explanation is neither congruent with the reduction in pro-ana searches in people who were referred to NIMH and the Eating Disorders Association website nor the increase in treatment searches. Thus, we can hypothesize that the change in searches may be reflective of the user's satisfaction related to information quality, feelings of being understood, and feeling of support and community adherence.

The most effective ads were those that addressed both the addictive search for thinness and control and the emotional suffering and distress. Moreover, varied ads are required for a successful campaign, which can elicit behavioral change. In addition, ads referring to NIMH and those with negative views of ED were less likely to be clicked. We hypothesize that the use of a complex motivational approach addressing both the irresistible addiction and the emotional suffering through the ad, instead of the standard psychoeducational health-oriented nondialectic wording, changes the search behavior. This is in line with the finding [33,34] which indicated that emotional ads are more effective than educational ads. Moreover, when targeting users showing an interest in EDs, it is important to use various ads that can elicit behavioral change. These varied ads may influence different types of populations dealing with EDs or populations that hold both aspects of addiction and distress. Interestingly, users and ED specialists only partially agreed on some aspects of the ads. This finding is in line with the previous studies showing that people dealing with ED issues or patients suffering from ED view ED topics differently from professional specialists [35]. It can be hypothesized that specialist ED workers interpret the ads adopting the role of a professional motivated to encourage change and are less *objective* than laypersons when characterizing the different meanings of the ads.

The main limitation of the study is that changing online searches does not necessarily mean real behavior changes offline. Moreover, this study did not include an actual model of behavior change. Though past studies have found that online behavior corresponds to offline behavior, this is not assured to happen in all cases. In addition, the study examined the ads and not the sites. This study was unable to statistically differentiate between users who were presented with the ads and those who also entered the websites via the provided links. Future studies should aim to differentiate between the two groups. Another limitation is that the keywords chosen to trigger the ads can be used by both people suffering from a ED and ones with a passing interest in them, and it is possible that more targeted forms of advertising can be even more effective. Therefore, any search changes we observed are likely to underestimate the true power of the ads. Finally, our demographic data were based on self-reports by part of the sample included.

Given these limitations, this study has important clinical implications. The main one is that a cost-effective use of online ads may change a user's searches and website visits. Users searching for pro-ana content or visiting pro-ana websites can potentially be redirected to search healthier content and to visit less harmful websites.

Our findings suggest that people preoccupied with ED issues, those who are suffering from an ED, and those who have the potential to develop an ED can be redirected to less pathological online searches when appropriate pathways are offered. However, sites should not be focused solely on providing formal information and preaching an urgent change. Future work will focus on new ways to attract users searching for ED content. These new ways require the acceptance of ambivalence and encouragement of self-disclosure, dialogue, and empathic support.

Authors' Contributions

All authors contributed to the conception and design of the study. EYT performed the experiments and the first pretest (for nonspecialists). He was also in charge of data preparation and statistical analysis; thus, he was in charge of the method section. ABK SF, AH, and OM made substantial contributions in the interpretation of the data and were in charge of the other sections. OM performed the second pretest (for specialists). All authors reviewed and approved the final manuscript.

Conflicts of Interest

EYT is an employee of Microsoft Research Israel.

Editorial notice: This randomized study was only retrospectively registered. The editor granted an exception of ICMJE rules for prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 302KB - mental_v5i1e6_app1.pdf]

References

1. Harshbarger JL, Ahlers-Schmidt CR, Mayans L, Mayans D, Hawkins JH. Pro-anorexia websites: what a clinician should know. Int J Eat Disord 2009 May;42(4):367-370. [doi: 10.1002/eat.20608] [Medline: 19040264]
2. Norris ML, Boydell KM, Pinhas L, Katzman DK. Ana and the Internet: a review of pro-anorexia websites. Int J Eat Disord 2006 Sep;39(6):443-447. [doi: 10.1002/eat.20305] [Medline: 16721839]
3. Yom-Tov E, Fernandez-Luque L, Weber I, Crain SP. Pro-anorexia and pro-recovery photo sharing: a tale of two warring tribes. J Med Internet Res 2012 Nov 7;14(6):e151 [FREE Full text] [doi: 10.2196/jmir.2239] [Medline: 23134671]
4. Abbate DG, Gramaglia C, Pierò A, Fassino S. Eating disorders and the Internet: cure and curse. Eat Weight Disord 2006 Jun;11(2):e68-e71. [Medline: 16809973]
5. Bardone-Cone AM, Cass KM. What does viewing a pro-anorexia website do? An experimental examination of website exposure and moderating effects. Int J Eat Disord 2007 Sep;40(6):537-548. [doi: 10.1002/eat.20396] [Medline: 17525952]
6. Harper K, Sperry S, Thompson JK. Viewership of pro-eating disorder websites: association with body image and eating disturbances. Int J Eat Disord 2008 Jan;41(1):92-95. [doi: 10.1002/eat.20408] [Medline: 17634964]
7. Rouleau CR, von Ranson KM. Potential risks of pro-eating disorder websites. Clin Psychol Rev 2011 Jun;31(4):525-531. [doi: 10.1016/j.cpr.2010.12.005] [Medline: 21272967]
8. Wilson JL, Peebles R, Hardy KK, Litt IF. Surfing for thinness: a pilot study of pro-eating disorder Web site usage in adolescents with eating disorders. Pediatrics 2006 Dec;118(6):e1635-e1643. [doi: 10.1542/peds.2006-1133] [Medline: 17142493]
9. Yom-Tov E, Brunstein-Klomek A, Hadas A, Tamir O, Fennig S. Differences in physical status, mental state and online behavior of people in pro-anorexia web communities. Eat Behav 2016 Aug;22:109-112. [doi: 10.1016/j.eatbeh.2016.05.001] [Medline: 27183245]
10. Brotsky SR, Giles D. Inside the “pro-ana” community: a covert online participant observation. Eat Disord 2007;15(2):93-109. [doi: 10.1080/10640260701190600] [Medline: 17454069]
11. Csipke E, Horne O. Pro-eating disorder websites: users' opinions. Eur Eat Disord Rev 2007 May;15(3):196-206. [doi: 10.1002/erv.789] [Medline: 17676689]
12. Tong ST, Heinemann-Lafave D, Jeon J, Kolodziej-Smith R, Warshay N. The use of pro-ana blogs for online social support. Eat Disord 2013;21(5):408-422. [doi: 10.1080/10640266.2013.827538] [Medline: 24044597]
13. Tierney S. The dangers and draw of online communication: pro-anorexia websites and their implications for users, practitioners, and researchers. Eat Disord 2006;14(3):181-190. [doi: 10.1080/10640260600638865] [Medline: 16807213]
14. Fox N, Ward K, O'Rourke A. Pro-anorexia, weight-loss drugs and the internet: an “anti-recovery” explanatory model of anorexia. Sociol Health Illn 2005 Nov;27(7):944-971 [FREE Full text] [doi: 10.1111/j.1467-9566.2005.00465.x] [Medline: 16313524]
15. Mulè A, Sideli L. Eating disorders on the web: risks and resources. Stud Health Technol Inform 2009;144:8-12. [Medline: 19592719]
16. Murphy R, Frost S, Webster P, Schmidt U. An evaluation of web-based information. Int J Eat Disord 2004 Mar;35(2):145-154. [doi: 10.1002/eat.10245] [Medline: 14994351]
17. Myers TC, Swan-Kremeier L, Wonderlich S, Lancaster K, Mitchell JE. The use of alternative delivery systems and new technologies in the treatment of patients with eating disorders. Int J Eat Disord 2004 Sep;36(2):123-143. [doi: 10.1002/eat.20032] [Medline: 15282683]
18. Carrard I, Rouget P, Fernández-Aranda F, Volkart AC, Damoiseau M, Lam T. Evaluation and deployment of evidence based patient self-management support program for Bulimia Nervosa. Int J Med Inform 2006 Jan;75(1):101-109. [doi: 10.1016/j.ijmedinf.2005.07.031] [Medline: 16115793]
19. Winzelberg AJ, Eppstein D, Eldredge KL, Wilfley D, Dasmahapatra R, Dev P, et al. Effectiveness of an Internet-based program for reducing risk factors for eating disorders. J Consult Clin Psychol 2000 Apr;68(2):346-350. [Medline: 10780136]
20. Evans DS. The online advertising industry: economics, evolution, and privacy. J Econ Perspect 2009;23(3):37-60. [doi: 10.1257/jep.23.3.37]
21. Kohavi R, Crook T, Longbotham R, Frasca B, Henne R, Ferres JL, et al. Online experimentation at Microsoft. Data Mining Case Stud 2009 [FREE Full text]
22. Yan J, Liu N, Wang G, Zhang W, Jiang Y, Chen Z. How much can behavioral targeting help online advertising? In: Proceedings of the 18th international conference on World wide web. 2009 Presented at: 18th international conference on World wide web; April 20-24, 2009; Madrid, Spain p. 261-270. [doi: 10.1145/1526709.1526745]
23. Yom-Tov E, Muennig P, El-Sayed AM. Web-based antismoking advertising to promote smoking cessation: a randomized controlled trial. J Med Internet Res 2016 Nov 21;18(11):e306 [FREE Full text] [doi: 10.2196/jmir.6563] [Medline: 27872032]
24. Yom-Tov E. Crowdsourced Health: How What You Do on the Internet Will Improve Medicine. Boston, MA, USA: MIT Press; 2016.
25. Yom-Tov E, Borsa D, Hayward AC, McKendry RA, Cox IJ. Automatic identification of Web-based risk markers for health events. J Med Internet Res 2015 Jan 27;17(1):e29 [FREE Full text] [doi: 10.2196/jmir.4082] [Medline: 25626480]
26. White RW, Horvitz E. Evaluation of the feasibility of screening patients for early signs of lung carcinoma in web search logs. JAMA Oncol 2017 Mar 1;3(3):398-401. [doi: 10.1001/jamaoncol.2016.4911] [Medline: 27832243]

27. National Eating Disorders. URL: https://www.nationaleatingdisorders.org// [accessed 2018-01-02] [WebCite Cache ID 6wAPEhbbl]
28. NIMH. Eating Disorders: About More Than Food URL: https://www.nimh.nih.gov/health/publications/eating-disorders/index.shtml [accessed 2018-01-02] [WebCite Cache ID 6wAPWp4B3]
29. Myproana. URL: http://www.myproana.com/ [accessed 2018-01-02] [WebCite Cache ID 6wAPgpjJq]
30. ComScore. ComScore Releases February 2016 U.S. Desktop Search Engine Rankings URL: https://www.comscore.com/Insights/Rankings/comScore-Releases-February-2016-US-Desktop-Search-Engine-Rankings [accessed 2017-12-26] [WebCite Cache ID 6w08lkXur]
31. Briggs R, Hollis N. Advertising on the Web: is there response before click-through? J Advert Res 1997;37(2):33-45.
32. Durkin S, Bayly M, Cotter T, Mullin S, Wakefield M. Potential effectiveness of anti-smoking advertisement types in ten low and middle income countries: do demographics, smoking characteristics and cultural differences matter? Soc Sci Med 2013 Dec;98:204-213. [doi: 10.1016/j.socscimed.2013.09.022] [Medline: 24331900]
33. Niederdeppe J, Farrelly MC, Nonnemaker J, Davis KC, Wagner L. Socioeconomic variation in recall and perceived effectiveness of campaign advertisements to promote smoking cessation. Soc Sci Med 2011 Mar;72(5):773-780. [doi: 10.1016/j.socscimed.2010.12.025] [Medline: 21316830]
34. Durkin SJ, Biener L, Wakefield MA. Effects of different types of antismoking ads on reducing disparities in smoking cessation among socioeconomic subgroups. Am J Public Health 2009 Dec;99(12):2217-2223 [FREE Full text] [doi: 10.2105/AJPH.2009.161638] [Medline: 19833980]
35. de la Rie S, Noordenbos G, Donker M, van Furth E. The quality of treatment of eating disorders: a comparison of the therapists' and the patients' perspective. Int J Eat Disord 2008 May;41(4):307-317. [doi: 10.1002/eat.20494] [Medline: 18095309]

Abbreviations

BT: behavioral targeting
CDC: Centers for Disease Control and Prevention
CTR: click-through rate
EDNOS: eating disorder not otherwise specified
EDs: eating disorders
IDC: Interdisciplinary Center
LSD: lysergic acid diethylamide
NEDA: National Eating Disorders Association
NIMH: National Institutes of Mental Health
Pro-ana: Pro-anorexia
RCT: randomized controlled trial
SE: standard error
URL: Uniform Resource Locator

Edited by G Eysenbach; submitted 15.06.17; peer-reviewed by A Milton, T Chen, R Rodgers; comments to author 29.09.17; revised version received 23.10.17; accepted 22.11.17; published 22.02.18.

Please cite as:
Yom-Tov E, Brunstein-Klomek A, Mandel O, Hadas A, Fennig S
Inducing Behavioral Change in Seekers of Pro-Anorexia Content Using Internet Advertisements: Randomized Controlled Trial
JMIR Ment Health 2018;5(1):e6
URL: http://mental.jmir.org/2018/1/e6/
doi:10.2196/mental.8212
PMID:29472176

Original Paper

Evaluation of an mHealth App (DeStressify) on University Students' Mental Health: Pilot Trial

Rebecca Anne Lee[1], MSc; Mary Elizabeth Jung[1], PhD

Faculty of Health and Social Development, University of British Columbia, Kelowna, BC, Canada

Corresponding Author:
Mary Elizabeth Jung, PhD
Faculty of Health and Social Development
University of British Columbia
1147 Research Road
FHSD-ART360
Kelowna, BC, V1V 1V7
Canada
Phone: 1 2508079670
Fax: 1 2508079965
Email: mary.jung@ubc.ca

Abstract

Background: One in five Canadians experience mental health issues with those in the age range of 15 to 24 years being most at risk of a mood disorder. University students have shown significantly higher rates of mental health problems than the general public. Current university support services are limited by factors such as available staff and finances, and social stigma has frequently been identified as an additional barrier that prevents students from accessing these resources. Mobile health (mHealth) apps are one form of alternative health support that is discrete and accessible to students, and although they are recognized as a promising alternative, there is limited research demonstrating their efficacy.

Objective: The aim of this study was to evaluate a mindfulness-based app's ("DeStressify") efficacy on stress, anxiety, depressive symptomology, sleep behavior, work or class absenteeism, work or school productivity, and quality of life (QoL) among university students.

Methods: Full-time undergraduate students at a Canadian university with smartphones and Internet access were recruited through in-class announcements and on-campus posters. Participants randomized into an experimental condition were given and instructed to use the DeStressify app 5 days a week for 4 weeks. Control condition participants were wait-listed. All participants completed pre- and postintervention Web-based surveys to self-assess stress, anxiety, depressive symptomatology, sleep quality, and health-related QoL.

Results: A total of 206 responses were collected at baseline, with 163 participants completing the study (86 control, 77 experimental). Using DeStressify was shown to reduce trait anxiety (P=.01) and improve general health (P=.001), energy (P=.01), and emotional well-being (P=.01) in university students, and more participants in the experimental condition believed their productivity improved between baseline and postintervention measurements than the number of participants expected to believe so randomly by chance (P=.01). The app did not significantly improve stress, state anxiety, physical and social functioning, and role limitations because of physical or emotional health problems or pain (P>.05).

Conclusions: Mindfulness-based apps may provide an effective alternative support for university students' mental health. Universities and other institutions may benefit from promoting the use of DeStressify or other mindfulness-based mHealth apps among students who are interested in methods of anxiety management or mindfulness-based self-driven health support. Future steps include examining DeStressify and similar mHealth apps over a longer period and in university staff and faculty.

(JMIR Ment Health 2018;5(1):e2) doi:10.2196/mental.8324

KEYWORDS

mHealth; mindfulness; mental health; students

Introduction

Prevalence of Mental Health Issues

One in five Canadians will experience a mental health issue [1], with those in the age range of 15 to 24 years being the most at risk of meeting criteria for a mood and substance abuse disorder [2]. University students are of particular concern as they have shown significantly higher rates of mental health problems than the general public [3]. In recent years, mental health support services on university campuses have experienced high volumes of appointment requests but are limited in the amount of support they are able to provide. Counseling center directors have previously listed wait-list issues and funding concerns among necessary improvements for Canadian postsecondary counseling services, with 78% reporting being unable to meet the growing demand for services [4]. Today, postsecondary counseling center staff have noted that centers are still in need of additional resources to meet student requests [5]. The average wait time to receive mental health treatment services in Canada is 19.3 weeks [6], and students at some institutions may have to wait up to 6 months for individual treatment [7], meaning many students are left without support.

Impact on Students

Mental health issues have been shown to negatively impact student academic performance [8,9], with stress, anxiety, and sleep difficulties found to be the top three factors most frequently reported by students [10]. Additionally, diagnosed depression has been associated with decreased academic performance [11] and health problems such as back pain, diabetes, irritable bowel syndrome, and migraine headaches [12]. Unfortunately, when students attempt to manage their mental health issues, they do not always engage in healthy coping mechanisms. A survey of 212 American college students found that only 5% reach out to a professional for stress-related management, with more students instead turning to drinking, smoking, and using illegal drugs [13]. Despairingly, avoidance of seeking professional help for assistance with mental health on university campuses is a worldwide problem [3,14-16]. Reasons for not engaging with professional mental health support included perceiving stress as normal for university or graduate school, fear of judgment, shame, and uncertainty of effectiveness [15,16].

Another notable barrier to seeking mental health aid is stigma [17-19], which may be perpetuated or endorsed by others or internalized by the individual [20]. Stigma associated with mental illness precludes many people from seeking face-to-face counseling [20,21], particularly for those experiencing depressive symptoms, stress, and anxiety [22,23]. Results from a study on help-seeking behaviors and access to health care within a university population showed that 20% of students who did not use support services despite reporting symptoms of anxiety and depressive disorders did so because they were worried about what people would think. Another 20% said that they did not seek help because they thought that others wouldn't understand their problems [16]. Among Japanese university students, feeling ashamed and worrying about other people's opinions were listed as barriers to visiting mental health professionals [15].

Issues With Current Resources

Canadian universities currently provide services and programs to support student mental health, but these services and programs have shortcomings. First, the rise in serious mental health concerns has been associated with an increase in demand for on-campus counseling; yet, university counseling centers have not been able to meet these demands with adequate staffing [5,6]. Furthermore, on-campus counselors are often advised to only take on patients short-term, with policies often limiting the number of sessions allowed per patient [4,24]. Although these policies may allow for a greater number of students to access counselors, it does not necessarily ensure that clients are receiving the long-term support that they are seeking or need. Some institutions have attempted to address this concern by providing group counseling sessions. However, as many students have reported concerns of stigma as a barrier to seeking mental health support [14,25], they may avoid group sessions for fear of being recognized by group members. Additionally, lack of time is a notable barrier to mental health service use [26,27], and group therapy sessions may be too time consuming for students to commit to.

Mindfulness and Mobile Health (mHealth) Apps as Alternative Resources

Taking into account the barriers to current university mental health support services, an appeal can be made for an alternative, more accessible service. Mobile health (mHealth) phone apps may be a service that addresses these barriers. Mobile phones are integrated into the daily lives of nearly all university community members and can be discreetly used by students to participate in app-based mental health support programs. Individuals seeking help can receive online assistance in a nonthreatening manner that is also feasible and capable of reaching a wide number of people [28]. mHealth apps have high acceptability among users [29,30] and are reportedly more comfortable to use in public compared with other intervention formats such as when used to track diet for weight loss purposes [29]. They are publicly accessible, can be used at a person's discretion, and hold promise of appealing to people who are not clinically diagnosed with a mental illness but nonetheless have concerns. mHealth apps may also cater to people's desire to manage their problems on their own [14,28] by providing a support that can be independently used. Additionally, mHealth apps are user friendly: they are easy to use, have minimal time commitment [29], and can be used at any time that is convenient or necessary. These features can help ensure user anonymity and accessibility, making mHealth apps an appealing mental health support alternative.

Apps provide an inconspicuous and convenient mode of delivery for health interventions and may assist in improving accessibility of evidence-based monitoring and self-help [30]. A systematic review of 24 studies concerning the behavioral functionality of mHealth apps found that apps may provide a feasible delivery method for health interventions and have shown potential to bring about behavioral changes such as increasing physical activity and reducing alcohol consumption [29]. However, a

systematic review of studies concerning mHealth app efficacy conducted by Donker et al [30] found that of over 3000 mental health apps available at time of study, only 8 studies within the systematic review were identified as evidence-based and only one study utilized a university sample. The latter study evaluated the effectiveness of an Italian mHealth app called Mobile Stress Management at decreasing anxiety and improving coping skills in female university students in comparison to a control condition. This study, as described in the Methods section, advances the literature by including nonfemale participants, using an English mHealth app, and evaluating additional outcomes. Donker et al [30] also found measurements regarding sleep disturbances and anxiety disorders to be particularly lacking in the literature. Similarly, Grist et al [31] argue that there is an insufficient amount of evidence to support the effectiveness of mHealth apps supporting the mental health of adolescents and youth. Both Payne et al [29] and Donker et al [30] identified small sample sizes as a limitation in the current literature on mHealth apps in their systematic reviews. A total of 227 participants were recruited across the 8 studies reviewed by Donker et al, and 17 of the 24 studies reviewed by Payne et al had sample sizes under 100.

Preliminary studies of nonapp-based interventions have shown mindfulness to be a promising tool for helping university students manage their stress and anxiety. Mindfulness is described as the focusing of attention on the present moment, including an awareness of the body and thoughts that is accomplished without judgment [32]. For example, one study involving first-year undergraduate students found that adapted mindfulness-based stress reduction (MBSR) interventions may improve students' physiological and psychological well-being [33]. The adapted MBSR techniques included reading assignments, discussion, meditation, and yoga and were performed 2 hours a week for 8 weeks. Students demonstrated enhanced personal-emotional adjustment and reduced physiological stress. Similarly, researchers at the University of Northampton found that students who participated in an 8-week mindfulness-based program demonstrated significant decreases in perceived stress, anxiety, and depression as compared with a wait-list control group [34]. These findings were supported by a study in 2014 involving 458 university students that found mindfulness to be associated with improved mental health (eg, reduction in symptoms of depression, anxiety, hostility, and paranoia) [35]. Mindfulness-based interventions are increasing in public interest, and these preliminary findings suggest it may be a promising way of helping university students improve their mental health.

Current Gap in the Literature

Recent studies have shown app-based supports and mindfulness to be promising ways of addressing mental health concerns, yet, there is a lack of research regarding mindfulness-based techniques delivered through apps. This finding is surprising considering the exhaustive number of mindfulness-based mHealth apps available for purchase. In a recent study evaluating the feasibility of an Internet-based mindfulness training program among university students in Sweden, researchers found that users generally enjoyed the program and its flexibility regarding time and location of use, yet, found no significant intervention effect on psychological well-being or depression symptoms when compared with an Internet-based "expressive writing" program [36]. It is important to note that the mindfulness training was extensive—with participants encouraged to practice 30 to 45 min a day for 6 or 7 days a week. Evaluation of mindfulness-based apps that are less time-intensive than the typical length of in-person mindfulness-based training is needed.

Research Objective and Hypotheses

This study addressed this gap in the literature by evaluating the efficacy of a commercially available mindfulness-based app, called DeStressify by Stress Refuge Inc (hereafter "DeStressify"), on stress, anxiety, and depressive symptomology within a university population. The cofounder and chairman of Stress Refuge, Inc claimed DeStressify was initially developed for teachers, organizations, and the general public. It was launched in 2014, and a study conducted by DeStressify staff showed a 20% reduction in self-reported stress levels after 4 weeks of app use within a sample of teachers (Ulco Visser, email communication, September 14, 2017). However, no previously published research evaluating DeStressify has been found by the authors of this study.

The app contains a core plan that delivers mindfulness-based exercises through audio, video, or text files that require between 3 to 23 min to complete. Example titles of these exercises include grounding visualization, gratitude, imagining the life you want, and finding meaning. There are free and purchasable "pro" versions of the app available for download. The core plan is available on both the free and pro version of DeStressify, with the pro version offering additional features including "my friends," "nutrition," and "shop" options. It was hypothesized that students who use DeStressify would report significantly lower stress, anxiety, and depressive symptomatology as compared with a wait-list control sample post intervention. Secondary outcomes relevant for this specific study population included sleep behavior, work or class absenteeism, work or school productivity, and quality of life (QoL). It was hypothesized that compared with matched wait-list control participants, the participants using DeStressify would report significantly greater sleep quality, school or work productivity and QoL and significantly less class or work absenteeism at postintervention.

Methods

Design

In the systematic review of mHealth app studies by Donker et al [30], recruitment within each study ranged from 8 to 117 participants. For this pilot, exploratory study, sample size was calculated through a power analysis using G*Power statistical power analysis software [37]. Effect size estimate calculations were made with the Cohen Perceived Stress Scale (PSS) values from a study by Chang et al [38] in which university students participated in an 8-week MBSR intervention that included group meditation sessions and home practice. Cronbach alpha was set at .05, power at 0.80, and effect size at 0.37. A power analysis indicated a sample size of 61 would be required to test the hypotheses. It is important to note that the intervention used

by Chang et al [38] included 20 hours of in-class mindfulness practice and 36 hours of assigned home practice. In consideration of the power analysis, the intervention design differences between this study and that of Chang et al [38], the sample size range in studies reviewed by Donker et al [30], and an anticipated dropout of some participants from pre- to postintervention, a recruitment goal of 200 participants was used.

Procedure

Participants were recruited through poster advertisements, in-class announcements, and emails to administrative assistants of various faculties across the University of British Columbia (UBC) Okanagan campus. Individuals interested in participating in the study emailed the researcher assistant and received a link to the Web-based eligibility survey, consent form, and baseline survey. Eligibility criteria included (1) enrollment in full course load during the winter term at the UBC Okanagan campus in an undergraduate program, (2) ownership of a smartphone, (3) regular access to the Internet, and (4) fluent comprehension of the English language. Participants indicated consent by clicking an "I consent" button after reading an information page regarding the study. Following the completion of the baseline survey, participants were randomized into either an experimental or wait-list control condition using a computer-generated random numbers table. Random numbers were generated in batches of 50 with equal counts for both treatment conditions (ie, 25 total for each). Individuals in the experimental condition were provided the pro version of DeStressify and were asked to not engage with other features of the app during the course of the study. According to the app's website, it takes about 1 month to complete the core plan if practicing 3 days a week. To help ensure that participants were completing the core plan, and in recognizing that users may not engage with the app as frequently as recommended, individuals in the experimental condition were instructed to use the app's core plan 5 days a week for 4 weeks. Participants could set reminders to use the app through the app itself, and an email reminding participants that they were to receive a follow-up email after 4 weeks of app use was sent to participants in the experimental condition half way through the intervention. Individuals in the control condition were given no treatment and no intervention material until after the postintervention survey was completed, at which time they were provided the app and similar guidelines for use as the experimental condition. The follow-up period was 4 weeks post baseline, at which point all participants were sent a second Web-based questionnaire. All participants who completed both surveys received an electronic Can $25 Amazon gift card. Data were collected and stored on secure systems and accessed through computers with password protection and encryption. This study was approved by the institutional review board.

Measures

All participants completed a baseline survey composed of questions regarding demographic characteristics and 6 validated self-reported measures of stress, anxiety, depressive symptomatology, sleep quality, QoL, and work productivity. Each measure was presented on a separate page in the survey, and participants were able to use a "back" button to review and change their answers before submitting their completed surveys. Participant responses were identified by their email addresses.

Demographic measurements of sex, age, income, ethnic origin, educational background, and university program of enrollment were included at the baseline assessment. Participants were also asked to identify any mental health disorder diagnoses they had, whether they were using mental health services, and if so, for how long.

Perceived stress was measured using the PSS, which contained 10 items requiring respondents to indicate how often they felt or thought a certain way over the past month [39]. Scores could range from 0 to 40 with a mean score of 14.2 for people in the age range of 18 to 29 years and 12.1 and 13.7 for males and females, respectively [39]. The PSS has shown validity and reliability within samples of college students [40].

Anxiety was measured using the State-Trait Anxiety Inventory for adults, which contained 40 items in two subscales: state anxiety and trait anxiety [41]. Each subscale included 20 statements that people may use to describe how they feel. Participants were asked to indicate how accurately each statement described them presently for state anxiety and in general for trait anxiety. Responses were scored to yield a collective score that could vary between 20 and 80 for each subscale. Both subscales have shown reliability, validity, and internal consistency within samples of high school and college students [41].

Symptoms of depression were measured using The Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR), with ratings made in consideration of the past 7 days [42]. It contained 16 items that divided into the nine symptom criterion domains associated with the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition for major depressive disorder (MDD): low mood, concentration, self-criticism, suicidal ideation, loss of interest in activities, energy or fatigue, sleep disturbance, changes in appetite or weight, and psychomotor agitation or retardation. Scores, which can range from 0 to 27, can be divided into 5 categories associated with different classifications of depression severity: none, mild, moderate, severe, and very severe, with a five-point change in score associated with a change in classification [43]. The QIDS-SR has shown validity and reliability within a sample of adults with chronic, nonpsychotic MDD [42].

Sleep quality was measured using the Pittsburg Sleep Quality Index (PSQI), which asked participants to complete the measure in consideration of their usual sleep habits over the past month [44]. The measure contained 19 questions for respondents that were scored and combined to form 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. These component scores were added to form a global PSQI score. A global score greater than 5 suggests that the respondent may have difficulties in 2 or more components [44]. An additional 5 questions were included for respondents with bed partners or roommates, although these questions did not contribute to score calculations. The PSQI

has shown reliability and validity among "good" and "poor" sleepers with and without sleep-related disorders [44].

Health-related QoL was measured using the RAND 36-Item Health Survey, which included 36 items to address 8 health concepts: physical functioning (eg, ability to perform any physical activity such as bathing and eating), bodily pain, physical health problems that limit ability to perform a specific role (eg, work and daily activities), personal or emotional problems that limit ability to perform a specific role, emotional well-being, social functioning, energy or fatigue, and general health perceptions (ie, beliefs regarding overall health) [45,46].Responses to all items were scored out of 100, and a score for each of the 8 health concepts was calculated by averaging a collection of item scores. These scores represent percentages, where "a higher score defines a more favorable health state" [47]. The RAND 36-Item Health Survey is a popular measure of QoL and has shown acceptable levels of reliability, validity, and internal consistency [48].

Work productivity was measured using the Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI) [49]. Respondents completed 2 to 6 items in consideration of "the effect of (their) health problems on (their) ability to work and perform regular activities" [49], where health problems were defined as "any physical or emotional problem or symptom" [49]. Responses were scored and 4 subscales, expressed in percentages, were calculated: absenteeism, "presenteeism" [49], work productivity loss, and activity impairment. Higher scores indicated greater impairment and productivity loss. The WPAI has shown reliability and validity within a sample of working individuals [49].

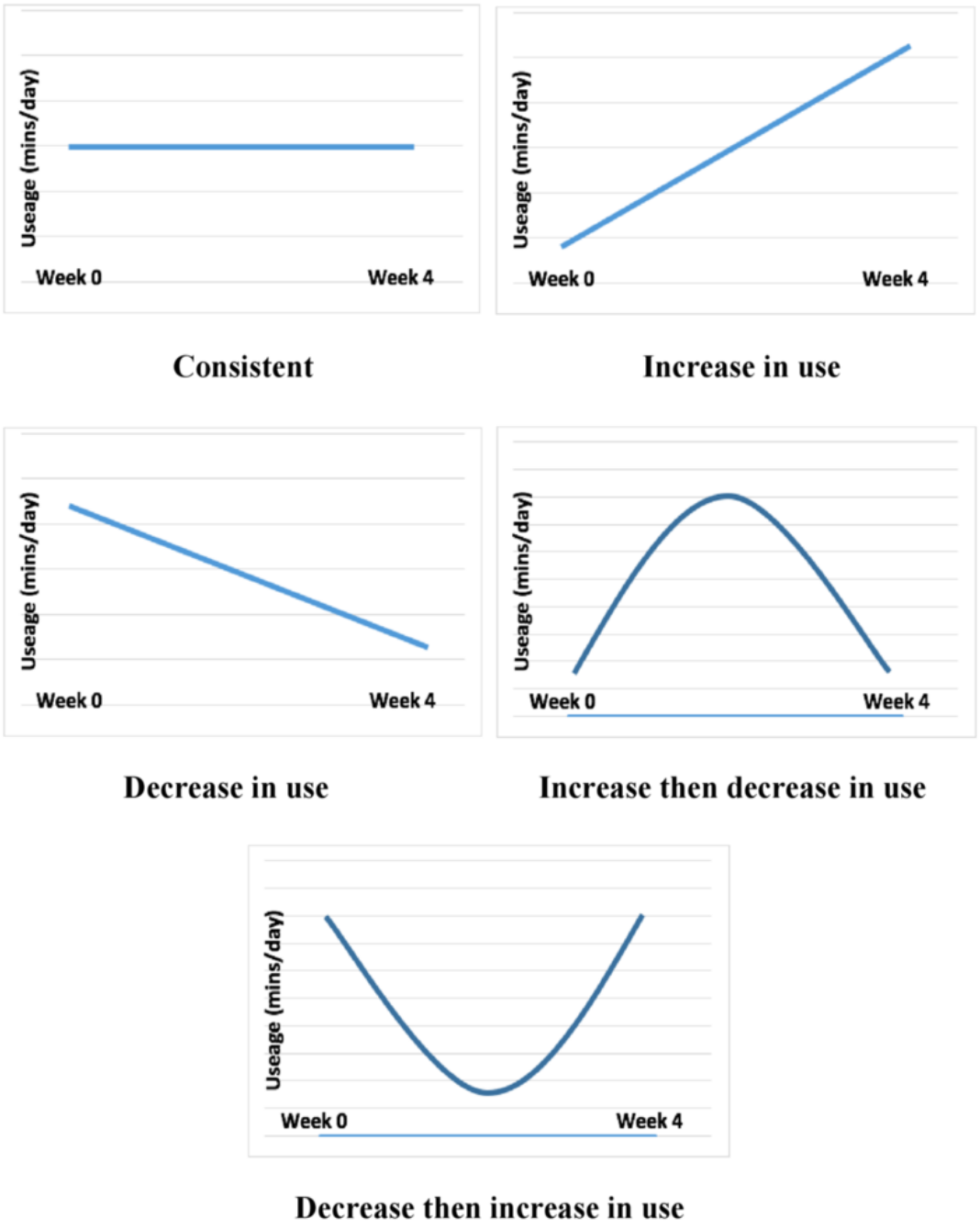
Two additional questions were included in the follow-up surveys for both the experimental and control conditions. For these questions, participants identified whether they believed their sleeping and work or school productivity improved, worsened, or stayed the same since baseline measurements were taken.

App use questions were included in the follow-up survey for the experimental condition. Participants were asked how frequently they used the app in comparison with what was requested at the beginning of the study and their pattern of app use over the 4 weeks. App use frequency was measured using a 10-point scale ranging from "did not use at all" to "used as often as requested." Response options to describe patterns of app use were increased, increased then decreased, consistent, decreased then increased, and decreased and included graphic representations (see Figure 1). All app use data were self-reported.

Analytic Plan

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 23 (IBM Corp). Age distribution of treatment conditions were compared using the Mann Whitney *U* test. Distribution of sex, mental health disorder diagnoses, and mental health service use within treatment conditions were compared using chi-square tests. Distribution of program enrollment within treatment conditions was compared using Fisher exact test. Ethnicity distributions were compared using either chi-square test or Fisher exact test, depending on whether or not the assumptions of the chi-square test were met within each ethnicity category. Changes in pre- and postintervention scores between treatment conditions for measurements of stress, depression, state and trait anxiety, sleep quality, QoL subscales, and work productivity subscales were assessed using analysis of covariance (ANCOVA). For all ANCOVA, postscores were treated as the dependent variable and prescores the covariate. A multivariate analysis of covariance (MANCOVA) was also conducted in which the baseline scores for both state and trait anxiety were assigned as covariates, and the dependent variables were the postintervention state and trait anxiety scores. Chi-square test was conducted to identify differences in perceived work productivity. An alpha level of .05 was used in all statistical tests of significance, and effect size was determined using partial eta squared values. In alignment with suggestions by Cohen, partial eta squared values of .0099, .0588, and .1379 were used to correspond to small, medium, and large effect sizes, respectively [50]. Normality was tested using the Kolmogorov-Smirnov test. Raw scores that were not normally distributed were transformed through square root calculations to produce normality [51]. Univariate outliers were identified as having z-scores with magnitude greater than 3.29 (P<.001). Mutivariate outliers were identified as having Mahalanobis distance values greater than χ^2_2=13.8 when analyzing anxiety scores and χ^2_8=26.1 when analyzing QoL scores, P<.001 [51]. When outliers were present, analyses were run with and without outliers.

Figure 1. Graphic representations of app use trends provided in experimental condition postintervention survey.



Results

Demographics

Responses from 206 students at UBC Okanagan were collected at baseline, with 104 randomized into the control condition and 102 into the experimental condition (see Figure 2). Of the 206 participants, 43 were excluded from analysis because of failure to complete postsurveys (n=41), having a phone that did not support the app (n=1), or a family emergency (n=1). This resulted in 163 responses being used in analysis (86 control, 77 experimental). There were no differences in age, sex, ethnicity, program enrollment, mental health diagnosis percentage, and mental health service use between conditions, $P>.05$ (see Table 1). The percent of participants in both conditions self-reporting mental health diagnoses is noteworthy, although a chi-square test confirmed that the number of people reporting such diagnoses was not statistically different between conditions, $P=.18$. There was also no difference in the percentage of participants in each condition who utilized health care services, $P=.80$. Human kinetics, general arts and sciences, and nursing were the three most common programs for enrollment in both treatment conditions.

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram (template obtained from consort-statement.org).

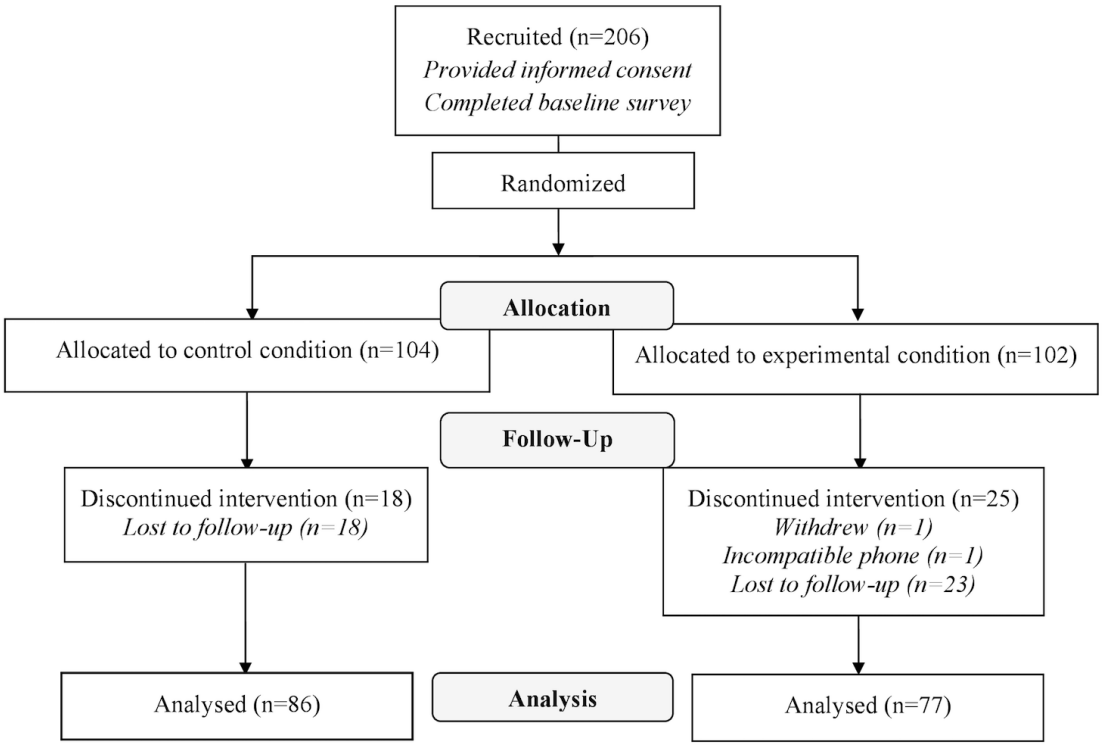


Table 1. Demographics of treatment conditions.

Characteristic	Control (n=86)	Experimental (n=77)
Age (years)		
Range	16-47	18-27
Average	20.9	20.3
Sex, n (%)		
Female	58 (67)	45 (58)
Ethnicity (3 most predominant listed), n (%)		
White	61 (71)	50 (65)
Chinese	9 (11)	12 (16)
South Asian	5 (6)	9 (12)
Program enrollment, n (%)		
Human kinetics	22 (26)	12 (16)
First year arts and sciences	12 (14)	14 (18)
Nursing	11(13)	11 (14)
Mental health diagnosis[a]		
Yes, n (%)	12 (14)	17 (22)
Bipolar, (n)	1	0
Depression, (n)	4	5
Anxiety, (n)	4	6
Other, (n)	3 (obsessive-compulsive disorder and dermotilamania; depression, anxiety, and mania; attention-deficit hyperactivity disorder [ADHD])	11 (adjustment disorder, anxiety, and depression; 3 ADHD; attention-deficit disorder; depression, anxiety, and ADHD; post-traumatic stress disorder [PTSD]; binge eating; depression and anxiety; bipolar, depression, and anxiety; depression, anxiety, and PTSD)
Mental health service use, n (%)		
Yes	10 (12)	10 (13)

[a]Diagnoses taken verbatim from participant responses.

Stress

Perceived stress scores within the experimental condition decreased in value, whereas control condition scores slightly increased in value from baseline to postintervention (see Table 2). However, differences in scores between conditions at postintervention did not reach statistical significance, $F_{1,160}$=3.54, P=.06, η_p^2=.02. Reliability of the PSS and other validated surveys, as determined by Cronbach alpha, is provided in Table 3.

Depression

One participant was excluded from analysis of the QIDS-SR questionnaire as baseline responses were not provided for this measure by the participant. Raw scores were transformed for normality. Mean values for the QIDS-SR scores in Table 2 were calculated using raw data. Postintervention transformed QIDS-SR scores for the experimental condition showed no significant difference from the control condition, $F_{1,159}$=3.01, P=.09, η_p^2=.02, when controlling for baseline scores. Tests were reconducted using nontransformed data, and results were similar, $F_{1,159}$=3.54, P=.06, η_p^2=.02.

Anxiety

One multivariate outlier was identified in the control condition. No univariate outliers were observed in either trait or state anxiety scores. Overall, omnibus F tests of the MANCOVA were significant when the outlier was included, $F_{1,160}$=4.25, P=.02, η_p^2=.05, and excluded, $F_{1,159}$=4.13, P=.02, η_p^2=.05. ANCOVA results demonstrate that individuals in the experimental condition reported less trait anxiety, $F_{1,160}$=8.23, P=.01, η_p^2=.049, than individuals in the control condition after 4 weeks of using the DeStressify app. State anxiety scores did not significantly differ between conditions at postintervention, $F_{1,160}$=1.93, P=.17, η_p^2=.01.

Table 2. Mean values of measures for control (n=86) and experimental (n=77) treatment conditions at baseline and 4 weeks post intervention, excluding outliers. Standard deviations are included in parentheses.

Dependent variable	Pre		Post	
	Control Mean (SD[a])	Experimental Mean (SD)	Control Mean (SD)	Experimental Mean (SD)
State-Trait Anxiety Inventory (STAI) state[b]	44.7 (13.0)	43.0 (12.0)	43.4 (13.2)	40.1 (12.1)
STAI trait[c]	47.6 (11.1)	47.4 (10.6)	47.5 (10.8)	44.5 (9.4)
QIDS-SR[d]	8.1 (4.5)	8.4 (4.3)	7.4 (4.7)	6.4 (3.9)
Physfunct[e,f]	93.8 (7.5)	92.1 (9.8)	93.3 (10.1)	92.1 (10.6)
Physlim[e]	78.2 (32.3)	79.2 (33.3)	77.0 (33.7)	83.8 (30.6)
Emolim[e]	50.4 (42.4)	52.4 (40.3)	49.2 (41.8)	58.4 (42.6)
Energy[e]	45.1 (17.8)	46.2 (20.1)	41.1 (18.9)	48.9 (19.4)
Emowell[e]	60.9 (18.6)	61.1 (20.0)	58.7 (20.1)	66.0 (17.2)
Socialfunct[e]	72.2 (22.4)	74.2 (24.4)	71.4 (24.5)	77.0 (20.2)
Pain[e,g]	78.3 (19.2)	83.5 (19.0)	78.0 (18.6)	84.3 (18.0)
Genhealth[e]	64.7 (20.5)	63.3 (19.5)	61.7 (20.4)	67.5 (17.4)
PSS[h]	19.6 (7.7)	18.6 (6.8)	19.8 (6.7)	17.8 (6.2)
WPAI[i] missedtime[j,k]	4.2 (13.6)	2.1 (3.5)	0.1 (0.2)	0.1 (0.1)
WPAI impairedtime[j,k]	16.6 (21.9)	11.0 (21.7)	20.7 (26.0)	14.3 (23.6)
WPAI overallworkimpair[j,k]	18.1 (25.4)	11.6 (23.4)	28.1 (32.1)	16.6 (27.4)
WPAI activimpair[j]	25.7 (26.5)	22.9 (25.0)	24.0 (26.7)	18.1 (23.5)
PSQI[l]	7.0 (2.8)	6.9 (3.1)	7.0 (3.7)	6.2 (3.1)

[a]SD: standard deviation.

[b]STAI state: State-Trait Anxiety Inventory for Adults—state anxiety.

[c]STAI trait: State-Trait Anxiety Inventory for Adults—trait anxiety.

[d]QIDS-SR: Quick Inventory of Depressive Symptomatology Self-Report.

[e]Physfunct, Physlim, Emolim, Energy, Emowell, Socialfunct, Pain, Genhealth: RAND 36-Item Health Survey—Physical functioning subscale, role limitations because of physical health subscale, role limitations because of emotional health subscale, energy or fatigue subscale, emotional well-being subscale, social functioning subscale, pain subscale, and general health subscale.

[f]Physfunct scores were calculated using n=156 (n_{exp}=75, n_{con}=81).

[g]Pain scores were calculated using n=162 (n_{exp}=76, n_{con}=86).

[h]PSS: Perceived Stress Scale.

[i]WPAI: Work Productivity and Activity Impairment Questionnaire: General Health V2.0.

[j]WPAI missedtime, impairedtime, overallworkimpair, activimpair: Percent work missed because of health, percent impairment while working because of health, percent overall work impairment because of health, and percent activity impairment because of health.

[k]WPAI impairedtime and overallworkimpair scores were calculated using n=50 (n_{exp}=21, n_{con}=29).

[l]PSQI: Pittsburg Sleep Quality Index.

Table 3. Cronbach alpha values for all validated measures using postintervention data (n_{con}=86, n_{exp}=77).

Survey component	Cronbach alpha
PSS[a]	.86
QIDS-SR[b]	.80
State-Trait Anxiety Inventory (STAI) state	.95
STAI trait	.90
PSQI[c]	.72
Physfunct	.88
Physlim	.83
Emolim	.83
Energy	.77
Emowell	.82
Socialfunct	.83
Pain	.83
Genhealth	.78

[a]PSS: Perceived Stress Scale.

[b]QID-SR: Quick Inventory of Depressive Symptomatology Self-Report.

[c]PSQI: Pittsburg Sleep Quality Index.

Sleep Quality

In regards to the baseline scores, there was 1 outlier from each treatment condition that was removed from analysis for sleep quality. Raw scores were transformed for normality. Transformed values were more normally distributed, although both the raw and the transformed scores were significant when tested for normality. Nonetheless, analysis of variances (ANOVAs) were conducted as they are robust given the data's traits [51]. There was no significant differences between treatment conditions in the postintervention scores for both raw, $F_{1,158}$=2.51, P=.12, η_p^2=.02, and transformed scores, $F_{1,158}$=1.89, P=.17, η_p^2=.01, when outliers were excluded. Results were similar when outliers were included (raw: $F_{1,160}$=2.58, P=.11, η_p^2=.016; transformed: $F_{1,160}$=1.91, P=.17, η_p^2=.01).

Quality of Life

Distributions of all subscores for the RAND 36-Item Health Survey were non-normally distributed with the exception of energy or fatigue at baseline for the experimental condition, energy or fatigue at follow-up for both treatment conditions, and general health at follow-up for the control condition. Additionally, the assumption of homogeneity of covariance matrices was not met. However, ANOVA is robust to violations of normality for this data when outliers are excluded [51], and MANOVAs are robust to heterogeneity of covariance matrices when sample sizes are equal [50,51].

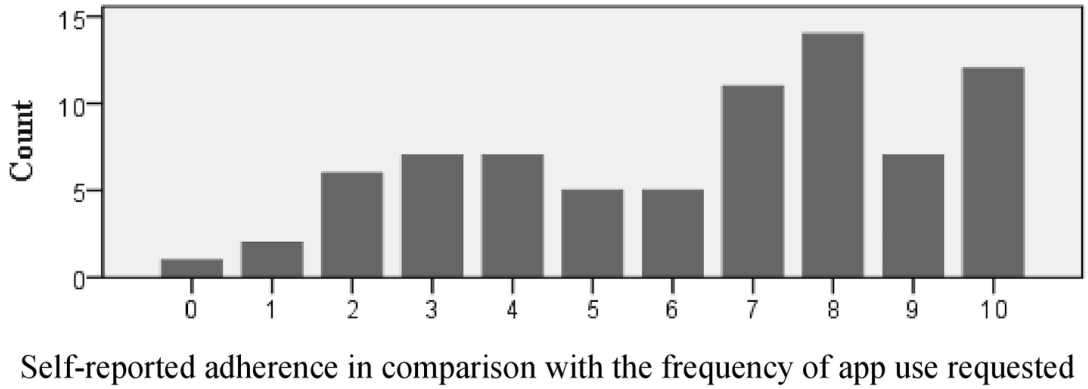
Researchers identified one univariate outlier from the pain subscale, seven univariate outliers from the physical functioning subscale, and six multivariate outliers. MANCOVA was conducted with outliers, and a significant interaction effect was found between condition assignment and time, $F_{1,160}$=2.06, P=.04, η_p^2=.10, warranting examination of individual QoL subscales, as discussed below. Eight outliers were removed from analysis for a second MANCOVA, resulting in the test being conducted on a sample size of 81 control condition participants and 74 experimental condition participants. Trends were similar in that mean subscale values decreased within the control condition from baseline to postintervention and increased within the experimental condition (see Table 2), although these trends were not found to be significant, $F_{1,152}$=1.86, P=.07, η_p^2=.10.

Vincent [52] warns that significance of certain dependent variables may be masked by nonsignificant variables in MANOVAs and therefore recommends ANOVA with the Bonferroni adjustment for assessing specific variables of interest. Thus, ANCOVAs were conducted on all subscales of the RAND 36-Item Health Survey. The general health subscale was shown to significantly differ in postintervention scores between treatment conditions, $F_{1,160}$=12.44, P=.001, η_p^2=.07, such that scores decreased in the control condition and increased in the experimental condition as illustrated in Table 2. A significant difference was also found between treatment conditions in regards to postintervention energy or fatigue subscale scores, $F_{1,160}$=8.19, P=.01, η_p^2=.05, with similar trends as the general health subscale. The results of the emotional well-being subscale did not meet the assumption of homogeneity of regression slopes for ANCOVA and were therefore analyzed using repeated measures ANOVA.

Table 4. Participant count for responses regarding changes in perceived work or school productivity over 4 weeks between baseline and postintervention measurements. Expected count is provided in parentheses.

Treatment	Control	Experimental
I think I was MORE productive	14 (22.2)	28 (19.8)
I think I was LESS productive	32 (26.4)	18 (23.6)
I think my productivity stayed about the same	40 (37.5)	31 (33.5)

Figure 3. Response counts from participants in the experimental condition when asked to identify how often they used the app in comparison with the frequency of use requested.



There was no main effect of time, $F_{1,161}$=1.21, P=.27, η_p^2=.01, or condition assignment $F_{1,161}$=1.89, P=.17, η_p^2=.01; however, there was an interaction effect, $F_{1,161}$=8.13, P=.01, η_p^2=.05, such that scores decreased over time for the control condition and increased over time for the experimental condition (see Table 2). All other tests were insignificant.

Work Productivity

Of the 163 participants who completed the follow-up survey, 29 people from the control condition and 21 from the experimental condition (n=50) reported having work at both baseline and postintervention and therefore completed all components of the WPAI. A subscore was calculated using these work-related data, labeled "percent overall work impairment due to health" [49]. No significant difference was found between treatment conditions, $F_{1,47}$=1.10, P=.30, η_p^2=.02.

All 163 participants completed the question, "During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?" [49] This question was used to calculate percent activity impairment because of health. No significant difference was found between treatment conditions, $F_{1,160}$=1.72, P=.19, η_p^2=.01.

When participants were asked to choose a description that best described how their work or school productivity has changed over the past 4 weeks, there was an association between treatment condition and responses, P=.01. More participants than expected by chance in the experimental condition reported an improvement in their productivity. Conversely, fewer participants than expected by chance in the control condition reported improved productivity. These results (Table 4) suggest that those in the experimental condition reported being more productive than those in the control condition.

Patterns of App Use and Self-Reported Adherence

One participant did not report app use trends and was thus excluded from the data regarding response frequencies of participants in the experimental condition (n=76) for self-reported trends in app use. The most frequently reported patterns of app use were consistent use (n=23) and decrease in use (n=23). The most infrequently reported app use trend was increase in use (n=4). The remaining responses of increase then decrease in use and decrease then increase in use had 14 and 11 responses, respectively.

When adherence was self-reported using a scale from 0 to 10 by participants in the experimental condition, the mean rating was 6.36 (standard deviation 2.79) with a median of 7. The most frequently reported adherence rating was 8. Counts for each response option are provided in Figure 3.

Discussion

Principal Findings

It was hypothesized that students who use DeStressify would report significantly lower stress, anxiety, depressive symptomatology, and class or work absenteeism and significantly greater sleep quality, school or work productivity, and QoL as compared with a wait-list control sample post intervention. The results support hypotheses that short-term use of DeStressify can reduce trait anxiety and improve general health, energy, emotional well-being, and work or school productivity in university students but do not support the other hypotheses. These findings are somewhat consistent with related literature, which have shown that MBSR techniques that are

delivered in person and through one- to two-hour-long sessions improve physiological and psychological well-being in university students [33-35]. Inconsistencies may be attributed to the difference in intervention delivery methods (ie, through a mobile phone rather than in person), shorter sessions, and lack of experimental control over app use frequency. Considering the study's design, these findings are encouraging as universities are in need of accessible alternative mental health management tools and services for students but should be considered cautiously given the small effect sizes.

The sample population of this study is representative of a large number of university students in Canada. Many universities are primarily composed of full-time undergraduate students, with a greater proportion of females attending in comparison with males. Specifically, 95% of first-year undergraduate students at Canadian universities are attending full-time, with 66% being female [53]; participants in this study were of similar demographics (enrolled full-time, 63.1% [103/163] female). Additionally, UBC is a Western Canadian university with approximately 8000 students registered in undergraduate programs on the Okanagan campus [54]. This size is comparative to small- to medium-sized Canadian universities.

The participant dropout rate from pre- to postintervention was 19.9% (41/206). This rate is comparable with the dropout rates of other studies using Web-based programs to support mental health [55]. One healthy lifestyle Web-based intervention with an adult population had an attrition rate over 75% at 1 month post intervention [56]. Apps, in particular, lose over 75% of daily active users 3 days after download [57]. The majority of dropouts were considered lost to follow-up. Two participants were an exception to this: one participant dropped out at the beginning of the study when they identified that the app did not work on their mobile device. A second participant identified their desire to drop out for personal reasons after they were invited to complete the follow-up survey.

Previous studies have found that students reportedly avoid mental health services such as counseling and medication because of fear of stigmatization, lack of time, and cost. Apps are an appealing platform for mental health support for university students that avoid many of the barriers associated with other forms of support, including those aforementioned and until recently have lacked evidence regarding effectiveness. App-based supports such as DeStressify can help university students avoid the stigma associated with mental health, as a large majority of students possess mobile phones and frequently engage with them, making app use a more discrete form of mental health maintenance. Additionally, mHealth apps do not generally require a large amount of time to use; the practices provided in DeStressify are approximately 10 min in length—much shorter than a standard counseling session. Participants in the experimental condition of this study were instructed to use the app 5 days a week, with no specifications regarding when it should be used. This allowed for greater flexibility in scheduling and thus, greater convenience, whereas still resulting in changes to trait anxiety, certain QoL components, and work or school productivity. In addition, apps are often inexpensive. The DeStressify app that was provided to participants is publicly available for Can $8.49 at the Apple iTunes store [58] and Can $8.23 at the Google Play store [59].

The changes in stress, anxiety, and related traits after short-term use of DeStressify are encouraging, yet, the effects of long-term use remain unknown. The most frequently reported patterns of app use for participants in the experimental condition were "consistent" and "decrease in use." Additionally, the average self-reported adherence rate in comparison to the requested amount was 64% (6.4/10), with 80% (8/10) being the most commonly reported adherence rate. Considering these self-reported adherence patterns, rates, and the magnitude of the changes in measured traits among DeStressify users, it would be interesting to determine whether the improvements observed in the experimental group of this study would persist with prolonged use of DeStressify.

Limitations

This study is among the first to provide empirical evidence regarding the effectiveness of a mindfulness-based mHealth app on stress, anxiety, depression, and related symptomatology within university students. In recognizing the novelty of this study, areas for future development should also be addressed. Although this study's objectives did not necessitate the use of a mindfulness measure, future studies should include one as it would provide a greater understanding in to the mechanism of action of DeStressify and would be useful in the design of future mental health apps and support services. Obtaining data directly from the app regarding participant use would also be more accurate than obtaining data from self-reported measures and should be considered in future studies. As some participants provided feedback regarding user satisfaction, future studies may also wish to include a measure of user satisfaction to enrich discussion regarding a mental health app's effectiveness and acceptance within a university population. Rickard et al [60] recommend providing opportunities for feedback directly in the app, particularly using established measures to allow for comparison between apps. Additionally, participant recruitment was dependent on self-selection, and thus, may not represent a random sample of the university population. However, individuals who would be inclined to use a mental health app may also be more likely to respond to this study's call for participants.

There is also the possibility that some participants in the control condition downloaded DeStressify, as it is a commercially available app. Therefore, we cannot discount the possibility that scores within the control condition may have been altered because of app use. If this were to have occurred, it is suspected that control condition scores would have been closer to experimental condition scores than what they would have been if the app had not been used.

What's more, some participants may have previously received mindfulness training and possibly interacted with DeStressify differently than participants who had not previously received mindfulness training. However, it is unknown how previous training would impact results. For example, if participants found the app's exercises to be similar to their current mindfulness exercises, then they may have incorporated the app more easily into their daily schedule and used it more consistently. This

consistent use could have yielded greater changes in their scores. Conversely, the similarities in the exercises could have yielded smaller changes in their scores. Including a measure of previous mindfulness training would be beneficial in future studies to control for its possible effects.

Finally, future directions may include comparing the effectiveness of a mental health app on different subpopulations such as university staff or high school students and gathering data beyond 4 weeks of app use to better understand long-term effectiveness of the app. Additional apps may also be considered, so as to provide a more generalized understanding of mindfulness-based mHealth apps.

Conclusions

Universities and other similar institutions may benefit from supporting the use of DeStressify or other mindfulness-based mHealth apps. It is a resource that can be easily incorporated into support services and used in addition to other mental health support services. Mindfulness-based mHealth apps such as DeStressify may be of interest to university students who are comfortable with apps and seek to manage their anxiety and mental health through an accessible, inexpensive, and discrete manner. Students interested in methods of anxiety management or mindfulness-based self-driven health support may be encouraged to try using the DeStressify app. As app use is self-directed, institutions that provide students with DeStressify may choose to conduct their own follow-up with students so as to track mental health progress. Regardless, an effective mHealth app would provide another means of addressing stress, anxiety, and related mental health concerns, allowing more students to receive the help they are seeking. This study has demonstrated how DeStressify can assist in improving some of these mental health traits in a short time frame and therefore, may be of interest to universities aiming to diversify their student mental health supports.

Conflicts of Interest

None declared.

Notice of editorial concern: This randomized study was not registered, in possible violation of ICMJE rules for prospective registration of randomized trials. The editor granted an exception because the risk of bias appears low and the study was considered formative, guiding the development of the application. However, readers are warned to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as failure to register does not prevent authors from changing their outcome measures retrospectively.

References

1. Smetanin P, Stiff D, Briante C, Adair CE, Ahmad S, Khan M. The Mental Health Commission of Canada. 2011. The life and economic impact of major mental illnesses in Canada: 2011 to 2041 URL: https://www.mentalhealthcommission.ca/sites/default/files/MHCC_Report_Base_Case_FINAL_ENG_0_0.pdf [WebCite Cache ID 6rMkRs8uw]
2. Statistics Canada. The Daily. 2013. Canadian community health survey: mental health, 2012 URL: http://www.statcan.gc.ca/daily-quotidien/130918/dq130918a-eng.pdf [accessed 2017-06-20] [WebCite Cache ID 6rMxrMeWW]
3. Stallman HM. Psychological distress in university students: a comparison with general population data. Aust Psychol 2010;45(4):249-257. [doi: 10.1080/00050067.2010.482109]
4. Crozier S, Willihnganz N. Docplayer. 2005. Canadian counselling centre survey URL: http://docplayer.net/3230999-Canadian-counselling-centre-survey.html [accessed 2017-06-20] [WebCite Cache ID 6rMlTDqmb]
5. Thielking M. Statnews. 2017 Feb 06. A dangerous wait: colleges can't meet soaring student needs for mental health care URL: https://www.statnews.com/2017/02/06/mental-health-college-students/ [WebCite Cache ID 6tOB9L6oW]
6. Barua B. Fraser Institute. 2015. Waiting your turn: wait times for health care in Canada URL: https://www.fraserinstitute.org/sites/default/files/waiting-your-turn-2015.pdf [WebCite Cache ID 6tOBRxaUP]
7. Ryerson University Centre for Student Development and Counselling. Ryerson University. How to book an appointment: how long will I wait after my initial appointment? URL: http://www.ryerson.ca/healthandwellness/counselling/students/Career_and_Educational_Concerns/Booking_an_Appointment/ [accessed 2017-06-01] [WebCite Cache ID 6rMlKzBhF]
8. Kitzrow MA. The mental health needs of today's college students: challenges and recommendations. NASPA J 2003;41(1):167-181. [doi: 10.2202/1949-6605.1310]
9. Richardson M, Abraham C, Bond R. Psychological correlates of university students' academic performance: a systematic review and meta-analysis. Psychol Bull 2012 Mar;138(2):353-387. [doi: 10.1037/a0026838] [Medline: 22352812]
10. Ualberta. 2011 Nov. Student health at the University of Alberta: 2011 University of Alberta national college health assessment URL: http://www.su.ualberta.ca/media/uploads/assets/CouncilPresentations/NCHA%20report%20January%2026:2012.pdf [accessed 2017-05-20] [WebCite Cache ID 6rMlmnMwZ]
11. Hysenbegasi A, Hass SL, Rowland CR. The impact of depression on the academic productivity of university students. J Ment Health Policy Econ 2005 Sep;8(3):145-151. [Medline: 16278502]
12. Doom JR, Haeffel GJ. Teasing apart the effects of cognition, stress, and depression on health. Am J Health Behav 2013 Sep;37(5):610-619. [doi: 10.5993/AJHB.37.5.4] [Medline: 23985283]

13. Pierceall EA, Keim MC. Stress and coping strategies among community college students. Community Coll J Res Pract 2007 Oct 08;31(9):703-712. [doi: 10.1080/10668920600866579]
14. Mackenzie CS, Erickson J, Deane FP, Wright M. Changes in attitudes toward seeking mental health services: a 40-year cross-temporal meta-analysis. Clin Psychol Rev 2014 Mar;34(2):99-106. [doi: 10.1016/j.cpr.2013.12.001] [Medline: 24486521]
15. Sasaki M. EPA-0231 - Barriers and facilitators to the use of mental health services by Japanese university students. Eur Psychiatry 2014;29(S1):1. [doi: 10.1016/S0924-9338(14)77685-0]
16. Eisenberg D, Golberstein E, Gollust SE. Help-seeking and access to mental health care in a university student population. Med Care 2007 Jul;45(7):594-601. [doi: 10.1097/MLR.0b013e31803bb4c1] [Medline: 17571007]
17. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. BMC Psychiatry 2010;10:113 [FREE Full text] [doi: 10.1186/1471-244X-10-113] [Medline: 21192795]
18. Jorm AF, Wright A, Morgan AJ. Where to seek help for a mental disorder? National survey of the beliefs of Australian youth and their parents. Med J Aust 2007 Nov 19;187(10):556-560. [Medline: 18021042]
19. Martin JM. Stigma and student mental health in higher education. Higher Education Research & Development 2010 Jun;29(3):259-274. [doi: 10.1080/07294360903470969]
20. Talebi M, Matheson K, Anisman H. Support, depressive symptoms, and the stigma towards seeking mental health help. Int J Soc Sci Stud 2013;1(1):133-144. [doi: 10.11114/ijsss.v1i1.36]
21. Andrews G, Issakidis C, Carter G. Shortfall in mental health service utilisation. Br J Psychiatry 2001 Nov;179:417-425 [FREE Full text] [Medline: 11689399]
22. Barney LJ, Griffiths KM, Jorm AF, Christensen H. Stigma about depression and its impact on help-seeking intentions. Aust N Z J Psychiatry 2006 Jan;40(1):51-54. [doi: 10.1111/j.1440-1614.2006.01741.x] [Medline: 16403038]
23. Griffiths KM, Crisp DA, Jorm AF, Christensen H. Does stigma predict a belief in dealing with depression alone? J Affect Disord 2011 Aug;132(3):413-417. [doi: 10.1016/j.jad.2011.03.012] [Medline: 21440305]
24. Stallman HM. University counselling services in Australia and New Zealand: activities, changes, and challenges. Aust Psychol 2012;47:249-253. [doi: 10.1111/j.1742-9544.2011.00023.x]
25. Bigam S. The Ubessey. 2014 Feb 10. Waits, complaints and constraints: the state of UBC Counselling Services URL: http://old.ubyssey.ca/news/state-of-ubc-counselling-services001/ [accessed 2017-06-10] [WebCite Cache ID 6rMly5TpG]
26. Yorgason JB, Linville D, Zitzman B. Mental health among college students: do those who need services know about and use them? J Am Coll Health 2008;57(2):173-182. [doi: 10.3200/JACH.57.2.173-182] [Medline: 18809534]
27. Robinson AM, Jubenville TM, Renny K, Cairns SL. Academic and mental health needs of students on a Canadian campus. Can J Counselling Psychother 2016;50(2):108-123 [FREE Full text]
28. Crisp DA, Griffiths KM. Participating in online mental health interventions: who is most likely to sign up and why? Depress Res Treat 2014;2014:790457 [FREE Full text] [doi: 10.1155/2014/790457] [Medline: 24804089]
29. Payne HE, Lister C, West JH, Bernhardt JM. Behavioral functionality of mobile apps in health interventions: a systematic review of the literature. JMIR mHealth uHealth 2015;3(1):e20 [FREE Full text] [doi: 10.2196/mhealth.3335] [Medline: 25803705]
30. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
31. Grist R, Porter J, Stallard P. Mental health mobile apps for preadolescents and adolescents: a systematic review. J Med Internet Res 2017 May 25;19(5):e176 [FREE Full text] [doi: 10.2196/jmir.7332] [Medline: 28546138]
32. Van Gordon W, Shonin E, Griffiths MD. Mindfulness in mental health: a critical reflection. J Psy Neuro Dis Brain Stim 2015 Jul 20;1(1):102. [doi: 10.19104/jpbd.2015.102]
33. Ramler TR, Tennison LR, Lynch J, Murphy P. Mindfulness and the college transition: the efficacy of an adapted mindfulness-based stress reduction intervention in fostering adjustment among first-year students. Mindfulness 2016 Feb;7(1):179-188. [doi: 10.1007/s12671-015-0398-3]
34. Lynch S, Gander M, Kohls N, Kudielka B, Walach H. Mindfulness-based coping with university life: a non-randomized wait-list-controlled pilot evaluation. Stress Health 2011 Mar 21;27(5):365-375. [doi: 10.1002/smi.1382]
35. Jang H, Jeon M. Relationship between self-esteem and mental health according to mindfulness of university students. Indian J Sci Technol 2015;8(21):1-5. [doi: 10.17485/ijst/2015/v8i21/78459]
36. Kvillemo P, Brandberg Y, Bränström R. Feasibility and outcomes of an internet-based mindfulness training program: a pilot randomized controlled trial. JMIR Ment Health 2016 Jul 22;3(3):e33 [FREE Full text] [doi: 10.2196/mental.5457] [Medline: 27450466]
37. Faul F, Erdfelder E, Buchner A, Albert-Georg L. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. Behav Res Methods 2009;41(4):1149-1160. [doi: 10.3758/BRM.41.4.1149] [Medline: 19897823]
38. Chang VY, Palesh O, Caldwell R, Glasgow N, Abramson M, Luskin F, et al. The effects of a mindfulness-based stress reduction program on stress, mindfulness self-efficacy, and positive states of mind. Stress and Health 2004 Aug;20(3):141-147. [doi: 10.1002/smi.1011]

39. Cohen S. Mind Garden. 1994. Perceived stress scale URL: https://www.mindgarden.com/documents/PerceivedStressScale.pdf [WebCite Cache ID 6tOFYh9Bg]
40. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [Medline: 6668417]
41. Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. State-Trait Anxiety Inventory for Adults Manual. Menlo Park, CA: Mind Garden, Inc; 2015.
42. Rush AJ, Trivedi MH, Ibrahim HM, Carmody TJ, Arnow B, Klein DN, et al. The 16-Item quick inventory of depressive symptomatology (QIDS), clinician rating (QIDS-C), and self-report (QIDS-SR): a psychometric evaluation in patients with chronic major depression. Biol Psychiatry 2003 Sep 01;54(5):573-583. [Medline: 12946886]
43. Ids-qids. Interpretation URL: http://www.ids-qids.org/interpretation.html [accessed 2017-12-09] [WebCite Cache ID 6vaNtfdqZ]
44. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. Psychiatry Res 1989 May;28(2):193-213. [Medline: 2748771]
45. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Conceptual framework and item selection. Med Care 1992 Jun;30(6):473-483. [Medline: 1593914]
46. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item health survey 1.0. Health Econ 1993 Oct;2(3):217-227. [Medline: 8275167]
47. RAND Health. 36-Item short form survey (SF-36) scoring instructions URL: http://www.rand.org/health/surveys_tools/mos/36-item-short-form/scoring.html [WebCite Cache ID 6rMmCF7te]
48. VanderZee KI, Sanderman R, Heyink JW, de Haes H. Psychometric qualities of the RAND 36-Item Health Survey 1.0: a multidimensional measure of general health status. Int J Behav Med 1996 Jun;3(2):104-122. [doi: 10.1207/s15327558ijbm0302_2] [Medline: 16250758]
49. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. Pharmacoeconomics 1993 Nov;4(5):353-365. [Medline: 10146874]
50. Field A. Discovering Statistics Using SPSS, 3rd edition. London, England: SAGE Publications Ltd; 2009.
51. Tabachnick BG, Fidell LS. Using Multivariate Statistics, 4th edition. Boston, MA: Allyn and Bacon; 2001.
52. Vincent WJ. Statistics in Kinesiology, 2nd edition. Champaign, IL: Human Kinetics; 1999.
53. Cusc-ccreu. 2016 First-year university student survey: master report URL: http://www.cusc-ccreu.ca/publications/CUSC_2016-First-Year-Report-EN.pdf [accessed 2017-08-11] [WebCite Cache ID 6se6qYo1B]
54. UBC. University of British Columbia 2016/17 annual report on enrolment URL: https://senate.ubc.ca/sites/senate.ubc.ca/files/downloads/UBC%20Enrolment%20Report%202016-17_Final%20-%209%20Jan%202017_0.pdf [accessed 2017-08-10] [WebCite Cache ID 6skCXvkHG]
55. Doherty G, Coyle D, Sharry J. Engagement with online mental health interventions: an exploratory clinical study of a treatment for depression. 2012 Presented at: Proc SIGCHI Conf Hum Factor Comput Syst; May 5-10, 2012; Austin, TX p. 1421-1430. [doi: 10.1145/2207676.2208602]
56. Van der Mispel C, Poppe L, Crombez G, Verloigne M, De Bourdeaudhuij I. A self-regulation-based eHealth intervention to promote a healthy lifestyle: investigating user and website characteristics related to attrition. J Med Internet Res 2017 Jul 11;19(7):e241 [FREE Full text] [doi: 10.2196/jmir.7277] [Medline: 28698168]
57. Chen A. Andrewchen. New data shows losing 80% of mobile users is normal, and why the best apps do better URL: http://andrewchen.co/new-data-shows-why-losing-80-of-your-mobile-users-is-normal-and-that-the-best-apps-do-much-better/ [accessed 2017-09-11] [WebCite Cache ID 6tOKcFVaX]
58. iTunes Preview. DeStressify PRO by stress iefuge, Inc URL: https://itunes.apple.com/ca/app/destressify-pro/id751845893?mt=8 [WebCite Cache ID 6rMmTgOia]
59. Google Play. DeStressify-PRO stress relief URL: https://play.google.com/store/apps/details?id=com.stressrefuge.destressify.pro [WebCite Cache ID 6rMnFf7mp]
60. Rickard N, Arjmand HA, Bakker D, Seabrook E. Development of a mobile phone app to support self-monitoring of emotional well-being: a mental health digital innovation. JMIR Ment Health 2016 Nov 23;3(4):e49 [FREE Full text] [doi: 10.2196/mental.6202] [Medline: 27881358]

Abbreviations

ANOVA: analysis of variance
ANCOVA: analysis of covariance
MANCOVA: multivariate analysis of covariance
MBSR: mindfulness-based stress reduction
MDD: major depressive disorder
mHealth: mobile health
PSQI: Pittsburg Sleep Quality Index
PSS: Perceived Stress Scale

QIDS-SR: Quick Inventory of Depressive Symptomatology Self-Report
QoL: quality of life
STAI: State-Trait Anxiety Inventory for Adults
WPAI: Work Productivity and Activity Impairment Questionnaire: General Health V2.0

Edited by J Prescott; submitted 30.06.17; peer-reviewed by K Reynolds, D Crisp, B Loo Gee; comments to author 21.08.17; revised version received 25.10.17; accepted 14.12.17; published 23.01.18.

Please cite as:
Lee RA, Jung ME
Evaluation of an mHealth App (DeStressify) on University Students' Mental Health: Pilot Trial
JMIR Ment Health 2018;5(1):e2
URL: http://mental.jmir.org/2018/1/e2/
doi:10.2196/mental.8324
PMID:29362209

Original Paper

Supporting Our Valued Adolescents (SOVA), a Social Media Website for Adolescents with Depression and/or Anxiety: Technological Feasibility, Usability, and Acceptability Study

Ana Radovic[1], MD, MSc; Theresa Gmelin[2], MSW, MPH; Jing Hua[1], MS; Cassandra Long[1], MSW; Bradley D Stein[3], MD, PhD; Elizabeth Miller[1], MD, PhD

[1]Department of Pediatrics, Children's Hospital of Pittsburgh of UPMC, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States
[2]Graduate School of Public Health, University of Pittsburgh, Pittsburgh, PA, United States
[3]Research and Development Corporation, Pittsburgh, PA, United States

Corresponding Author:
Ana Radovic, MD, MSc
Department of Pediatrics
Children's Hospital of Pittsburgh of UPMC
University of Pittsburgh School of Medicine
3420 Fifth Avenue
Pittsburgh, PA, 15213
United States
Phone: 1 412 692 7227
Fax: 1 412 692 8584
Email: ana.radovic@chp.edu

Abstract

Background: Supporting Our Valued Adolescents (SOVA), a social media website for adolescents, was designed to increase mental health literacy and address negative health beliefs toward depression and/or anxiety diagnosis and treatment. This stakeholder-informed site underwent iterative user testing to evolve into its current version with daily blog posts, round-the-clock site moderation, and Web-based peer interaction to create an online support community.

Objective: The aim of this study was to evaluate the technological feasibility (at least 100 users on the site, logging in 12 to 18 times in the first 6 weeks) and acceptability of the SOVA site determined by the System Usability Scale (SUS).

Methods: Adolescents and young adults (aged 14-26 years) with a self-reported history of depressive and/or anxiety symptoms were recruited to access the research website (sova.pitt.edu). Participants were screened out if they reported active suicidality or a prior suicide attempt. Baseline survey measures included demographics, symptomatology using the Patient Health Questionnaire-9 modified for adolescents (PHQ-9A) and Screen for Child Anxiety Related Disorders (SCARED-C), and mental health treatment history. The 6-week follow-up measures taken in addition to the symptomatology, included feasibility (total number of log-ins), usability, and acceptability of SOVA using SUS.

Results: Most of the 96 participants identified as female (75% [72/96]) and white (67% [64/96]). Most participants (73% [70/96]) reported having taken prior professional psychological help. The average PHQ-9A score was 11.8 (SD 5.5), and for SCARED-C, 85% (80/94) of the participants reported a score consistent with being susceptible to a diagnosed anxiety disorder. There were 46% (41/90) of eligible users who ever logged in. Out of the total users who ever logged in, the mean of total log-ins over the entire study was 4.1 (SD 6.9). Median number of users rated the user-friendliness of the site as “good.” The average SUS score was 71.2% (SD 18.7), or a “C-grade,” which correlated to an acceptable range. The participants reported to have liked the “easy-to-understand format” and “positive, helpful atmosphere,” but they also reported a desire for greater social interaction. Iterative recruitment resulted in incremental improvements to the site.

Conclusions: The SOVA site met feasibility goals of recruiting almost 100 users and establishing acceptable usability. Subsequent interventions are planned to increase site engagement and to evaluate efficacy in increasing uptake of primary care–recommended depression and/or anxiety treatment.

(JMIR Ment Health 2018;5(1):e17) doi:10.2196/mental.9441

KEYWORDS

adolescent; adolescent health services; technology; depression; anxiety

Introduction

Background

Suicide is the second most common cause of death in adolescents and young adults in the United States [1]; the most common risk factor for suicide is mental illness [2,3]. Alarmingly, as per a 2017 national survey, less than one third of suicidal youth had used mental health services [4]. A primary predictor of not utilizing mental health services is the harboring of negative beliefs about mental illness and treatment seeking [5]. For example, youth who do not seek help have a higher degree of self-stigma, as well as self-reliance, or a belief that they do not need others' help [6]. Digital health interventions may be a promising avenue to change these negative health beliefs, particularly among young people. Digital interventions can reach a wide audience [7] of young people who commonly use the Internet to find health resources [8] and specifically talk about their mental health [9,10], thereby serving as a potential bridge to face-to-face psychotherapy [11,12].

To seize this potential, we designed a social media website for adolescents called SOVA (Supporting Our Valued Adolescents) and a separate companion website for parents called wiseSOVA (not discussed in this paper). SOVA aims to (1) challenge negative health beliefs and increase depression and anxiety knowledge through daily blog posts enhanced with peer commentary, (2) promote social support through Web-based peer interactions, and (3) encourage parent-adolescent mental health offline communication through same-day blog posts with questions for discussion. SOVA's goal is to increase the perceived need for services in both, adolescents referred for treatment and their parents, ultimately leading to increasing the use of adolescent mental health services.

Objectives

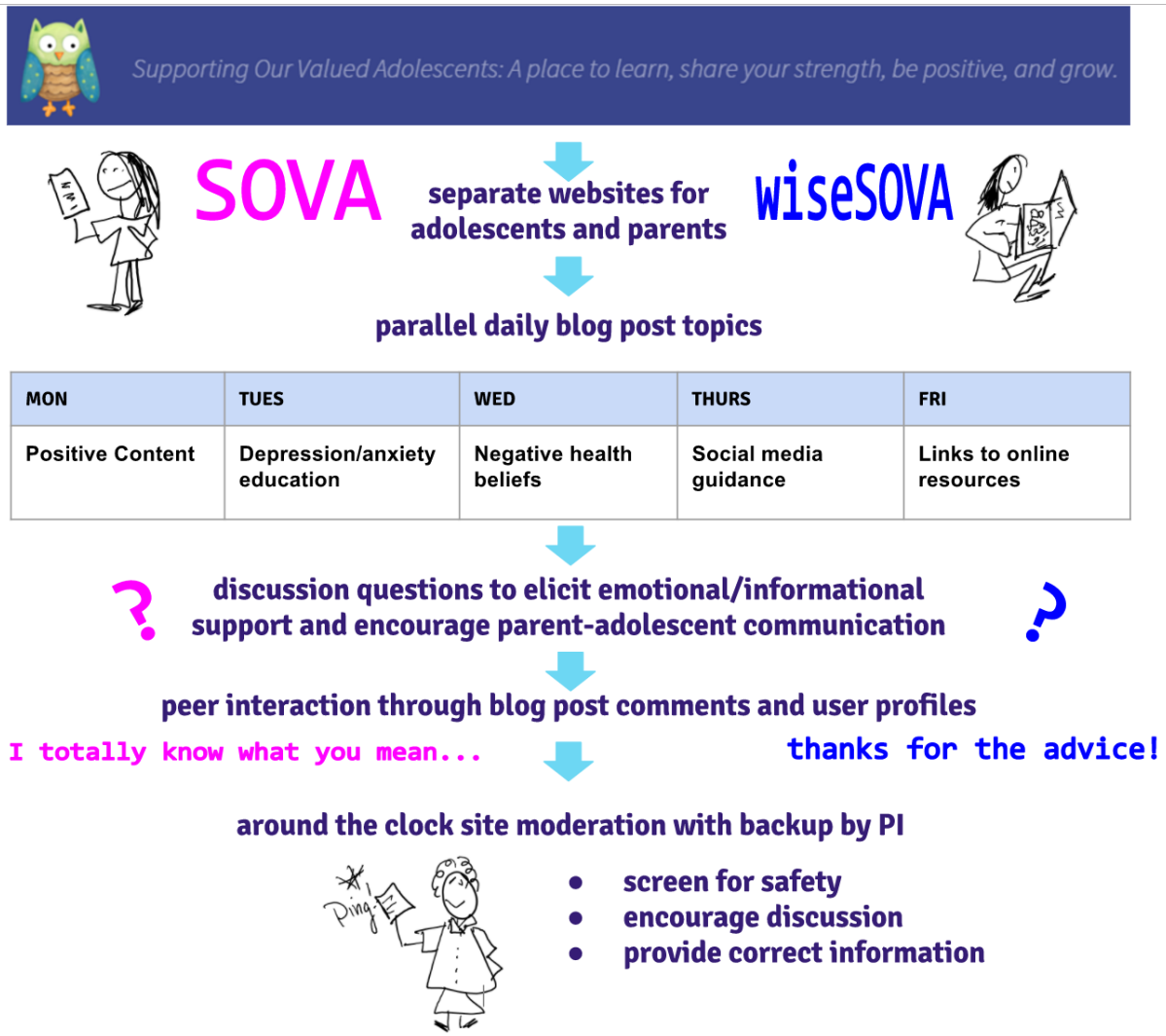
From the inception of the SOVA sites, we knew we would need to use multiple strategies to buffer against the lack of engagement which affects many ehealth interventions [13]. Our main strategy was to involve end users [14] to help increase engagement [15] by recognizing important concerns in the specific population. For example, for adolescents and young adults with mental health problems, a salient concern is ensuring confidentiality [16]. To accomplish this, we took a stepwise approach, incorporating technology development principles and behavioral intervention testing. This approach is based on a slightly modified structure recommended by the Office of Behavioral and Social Sciences Research and multiple NIH institution collaboration for behavioral intervention development, the ORBIT model [17]. The phase 1 design stage involved formative work and iterative user-testing with adolescent or young adults, parents, and provider stakeholders. This led to the development of the current versions of the sites with daily blog posts, round-the-clock site moderation by behavioral health professionals or trainees, and Web-based interaction with peers interacting in an online support community (one for adolescents and young adults and another one for parents) [18]. As part of phase 2 of the ORBIT model, we conducted a preparatory study to refine the SOVA intervention and determine its usability through beta testing. Specifically, we sought to evaluate the technological feasibility, defined as the ability to recruit users to the site, and frequency of log-ins, as well as the acceptability of the SOVA site, as determined by the System Usability Scale (SUS) [19]. We expected to recruit 100 adolescents and young adults to the site and that they would log in for a mean of 12 to 18 times over the 6-week study. We expected that users would find SOVA to have at least "good" user-friendliness and a corresponding SUS acceptability mean of 73 [19]. This manuscript provides usability data only on SOVA, the adolescent or young adult site, and describes preliminary changes in some potential outcomes of interest, including depression and anxiety symptoms and positive youth development characteristics, such as caring and connection.

Methods

Intervention

The SOVA site's process of iterative development and design is described in detail elsewhere [18]. A secure password-protected site was developed (sova.pitt.edu) using WordPress [20], a popular content-management system frequently updated for function and security [21]. A simple central interface allows a novice to add and organize site content [22] but results in a professional-looking website in a blog post format [20,21]. The research team contributed to daily weekday blog posts written with a youth audience in mind, tailored for cultural sensitivity and reviewed for health literacy [23] and readability [24] of grade level 8 or lower. Topics were categorized under the headings (1) "Be Positive" or posts with positive content, such as an inspiring quote or video (eg, "The Power of Hugs"); (2) "Educate Yourself" or posts addressing depression and anxiety psychoeducation [25] or negative health beliefs that may prevent someone from seeking care [26-29] (eg, "Because I felt like I didn't deserve to get better"); (3) "Social Media Guide" or posts providing information or guidance on social media use based on our prior qualitative study with depressed youth [30] (eg, "Instagram's newest safety tool"); and (4) "Links" or posts describing an existing resource (eg, "Getting Help: The National Suicide Prevention Hotline"; see Figure 1). At the bottom of each post, a question was placed to promote user discussion (eg, "Have you ever felt guilty for something you realized later was not actually your fault?"). A graduate student of information science addressed technical challenges, created a user-tracking mechanism and data-visualization module. Moderators for the website were behavioral health graduate students (ie, social work and psychology) and clinician members of the research team. Each moderator participated in an in-person training session and received a detailed protocol. Weekly group supervision sessions were held with the principal investigator and a licensed social worker research assistant.

Figure 1. Supporting Our Valued Adolescents (SOVA) key intervention components.



Study Participants and Setting

Adolescents and young adults (AYA) aged 14 to 26 years were recruited in-person from clinical settings by behavioral health clinicians and from online websites (eg, Craigslist, University of Pittsburgh Research Registry). Young adults up to the age of 26 years were included as the online community we sought to form that could benefit from peer involvement from young adults who had had positive experiences in the mental health care system and exhibited resilience [31]. Recruitment advertising was directed toward those AYA who were experiencing symptoms of depression and/or anxiety and were interested in providing feedback about a new website that would allow anonymous Web-based interaction with other people their age who were also experiencing these symptoms. Interested participants were asked to go to the website (sova.pitt.edu) and were required to register and log in to access any site content. Toward the end of the study, after 80% (77/96) of the sample had been recruited, we changed this log-in requirement. This was based on participant feedback that engagement may increase if we made some website content public so that participants could view it before deciding whether to log in and enroll in the study. After this change, the content of all blog articles was made public, but online community features (eg, creating a profile, creating and viewing comments on blog posts, and receiving email updates on new blog posts) still required the users to log in.

Data Collection

After creating a username, password, and agreeing with a set of common-ground rules emphasizing anonymity on the main website, participants were automatically redirected to a Web-based survey (Qualtrics, Provo, UT). Individuals aged 14 to 26 years were included if they self-reported a history of depression and/or anxiety symptoms, had Internet and email access, could read and write in English, and had completed the 6th grade. We obtained a waiver of parental permission because of anticipated difficulty with recruitment due to the study being online, and because minors aged 14 years and older can seek mental health services without parental permission in Pennsylvania, United States. Due to the unknown safety profile of the intervention, we excluded participants with active suicidality, defined by thoughts with intent to act on these thoughts, or a history of a suicide attempt. Participants screening in were asked for their contact information and for 1 supportive adult; this was described as a requirement of the study for safety

reasons. Those screening in would be redirected to complete a baseline 52-item Web-based survey. After 6 weeks, they received a follow-up 63-item Web-based survey by email. Passive data were also collected regarding the number of log-ins and text from comments in response to blog posts. Participants received compensation in the form of a prepaid debit card on the completion of the first and 6-week surveys.

Measures

Demographics

At baseline, participants were asked their age, gender, and race.

Depression and Anxiety

Depression symptoms were measured using the Patient Health Questionnaire-9 Item (PHQ-9) modified for adolescent use and using the cut-off score of 11 for detecting major depression [32]. Higher PHQ-9 scores have been correlated with greater functional impairment and parental report of psychosocial problems.

Anxiety symptoms were measured using the 5-item version of the Screen for Child Anxiety Related Emotional Disorders (5-item SCARED-C) [33]. This brief version of SCARED-C, including questions regarding panic or somatic, general anxiety, separation anxiety, social phobia, and school phobia has been found to have 74% sensitivity and 73% specificity for detecting clinically significant anxiety using a score of 3 or greater.

Mental health treatment history was ascertained by asking AYA whether they had ever received treatment from a professional psychologist or counselor and/or taken a medication such as an antidepressant [34].

Positive Youth Development Scale

The Positive Youth Development 17-item Very Short Form (PYD-VSF) is an abbreviated version of the full PYD, which has been used to measure positive attributes in AYA based on the Lerner and Lerner Five Cs Model of PYD [35]. This model operationalizes PYD by assessing (possible subscale score values in parentheses) competence (1-12), confidence (1-13), character (1-19), connection (1-20), and caring (1-15), with the total score ranging from 1 to 79. PYD-VSF has been validated in multiple groups of adolescents [36].

Feasibility: Frequency and Patterns of Use

User log-in data over the initial 6 weeks of site use and afterwards (some individuals continued to use the site after 6 weeks) was collected, as well as the frequency of viewing specific blog post categories, such as Education (twice as many posts as other categories), Social Media, Positivity, and Resources was also reported. Aggregate data of site use was also collected by views of unique Internet protocol (IP) addresses, filtering out the IP addresses of the study team. A data visualization module was created to view daily, weekly, and monthly log-ins, unique IP addresses, and blog post article comments on the same display over time and allowed notation of events that may affect use (eg, opening site articles to public).

Usability and Acceptability

Website usability and acceptability were measured using the modified SUS [19] and 2 open-ended questions. The modified SUS consists of 10 questions regarding usability with responses on a 1 to 5 Likert scale in terms of agreement and an additional 11th question with response on an adjective rating scale. Scores based on the first 10 questions were manipulated to a 0 to 4 rating and multiplied by 2.5 to get to a score within a range of 0 to 100, with higher scores denoting higher usability. Question 11 asks the user to rate the overall user-friendliness of the site as worst imaginable, awful, poor, OK, good, excellent, or best imaginable. Bangor et al reviewed 200 studies and found the highest quarter of study means for SUS ranged from 78.51 to 93.93 [19]. Factor analysis has shown only 1 significant factor for the 10 SUS statements, implying a good fit for usability, and reliability analysis has shown a Cronbach alpha of .911 [19]. The following two open-ended questions were asked: (1) “What did you like about this website?” and (2) “What would you change about the website?” with free-text entry responses. Phone or email interviews were also offered to participants to provide further feedback, but only 4 individuals chose to participate.

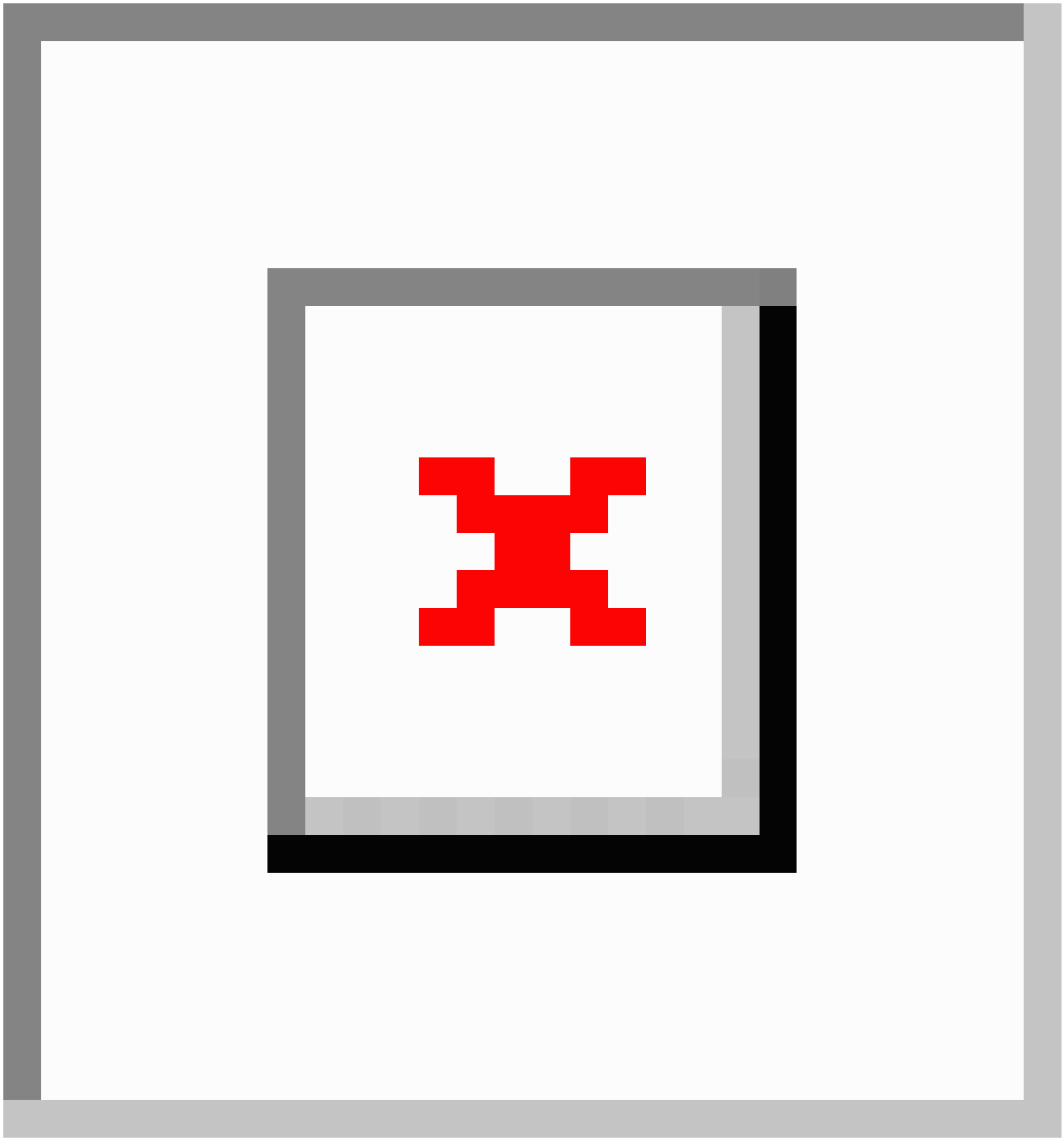
Analysis

Descriptive analyses were used for summary statistics of all measures listed above. The primary outcome for feasibility was mean number of log-ins over a 6-week period, and for usability and acceptability, the SUS mean score. Paired *t* tests (for continuous outcomes) and McNemar tests (for categorical outcomes) were used to compare change in pre- and postintervention repeated measures in the same sample which completed both baseline and 6-week measures. Before the study, we calculated that a sample size of 100 AYA would give sufficient precision to estimate the mean number of log-ins and mean usability score within 0.20 standard deviations (with the 95% CI). SPSS Version 24.0 (IBM) was used for statistical analyses. Open-ended responses and interviews were reviewed by 2 team members using thematic coding to gather specific content about usability. This study was approved by the University of Pittsburgh Human Research Protection Office.

Results

Screening for eligibility took place with 226 individuals, of whom 130 were ineligible, mostly because of suicidality (N=121; see Figure 2). Out of 96 eligible participants, all completed the baseline survey, but 6 withdrew or were withdrawn afterwards by the research team (eg, due to attempts to complete the survey multiple times) and did not create a username for the site. Out of these 90 users, 70 completed the 6-week survey (78% [70/90]), although the N reported for some measures below is lower due to incomplete completion of specific survey items.

Figure 2. Participant flowchart.



The baseline sample (Table 1) included 15 adolescents (aged 14-19 years) and 80 young adults (aged 20-26 years; 1 missing age data). Race was fairly representative of US demographics, except for twice as high a rate of Asian or Pacific Islander. At baseline, the mean PHQ-9 score was 11.8 (SD 5.5), which is above the cut-off score for depression in adolescents [32], and about 30% reported moderately severe to severe symptoms. Using SCARED-C, 85% (80/94) of the participants reported a score consistent with being susceptible to being diagnosed with an anxiety disorder. Over half of the participants had ever received a medication such as an antidepressant (57% [55/96]) or help from a professional psychologist or counselor (73% [70/96]). The baseline PYD-VSF total score was 54.4 (SD 7.5), with the subscale scores listed in Table 1.

Feasibility

There were 46% (41/90) of participants who ever logged in. As 61 participants completed the 6-week survey on usability, as many as 13 may have viewed content without logging in once it was public or only viewed the content in their notification email, but this cannot be determined from the data collected because of anonymity of 6-week data collection and inability to match it to usernames. Out of those who ever logged in (users), the mean total log-ins over the initial 6 weeks were 1.9 (SD 2.3) and over the total study were 4.1 (SD 6.9; see Table 2). The most frequently viewed blog posts over the initial 6 weeks were education posts (of which there were double the number of posts) with a mean of 5.1 (SD 14.7) views, and the

second most-commonly viewed posts were positivity posts with a mean of 2.8 (SD 6.9).

Data visualization showed a sharp increase in site views by unique IP addresses in June 2016 after the site blog posts were made public and a problem with users not getting notification emails was resolved (Figure 3). Beside this problem, there were no major site errors and no safety concerns. Figure 3 shows in red, the number of unique views of the site per month (omitting the study team's views); in blue, the number of log-ins per month ranged 21 to 56 (until October when the study was almost over); and in green, the number of comments per month ranged 8 to 36.

Table 1. Demographics and baseline measures of study population (N=96).

Variable	Value
Age in years, median (range)	23 (14-26)
Gender, n (%)	
Female	72 (75)
Female to male transgender	0 (0)
Male	21 (22)
Male to female transgender	0 (0)
Not sure	0 (0)
Other	3 (3)
Race, n (%)[a]	
White	64 (67)
Black	14 (15)
Asian/Pacific Islander	12 (12)
Hispanic	7 (7)
North American Native	1 (1)
Other	0 (0)
Don't want to answer	2 (2)
Depressive symptoms: PHQ-9 Score[b], mean (SD)[c]	11.8 (5.5)
Feeling sad most days in the past year, n (%)	67 (70)
Difficulty experienced with normal functioning, n (%)[c]	
Not difficult at all	9 (9)
Somewhat difficult	55 (58)
Very difficult	23 (24)
Extremely difficult	8 (8)
Depression severity (PHQ-9 Score), n (%)[c]	
None (1-4)	8 (8)
Mild (5-9)	30 (32)
Moderate (10-14)	27 (28)
Moderately severe (15-19)	21 (22)
Severe (20-27)	9 (9)
SCARED-C[d] score consistent with anxiety (≥3), n (%)[e]	80 (85)
Treatment history (yes to having ever received), n (%)	
Professional psychologist or counselor	70 (73)
Medication like antidepressants	55 (57)
Positive Youth Development-VSF score, median (SD)[f]	54.4 (7.5)
Competence	7.6 (2.0)
Confidence	8.0 (2.5)
Character	13.6 (2.6)
Caring	13.0 (2.2)
Connection	12.2 (3.2)

[a]Percentage may equal greater than 100 due to participants answering more than one racial category.

[b]PHQ-9: Patient Health Questionnaire-9 modified for adolescents.

[c]N=95 due to exclusion of those who did not answer all PHQ-9 questions.

[d]SCARED-C: 5-item Screen for Child Anxiety Related Emotional Disorders.

[e]N=94 due to those who did not answer all SCARED-C questions.

[f]N=92 due to those who did not answer questions for all PYD categories.

Table 2. Feasibility and usability of Supporting Our Valued Adolescents (SOVA).

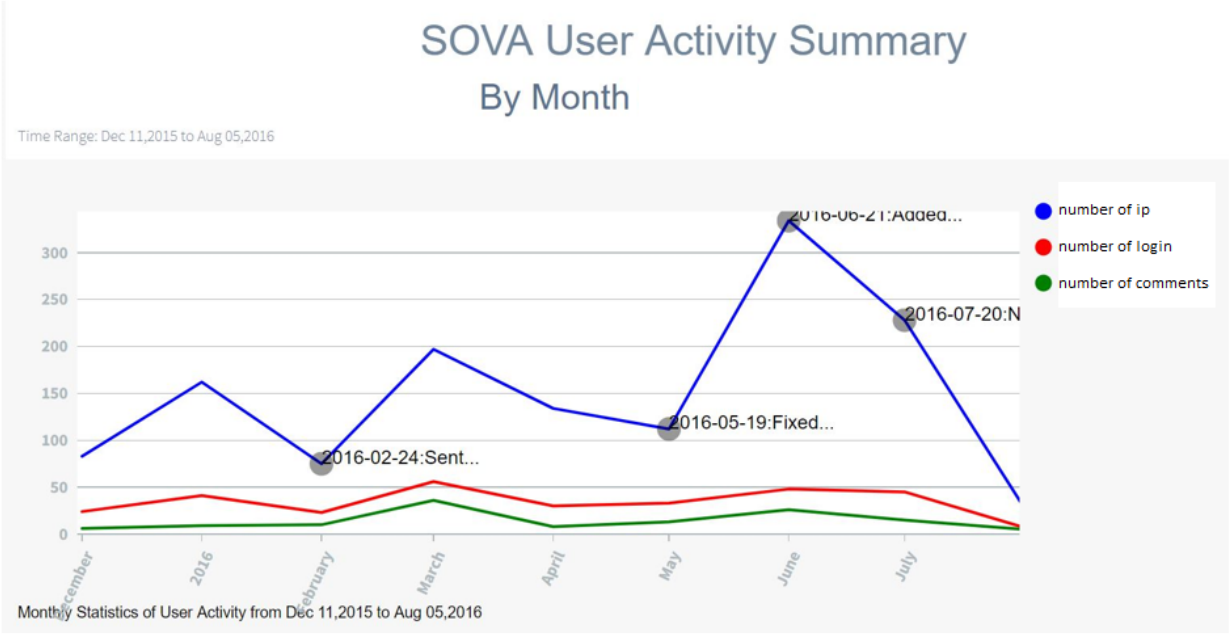
Outcomes	Value
Frequency of use, mean (SD)	
Total log-ins/user over initial 6 weeks of use[a]	
All users	0.9 (1.8)
Users who ever logged in	1.9 (2.3)
Total log-ins/user ever	
All users	1.8 (5.0)
Users who ever logged in	4.1 (6.9)
Patterns of use over initial 6 weeks[b], mean (SD)	
Total education blog post views/user	
All users	2.3 (10.1)
Users who ever logged in	5.1 (14.7)
Total social media blog post views/user	
All users	0.9 (3.7)
Users who ever logged in	2.0 (5.3)
Total positivity blog post views/user	
All users	1.2 (4.8)
Users who ever logged in	2.8 (6.9)
Total resources blog post views/user	
All users	0.8 (3.4)
Users who ever logged in	1.8 (4.9)
System Usability Scale score[c], mean (SD)	71.2 (18.7)
User-friendliness of site, n (%)	
Worst imaginable	0 (0)
Awful	1 (2)
Poor	3 (5)
OK	11 (18)
Good	19 (31)
Excellent	21 (34)
Best imaginable	6 (10)

[a]Data available for 90 accounts as 6 users requested to be withdrawn.

[b]Differences were not statistically significant ($P>.05$) using ANOVA.

[c]N=61 due to loss to follow-up; 70 users completed follow-up but not all completed each measure.

Figure 3. Data visualization.



2016-02-24	Sent welcome email to all users
2016-05-19	Fixed notification email problem
2016-06-15	Opened site to public (only blog posts)
2016-06-21	Added share function to articles
2016-06-24	Stopped recruiting new users for feasibility study (switched to just follow-up)
2016-07-20	New buddypress profiles started

Usability and Acceptability

The median number of users thought the user-friendliness of the site was "good." Over a third of users (34% [21/61]) thought the user-friendliness of the site was excellent (Table 2). The average SUS scale score was 71.2 (SD 18.7) or a C-grade, which is within an acceptable range [19]. From these, 49 users responded to the open-ended question "What did you like about the website?." They liked the "easy-to-understand format" and "positive, helpful atmosphere," but desired greater social interaction. They liked that (1) "new content was added,"(2) "spread out to make me see every topic," (3) "very interactive," and (4) "I liked how one person's comment would trigger a larger conversation."

Only 4 users participated in poststudy interviews. One interviewee commented the site was, "better than I expected it to be" and later clarified:

> *I didn't expect [the site] to be that very in-depth. I thought it was very straightforward, but it was very in-depth and very fun to be on. The blog posts on positive quotes and stories, I'd say they felt very uplifting actually. I really enjoyed it. It felt like I wasn't reading something in a psychological book. It felt like on a personal level.* [ID 3]

On comments to an article on what to share and what not to share on social media, users remarked that although they don't feel comfortable posting on other websites, they do feel comfortable on sova.pitt.edu due to its anonymity (Figure 4).

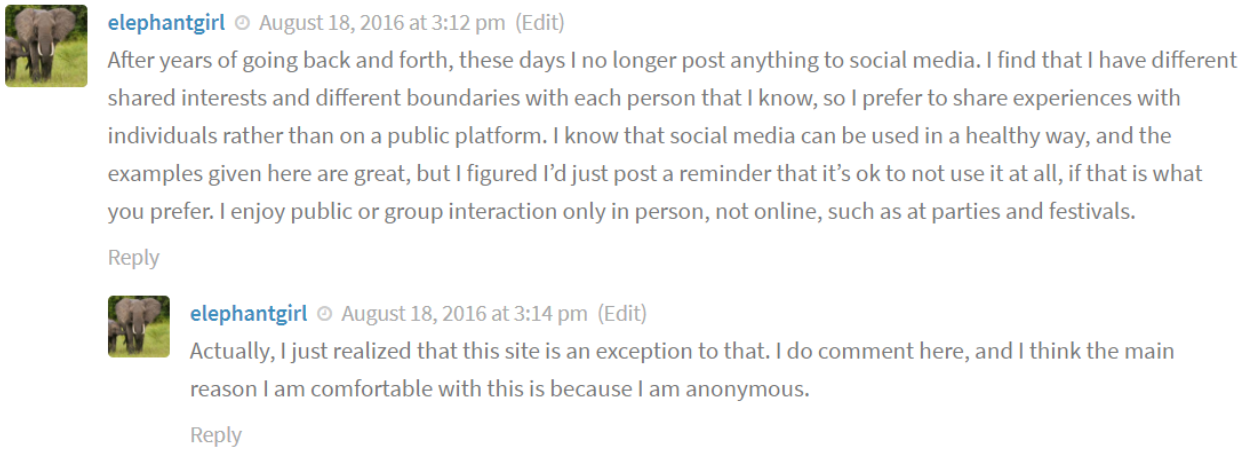
In open-ended questions, remarks on what to change mostly centered around increasing interactivity of the site and including less structured ways for users to communicate, such as on a discussion forum. In poststudy interviews, users remarked an app would improve usability due to logging in:

> *Definitely now with smartphones like if there's an app it's so much better than having to log onto the Internet.* [ID 2]

When asked about a potential future direction of including peer users who compose their own blog posts, a user remarked:

> *I think that's a great idea. I think that's what makes it more likeable you know when people have their own input so they can share their own stories. They write their own journals per se about their experiences. That's a good idea.* [ID 3]

Figure 4. User commenting on anonymity.



Changes in Mental Health and Social Outcomes

Due to loss to follow-up and missing data, only 57 participants completed enough of the 6-week survey to calculate scoring scales for depression, anxiety, and positive youth development.

There was a statistically significant *(P*=.04) decrease in depression symptoms from baseline to 6 weeks, although the change in score (1.4) was less clinically significant. There was no change in the number of AYA with a SCARED-C score consistent with anxiety (*P*=.34) There was not a significant increase in the number of AYA accessing mental health treatment at follow-up, although the population purposely recruited for this study already had higher than average levels of accessing treatment (Table 3).

Overall, there was a statistically significant positive change in mean total PYD-SF from baseline (54.0, SD 7.6) to 6-week (57.6, SD 8.0), t_{56}=4.32, *P*<.001, with significant increases in subscale scores for competence, confidence, and connection and nonsignificant increases in character and caring (Table 4).

Participants commenting on blog posts shared personal stories and support (Figure 5).

Table 3. Change in depression, anxious symptoms and obtaining treatment at follow-up, N=56. N differs from original group due to loss to follow-up and incomplete data, for example, not completing full scale.

Outcome	Baseline	6-week	Test parameter	Difference	*P* value
PHQ-9[a] score, mean (SD)	11.6 (5.1)	10.2 (6.1)	Paired *t* test	*t* (df)=2.066 (55)	*P*=.04
SCARED-C[b] score, score consistent with anxiety (≥3), n (%)	48 (86)	49 (88)	McNemar test	N=56	*P*=.34
Treatment history (yes to having ever received), n (%)					
Professional psychologist/counselor	43 (66)	45 (69)	McNemar test	N=57	*P*=.34
Medication such as antidepressant	32 (56)	34 (52)	McNemar test	N=57	*P*>.99

[a]PHQ-9: Patient Health Questionnaire-9 modified for adolescents.

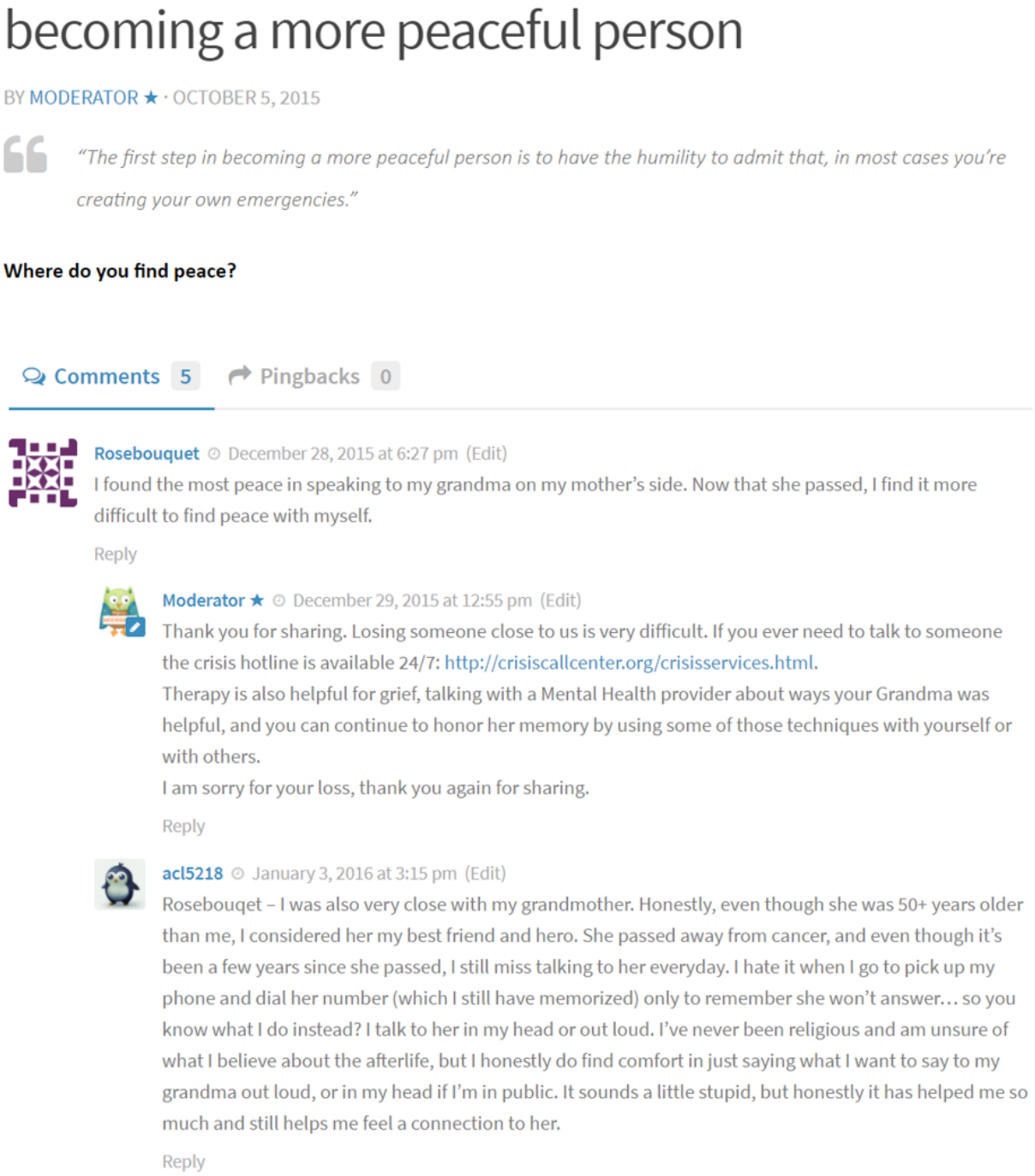
[b]SCARED-C: 5-item Screen for Child Anxiety Related Emotional Disorders.

Table 4. Changes in Positive Youth Development-Short Form score (N=57). N differs from original group due to loss to follow-up.

Outcome	Baseline	6-week	Test parameter	Difference	*P* value
PYD-SF[a] score, mean (SD)	54.0 (7.6)	57.6 (8.0)	Paired *t* test	*t* (df)=−4.32 (56)	*P*<.001
Competence	7.6 (1.9)	8.2 (2.1)	Paired *t* test	*t* (df)=−2.87 (57)	*P*=.006
Confidence	7.9 (2.5)	8.6 (2.3)	Paired *t* test	*t* (df)=−2.27 (57)	*P*=.03
Character	13.4 (2.6)	14.0 (3.1)	Paired *t* test	*t* (df)=−1.11 (57)	*P*=.27
Caring	12.9 (2.2)	13.2 (2.2)	Paired *t* test	*t* (df)=−0.48 (56)	*P*=.63
Connection	12.2 (3.2)	13.6 (3.1)	Paired *t* test	*t* (df)=−3.48 (56)	*P*=.001

[a]PYD-SF: Positive Youth Development-Short Form.

Figure 5. User commenting on providing support.



Discussion

Principal Findings

The aim of this study was to determine the usability of a social media website designed to challenge negative health beliefs and increase depression and anxiety knowledge in adolescents and young adults through daily blog posts enhanced with peer commentary from an online community. We found that maintaining the site was technologically feasible as we experienced very few major errors, aside from finding that notification emails were not being sent because of incorrect settings. We were able to moderate the site and examine all new content in a timely manner. Additionally, there were no safety concerns identified. Feasibility goals were not fully achieved. While we were able to recruit about 100 AYA to the study, which implied interest about the site, only about half of the users ever logged in. We expected that all users would log in and the mean number of log-ins to the site would be 12 to 18 over the 6-week study, but the actual mean of 2 log-ins over the first 6 weeks was much lower than the mean value we expected. We reached our usability goals and found that the median number of users found that SOVA sites had "good" user-friendliness and the SUS scale acceptability mean was 71.2, only slightly lower than our goal of 73. We also found users in this study experienced a slight decrease in depression

symptoms and increase in competence, confidence, and connection.

We think we were able to achieve good usability results mainly because of the stepwise stakeholder-informed approach we took, which employed human computer interaction techniques and uncovered user preferences such as a desire for anonymity and functionality to allow them to share their experiences with others [18]. Like other ehealth interventions, we struggled to achieve adequate engagement defined as users logging in and commenting on blog posts, likely due to not having directed engagement interventions in this part of the design and refinement process. One intervention which did seem to increase views, especially from the public, included removing the requirement to log-in to read blog posts and only requiring log-in to join the online community (Figure 3). Initially, due to the at-risk nature of the studied population, we refrained from doing this until we had several months of recruitment without any safety concerns. This is an example of how throughout the design process of this intervention, we had to make multiple decisions that balanced the goal of increasing usability while meeting the goals of the research intervention in this specific population, including safety. Another example is not permitting private conversations between individual users or posts on a newsfeed. Although those features were available in the WordPress plug-in used to employ social media features, Buddy Press [37], these would be too difficult and time-consuming for our team to moderate. Initially, we did try discussion boards, which were easier to moderate, but then removed them in an effort to concentrate the growing online community in fewer locations (only within replies to blog posts) and to avoid the "empty-room phenomenon" (ie, when 1 user comments, there are a low number of concurrent users available to respond) [38].

A review of the literature finds few comparable studies in adolescent and young adult mental health which were tested for usability in the same stage of development or having similar intervention components or goals. The most comparable is a recent study evaluating the feasibility and acceptability of a minimal viability version of ProjectTECH, a Web-based skill-building intervention for adolescents at risk for depression including peer support, in 4 groups of 8 to 12 individuals over an 8-week period [39]. ProjectTECH found a higher median number of log-ins of 26 over an 8-week trial although the log-ins decreased over time and had a lower mean SUS scale score of 67.5 (SD 18.1). The log-in number in this study may have been higher due to the user being aware of planned lessons and a desire to move through materials, as well as phone contact with the research team at recruitment and follow-up, and the use of peer moderators. Compared with this, SOVA did not provide users with instructions on how to use the site and direct communication (beside templated emails) occurred only if necessary, thus limiting opportunities for rapport-building with participants. Also, our moderators are team members. Through further adolescent and young adult stakeholder feedback, we have now incorporated a "how to use the site" video to the current version of SOVA and the involvement of peer bloggers who also frequently comment. In recruitment for future studies, we also plan to use an introductory phone call as an on-boarding process for using the site and to answer participant questions before use.

Web-based interventions to facilitate mental health help-seeking in young adults are feasible [40] and can increase readiness to seek help and decrease stigma [41] and can be used to increase mental health literacy [42,43]. Although Web-based interventions have had positive effects, problems with lack of user engagement with them, especially in less controlled trials and settings, are well-described [44-46]. Reasons for lower than anticipated engagement with our intervention include (1) newness of the site and 100 users recruited slowly over time so that at any moment, an "empty room" may be experienced [38]; (2) high dropout rates experienced in most ehealth trials or "law of attrition," where many initial users quickly stop accessing the site [13]; and (3) "superuser" effect or 1% rule, where 90% users observe, 9% users contribute sparingly, and 1% users contribute most new content; demonstrated across even long-standing digital health social networks [45]. SOVA users actually outperformed the "90-9-1" rule, as out of the initial almost 100 users, 16 users ever commented and 5 users commented more than 5 times. Unanswered questions remain for technology interventions regarding what amount of engagement is sufficient to achieve the desired health outcome and which techniques increase user engagement [14].

A recent review of 19 Internet-based cognitive behavioral therapy programs for adolescent depression found that some techniques may increase user engagement. For example, real-time guidance, surface credibility or a competent "look and feel" of the site, including video, animation, and interactive exercises, tailoring, and self-monitoring components [47]. Other techniques, including employing peer support [48], incorporating gamification [49], using a supportive accountability model [50], and using mobile phone apps may help increase adherence to adolescent Web-based interventions [39]. A Web-based social media intervention for depression relapse prevention called "Rebound," which employed both supportive accountability and peer moderators, was found to be acceptable, feasible, highly usable, and safe; and young people with major depression also experienced improvement in their depression scores with this [51].

This study was not designed to test effectiveness, but the direction of slightly decreasing depression symptoms is encouraging. Overall, the AYA participating in this study had high levels of caring and altruistic intentions. Contributing to Web-based interventions which have a goal of sharing experiences in a safe and positive environment may offer opportunities for these AYA to increase aspects of positive development, especially competence, confidence, and connection. Recruiting new users to the site who have high levels of the caring characteristic and have a desire to share what they have learned about being mentally healthy may be a method to increase site engagement as well.

Limitations

There are several limitations of this study. Due to finding that anonymity was important to users in our previous design study [18], we used a respondent-driven personal identifier code [52] to preserve confidentiality in survey data collection. This in

turn limited our ability to confirm whether the 6-week survey respondents included users who had in fact viewed site content. Due to recruitment being online and the majority recruited through Craiglist, there was a high loss to follow-up, and a relatively higher number of young adults were recruited. Although this limits generalizability, the young adults may have been also able to reflect on their experiences throughout adolescence when providing feedback. More than half of the group screened out due to suicidality and mostly due to a history of a previous suicide attempt; usability results may have differed in this group. Due to the unknown safety profile of the intervention before beta testing, we directed recruitment toward a sample which had experienced depression and anxiety but had mostly received treatment. As we found no safety risk in this study, in future studies we will also include those participants who have had a history of suicide attempt but have received treatment. There was no comparison group for the exploratory outcomes, although this was not needed in the overall aim of this study, that is, feasibility and usability. Due to the iterative nature of Internet interventions and differential length of time that different users would participate on the site, the intervention exposure is likely different for each user, albeit this did not detract us from our goal to achieve a desirable usability score. Iterative recruitment resulted in incremental improvements to the site, including opening the blog part of the site to nonusers and correcting a problem with sending daily emails, as well as upgrading to a better user profile design and comment notification. Although there is a risk in a randomized trial to intervention cross-over and limitations to capturing data, we learned that allowing potential participants to view part of a Web-based intervention and "test drive" it (ie, viewing blog articles) before full use and study participation (ie, logging in) simulates more of a real-world experience of trying out a technology intervention before subscribing to it, which may improve user engagement.

Conclusions

In conclusion, we found that using a stakeholder-informed user design process [18] may increase the subsequent usability of Web-based interventions directed at adolescents and young adults with depression and/or anxiety. Additionally, including adolescents and young adults in shaping Web-based health interventions may take advantage of their preexisting altruism and desire to help peers and help them to develop their strengths. In anticipation of difficulties with engagement, specific procedures need to be incorporated as part of the design process. Future engagement interventions for SOVA will include app development, use of peer bloggers, gamification, and incorporating the supportive accountability model in moderator interactions [50].

Acknowledgments

AR was supported by an institutional career development award during this study (AHRQ PCOR K12 HS 22989-1) and is currently on a second career development award (NIMH 1K23MH111922-01A1). This research was also supported by the National Institutes of Health through Grant Number UL1TR000005AR and, in part, by Children's Hospital of Pittsburgh of the UPMC Health System.

The authors thank Yves Patrick Tagasi Fotso, Siddharth Coontoor, Prashanth Kumar Ravindragopal, and Dr Michael Spring for technical assistance with measuring usability and website development. The authors thank Dr Bruce Rollman and Dr Bea Belnap and their research team with technical and study design assistance. The authors thank Alexandra DeMand, Laura Liuyi Lin, and Shannon Donofy and also former social work students and graduates Kara Mackinson Peters, Amie Ditomasso, Katrina Keane, Kaitlin Glover, Danielle Washington, and Anna Rastatter for assistance in blog writing and site moderation. The authors thank and acknowledge the SOVA community members and stakeholders for informing this study and making it possible.

Authors' Contributions

AR, TG, BS, and EM contributed to study design. AR and TG collected the data. AR, TG, CL, and JW contributed to the analysis. All authors contributed to interpretation of the data. AR wrote the manuscript with guidance from the other authors. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

References

1. Centers for Disease Control and Prevention. CDC. 2017. LCWK1. Deaths, percent of total deaths, and death rates for the 15 leading causes of death in 5-year age groups, by race and sex: United States, 2015 URL: https://www.cdc.gov/nchs/data/dvs/LCWK1_2015.pdf [accessed 2018-02-14] [WebCite Cache ID 6xE667lmH]
2. Brown GK, Beck AT, Steer RA, Grisham JR. Risk factors for suicide in psychiatric outpatients: a 20-year prospective study. J Consult Clin Psychol 2000 Jun;68(3):371-377. [Medline: 10883553]
3. Brent DA. Risk factors for adolescent suicide and suicidal behavior: mental and substance abuse disorders, family environmental factors, and life stress. Suicide Life Threat Behav 1995;25 Suppl:52-63. [Medline: 8553429]
4. LeCloux M, Maramaldi P, Thomas K, Wharff E. Health care resources and mental health service use among suicidal adolescents. J Behav Health Serv Res 2017 Apr;44(2):195-212. [doi: 10.1007/s11414-016-9509-8] [Medline: 27146895]

5. Merikangas KR, He JP, Burstein M, Swendsen J, Avenevoli S, Case B, et al. Service utilization for lifetime mental disorders in U.S. adolescents: results of the National Comorbidity Survey-Adolescent Supplement (NCS-A). J Am Acad Child Adolesc Psychiatry 2011 Jan;50(1):32-45 [FREE Full text] [doi: 10.1016/j.jaac.2010.10.006] [Medline: 21156268]
6. Jennings KS, Cheung JH, Britt TW, Goguen KN, Jeffirs SM, Peasley AL, et al. How are perceived stigma, self-stigma, and self-reliance related to treatment-seeking? A three-path model. Psychiatr Rehabil J 2015 Jun;38(2):109-116. [doi: 10.1037/prj0000138] [Medline: 25844914]
7. Ben-Zeev D. Mobile health for all: public-private partnerships can create a new mental health landscape. JMIR Ment Health 2016 Jun 6;3(2):e26 [FREE Full text] [doi: 10.2196/mental.5843] [Medline: 27268283]
8. Murphy JM, Nguyen T, Lucke C, Chiang C, Plasencia N, Jellinek M. Adolescent self-screening for mental health problems; demonstration of an internet-based approach. Acad Pediatr 2018;18(1):59-65. [doi: 10.1016/j.acap.2017.08.013] [Medline: 28870650]
9. Dunlop SM, More E, Romer D. Where do youth learn about suicides on the Internet, and what influence does this have on suicidal ideation? J Child Psychol Psychiatry 2011 Oct;52(10):1073-1080. [doi: 10.1111/j.1469-7610.2011.02416.x] [Medline: 21658185]
10. Marchant A, Hawton K, Stewart A, Montgomery P, Singaravelu V, Lloyd K, et al. A systematic review of the relationship between internet use, self-harm and suicidal behaviour in young people: the good, the bad and the unknown. PLoS One 2017;12(8):e0181722 [FREE Full text] [doi: 10.1371/journal.pone.0181722] [Medline: 28813437]
11. Younes N, Chollet A, Menard E, Melchior M. E-mental health care among young adults and help-seeking behaviors: a transversal study in a community sample. J Med Internet Res 2015 May 15;17(5):e123 [FREE Full text] [doi: 10.2196/jmir.4254] [Medline: 25979680]
12. Pinto MD, Hickman Jr RL, Clochesy J, Buchner M. Avatar-based depression self-management technology: promising approach to improve depressive symptoms among young adults. Appl Nurs Res 2013 Feb;26(1):45-48 [FREE Full text] [doi: 10.1016/j.apnr.2012.08.003] [Medline: 23265918]
13. Eysenbach G. The law of attrition. J Med Internet Res 2005 Mar 31;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]
14. van Gemert-Pijnen JE, Nijland N, van Limburg L, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011 Dec 5;13(4):e111 [FREE Full text] [doi: 10.2196/jmir.1672] [Medline: 22155738]
15. de Beurs D, van Bruinessen I, Noordman J, Friele R, van Dulmen S. Active involvement of end users when developing web-based mental health interventions. Front Psychiatry 2017;8:72 [FREE Full text] [doi: 10.3389/fpsyt.2017.00072] [Medline: 28515699]
16. Chan JK, Farrer LM, Gulliver A, Bennett K, Griffiths KM. University students' views on the perceived benefits and drawbacks of seeking help for mental health problems on the internet: a qualitative study. JMIR Hum Factors 2016 Jan 19;3(1):e3 [FREE Full text] [doi: 10.2196/humanfactors.4765] [Medline: 27026140]
17. Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, et al. From ideas to efficacy: the ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol 2015 Oct;34(10):971-982 [FREE Full text] [doi: 10.1037/hea0000161] [Medline: 25642841]
18. Radovic A, DeMand AL, Gmelin T, Stein BD, Miller E. SOVA: design of a stakeholder informed social media website for depressed adolescents and their parents. J Technol Hum Serv 2017;35(3):169-182. [doi: 10.1080/15228835.2017.1347552]
19. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. Int J Hum Comput Interact 2008;24(6):574-594. [doi: 10.1080/10447310802205776]
20. Wordpress. Meet WordPress URL: https://wordpress.org/ [accessed 2015-05-21] [WebCite Cache ID 6xE6lmvOx]
21. BuiltWith. CMS Usage Statistics: Statistics for websites using CMS technologies URL: https://trends.builtwith.com/cms [WebCite Cache ID 6xE6sfqA4]
22. White M. The Content Management Handbook. London: Facet Publishing; 2005.
23. Health.gov. Health Literacy Online: A Guide for Simplifying the User Experience URL: https://health.gov/healthliteracyonline/ [WebCite Cache ID 6xE6xLOwF]
24. Office Support: Microsoft Office help and training. Test your documents readability URL: https://support.office.com/en-us/article/Test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2 [WebCite Cache ID 6xE6zESn9]
25. National Institute of Mental Health. Teen Depression Study: Understanding Depression in Teenagers URL: https://www.nimh.nih.gov/health/publications/teen-depression/index.shtml [WebCite Cache ID 6xE70FNwW]
26. Van Voorhees BW, Fogel J, Houston TK, Cooper LA, Wang NY, Ford DE. Attitudes and illness factors associated with low perceived need for depression treatment among young adults. Soc Psychiatry Psychiatr Epidemiol 2006 Sep;41(9):746-754. [doi: 10.1007/s00127-006-0091-x] [Medline: 16896516]
27. Owens PL, Hoagwood K, Horwitz SM, Leaf PJ, Poduska JM, Kellam SG, et al. Barriers to children's mental health services. J Am Acad Child Adolesc Psychiatry 2002 Jun;41(6):731-738. [doi: 10.1097/00004583-200206000-00013] [Medline: 12049448]
28. Meredith LS, Stein BD, Paddock SM, Jaycox LH, Quinn VP, Chandra A, et al. Perceived barriers to treatment for adolescent depression. Med Care 2009 Jun;47(6):677-685. [doi: 10.1097/MLR.0b013e318190d46b] [Medline: 19434001]

29. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. BMC Psychiatry 2010 Dec 30;10:113 [FREE Full text] [doi: 10.1186/1471-244X-10-113] [Medline: 21192795]
30. Radovic A, Gmelin T, Stein BD, Miller E. Depressed adolescents' positive and negative use of social media. J Adolesc 2017 Feb;55:5-15 [FREE Full text] [doi: 10.1016/j.adolescence.2016.12.002] [Medline: 27997851]
31. Curtis AC. Defining adolescence. J Adolesc Fam Health 2015;7(2).
32. Richardson LP, McCauley E, Grossman DC, McCarty CA, Richards J, Russo JE, et al. Evaluation of the Patient Health Questionnaire-9 Item for detecting major depression among adolescents. Pediatrics 2010 Dec;126(6):1117-1123 [FREE Full text] [doi: 10.1542/peds.2010-0852] [Medline: 21041282]
33. Birmaher B, Brent DA, Chiappetta L, Bridge J, Monga S, Baugher M. Psychometric properties of the Screen for Child Anxiety Related Emotional Disorders (SCARED): a replication study. J Am Acad Child Adolesc Psychiatry 1999 Oct;38(10):1230-1236. [doi: 10.1097/00004583-199910000-00011] [Medline: 10517055]
34. Carlton PA, Deane FP. Impact of attitudes and suicidal ideation on adolescents' intentions to seek professional psychological help. J Adolesc 2000 Feb;23(1):35-45. [doi: 10.1006/jado.1999.0299] [Medline: 10700370]
35. Lerner RM, Lerner JV, Almerigi JB, Theokas C, Phelps E, Gestsdottir S, et al. Positive youth development, participation in community youth development programs, and community contributions of fifth-grade adolescents. J Early Adolesc 2016 Jul 26;25(1):17-71. [doi: 10.1177/0272431604272461]
36. Geldhof G, Bowers EP, Boyd MJ, Mueller MK, Napolitano CM, Schmid K, et al. Creation of short and very short measures of the five Cs of positive youth development. J Res Adolesc 2013 Mar 25;24(1):163-176. [doi: 10.1111/jora.12039]
37. BuddyPress. URL: https://buddypress.org/ [accessed 2018-02-14] [WebCite Cache ID 6xE7bajtz]
38. Bull SS, Levine DK, Black SR, Schmiege SJ, Santelli J. Social media-delivered sexual health intervention: a cluster randomized controlled trial. Am J Prev Med 2012 Nov;43(5):467-474 [FREE Full text] [doi: 10.1016/j.amepre.2012.07.022] [Medline: 23079168]
39. Ho J, Corden ME, Caccamo L, Tomasino KN, Duffecy J, Begale M, et al. Design and evaluation of a peer network to support adherence to a web-based intervention for adolescents. Internet Interv 2016 Nov;6:50-56 [FREE Full text] [doi: 10.1016/j.invent.2016.09.005] [Medline: 27722095]
40. Kauer SD, Buhagiar K, Blake V, Cotton S, Sanci L. Facilitating mental health help-seeking by young adults with a dedicated online program: a feasibility study of Link. Br Med J Open 2017 Jul 09;7(7):e015303 [FREE Full text] [doi: 10.1136/bmjopen-2016-015303] [Medline: 28694345]
41. King CA, Eisenberg D, Zheng K, Czyz E, Kramer A, Horwitz A, et al. Online suicide risk screening and intervention with college students: a pilot randomized controlled trial. J Consult Clin Psychol 2015 Jun;83(3):630-636 [FREE Full text] [doi: 10.1037/a0038805] [Medline: 25688811]
42. Li TM, Chau M, Wong PW, Lai ES, Yip PS. Evaluation of a Web-based social network electronic game in enhancing mental health literacy for young people. J Med Internet Res 2013 May 15;15(5):e80 [FREE Full text] [doi: 10.2196/jmir.2316] [Medline: 23676714]
43. Gulliver A, Griffiths KM, Christensen H, Mackinnon A, Calear AL, Parsons A, et al. Internet-based interventions to promote mental health help-seeking in elite athletes: an exploratory randomized controlled trial. J Med Internet Res 2012 Jun 29;14(3):e69 [FREE Full text] [doi: 10.2196/jmir.1864] [Medline: 22743352]
44. Christensen H, Griffiths KM, Farrer L. Adherence in internet interventions for anxiety and depression. J Med Internet Res 2009 Apr 24;11(2):e13 [FREE Full text] [doi: 10.2196/jmir.1194] [Medline: 19403466]
45. van Mierlo T. The 1% rule in four digital health social networks: an observational study. J Med Internet Res 2014 Feb 04;16(2):e33 [FREE Full text] [doi: 10.2196/jmir.2966] [Medline: 24496109]
46. Kvillemo P, Brandberg Y, Bränström R. Feasibility and outcomes of an internet-based mindfulness training program: a pilot randomized controlled trial. JMIR Ment Health 2016 Jul 22;3(3):e33 [FREE Full text] [doi: 10.2196/mental.5457] [Medline: 27450466]
47. Wozney L, Huguet A, Bennett K, Radomski AD, Hartling L, Dyson M, et al. How do eHealth programs for adolescents with depression work? A realist review of persuasive system design components in internet-based psychological therapies. J Med Internet Res 2017 Aug 09;19(8):e266 [FREE Full text] [doi: 10.2196/jmir.7573] [Medline: 28793983]
48. Davidson L, Bellamy C, Guy K, Miller R. Peer support among persons with severe mental illnesses: a review of evidence and experience. World Psychiatry 2012 Jun;11(2):123-128 [FREE Full text] [Medline: 22654945]
49. Ryan J, Edney S, Maher C. Engagement, compliance and retention with a gamified online social networking physical activity intervention. Transl Behav Med 2017 Dec;7(4):702-708 [FREE Full text] [doi: 10.1007/s13142-017-0499-8] [Medline: 28523603]
50. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing human support to enhance adherence to eHealth interventions. J Med Internet Res 2011 Mar 10;13(1):e30 [FREE Full text] [doi: 10.2196/jmir.1602] [Medline: 21393123]
51. Rice S, Gleeson J, Davey C, Hetrick S, Parker A, Lederman R, et al. Moderated online social therapy for depression relapse prevention in young people: pilot study of a 'next generation' online intervention. Early Interv Psychiatry 2016 Jun 17. [doi: 10.1111/eip.12354] [Medline: 27311581]

52. Ripper L, Ciaravino S, Jones K, Jaime MC, Miller E. Use of a Respondent-Generated Personal Code for Matching Anonymous Adolescent Surveys in Longitudinal Studies. J Adolesc Health 2017 Jun;60(6):751-753. [doi: 10.1016/j.jadohealth.2017.01.003] [Medline: 28279541]

Abbreviations

AYA: Adolescents and young adults
IP: Internet protocol
PHQ-9: Patient Health Questionnaire-9
PHQ-9A: Patient Health Questionnaire-9 modified for adolescents
PYD-VSF: Positive Youth Development-Very Short Form
SCARED: Screen for Child Anxiety Related Emotional Disorders, 5-item version
SOVA: Supporting Our Valued Adolescents
SUS: System Usability Scale

Edited by J Prescott; submitted 12.12.17; peer-reviewed by N Nasr, K Machin; comments to author 30.12.17; revised version received 08.01.18; accepted 08.01.18; published 26.02.18.

Please cite as:
Radovic A, Gmelin T, Hua J, Long C, Stein BD, Miller E
Supporting Our Valued Adolescents (SOVA), a Social Media Website for Adolescents with Depression and/or Anxiety: Technological Feasibility, Usability, and Acceptability Study
JMIR Ment Health 2018;5(1):e17
URL: http://mental.jmir.org/2018/1/e17/
doi:10.2196/mental.9441
PMID:29483067

Original Paper

Web-Based Decision Aid to Assist Help-Seeking Choices for Young People Who Self-Harm: Outcomes From a Randomized Controlled Feasibility Trial

Sarah L Rowe[1], PhD; Krisna Patel[2], MSc; Rebecca S French[3], PhD; Claire Henderson[4], MRCPsych, PhD; Dennis Ougrin[5], MD, PhD; Mike Slade[6], PhD, PsychD; Paul Moran[7], MD, FRCPsych

[1]Division of Psychiatry, University College London, London, United Kingdom

[2]Department of Psychosis, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom

[3]Department of Social and Environmental Health Research, Faculty of Public Health & Policy, London School of Hygiene and Tropical Medicine, London, United Kingdom

[4]Health Service and Population Research Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom

[5]Child and Adolescent Psychiatry Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom

[6]School of Health Sciences, Institute of Mental Health, University of Nottingham, Nottingham, United Kingdom

[7]Centre for Academic Mental Health, School of Social & Community Medicine, University of Bristol, Bristol, United Kingdom

Corresponding Author:
Sarah L Rowe, PhD
Division of Psychiatry
University College London
Maple House, 149 Tottenham Court Road, 6th Floor
London, W1T 7NF
United Kingdom
Phone: 44 07415078280
Email: s.rowe@ucl.ac.uk

Abstract

Background: Adolescents who self-harm are often unsure how or where to get help. We developed a Web-based personalized decision aid (DA) designed to support young people in decision making about seeking help for their self-harm.

Objective: The aim of this study was to evaluate the feasibility and acceptability of the DA intervention and the randomized controlled trial (RCT) in a school setting.

Methods: We conducted a two-group, single blind, randomized controlled feasibility trial in a school setting. Participants aged 12 to 18 years who reported self-harm in the past 12 months were randomized to either a Web-based DA or to general information about mood and feelings. Feasibility of recruitment, randomization, and follow-up rates were assessed, as was acceptability of the intervention and study procedures. Descriptive data were collected on outcome measures examining decision making and help-seeking behavior. Qualitative interviews were conducted with young people, parents or carers, and staff and subjected to thematic analysis to explore their views of the DA and study processes.

Results: Parental consent was a significant barrier to young people participating in the trial, with only 17.87% (208/1164) of parents or guardians who were contacted for consent responding to study invitations. Where parental consent was obtained, we were able to recruit 81.7% (170/208) of young people into the study. Of those young people screened, 13.5% (23/170) had self-harmed in the past year. Ten participants were randomized to receiving the DA, and 13 were randomized to the control group. Four-week follow-up assessments were completed with all participants. The DA had good acceptability, but qualitative interviews suggested that a DA that addressed broader mental health problems such as depression, anxiety, and self-harm may be more beneficial.

Conclusions: A broad-based mental health DA addressing a wide range of psychosocial problems may be useful for young people. The requirement for parental consent is a key barrier to intervention research on self-harm in the school setting. Adaptations to the research design and the intervention are needed before generalizable research about DAs can be successfully conducted in a school setting.

Trial Registration: International Standard Randomized Controlled Trial registry: ISRCTN11230559; http://www.isrctn.com/ISRCTN11230559 (Archived by WebCite at http://www.webcitation.org/6wqErsYWG)

(JMIR Ment Health 2018;5(1):e10) doi:10.2196/mental.8098

KEYWORDS

adolescent; self-harm; decision aid; intervention; schools; feasibility; randomized controlled trials; ethics

Introduction

Background

Self-harm is common among young people, affecting about 1 in 10 people [1,2]. A past history of self-harm is also the strongest predictor of suicide, and so self-harm is a major public health concern [3].

Between a third and one half of young people who self-harm do not know where to seek help [4]. Given the reach of the Internet, Web-based approaches to supporting decision making may provide an important new way of providing decisional support.

Decision aids (DAs) are tools that assist the decision-making process by identifying the options available and the attributes associated with these options, as well as clarifying personal values and preferences [5,6]. They have been shown to increase knowledge, decrease decisional conflict, and encourage more active participation in decision making around matters relating to health [7]. DAs are more commonly used in adult populations, and little research has examined their potential utility within populations of young people or indeed, within the area of mental health [8,9]. We have developed (with the help of young people and clinicians) a Web-based personalized DA based on the principles of multi-criteria decision analysis (MCDA) [10] and designed to support young people in making help-seeking choices for their self-harm.

Aims and Objectives

Our aim was to evaluate the feasibility and acceptability of the DA intervention and the randomized controlled trial (RCT) in a school setting. The objectives were as follows:

1. To assess recruitment or attrition rates, acceptability of randomization, data completeness, and feasibility of school-based sampling
2. To inform the design of an adequately powered, future effectiveness study through the reporting of descriptive data on candidate measures
3. To explore the views and experiences of the intervention and participating in the study with young people, staff, and parents

Methods

Trial Design

This was a two-group, parallel arm, single blind RCT. The trial protocol has been previously published [11], and in brief, outlines the development and piloting of the DA and plans for this feasibility study. We randomized school students who were screened for self-harming behavior to either receiving a DA (intervention group) or general information about mood and feelings (control group). Outcome measures using self-report questionnaires were completed at baseline (pre intervention), post intervention, and 4-week follow-up. Qualitative interviews were conducted with a subset of young people, staff, and parents to explore their views and experiences of the intervention and participating in the study.

Participants

Inclusion criteria were young people aged 12 to 18 years attending the study site secondary school, with a basic proficiency in English language, and who had self-harmed in the past 12 months. Participants were excluded if they were lacking capacity to consent. This refers to young people who had cognitive or language difficulties that would preclude subjects being able to understand, retain, and weigh up information about the study and then communicate their decision regarding participation (ie, providing informed consent).

Procedure

Potential participants were identified at a secondary school in an inner London borough. Parents or carers of students in the school were sent information by post, asking for their consent to invite their child to participate. This was followed by presentations at school assemblies (to students), school newsletters, circulation of a link to a podcast (audio recording) about the study, and a reminder email. Where consent was given, their child was invited to participate, and once consented, the participant completed a Web-based questionnaire at school (in their lunch break or after school) asking demographic questions (eg, age and gender), a short standardized questionnaire about their mood and feelings, and two questions about the occurrence of any self-harm behavior in the previous year. If the participant did not report self-harming in the previous year (including those who had never self-harmed and those who had self-harmed more than 12 months ago), the questionnaire ended, and they were given a paper copy of general information about feelings and emotions from the ChildLine website. For these participants, completion of the questionnaire was a onetime only occurrence that took approximately 5 to 10 min. All participants received a £5 voucher upon completion of the assessment to thank them for their time.

If the participant reported that they had self-harmed in the previous 12 months, they completed baseline measures and were then randomized by a computer program to one of two groups: (1) a DA group who completed the DA and were then presented with help-seeking options that were based on information they provided while using the DA. Once they completed the DA, they received a paper copy of information on how to access any of the help-seeking options that were listed in the DA and (2) a control group allocated to general

information about feelings and emotions from the ChildLine website.

All randomized participants completed the measures before and after they went through the DA or control condition and at 4-week follow-up.

At the 4-week follow-up appointment, participants were invited for a qualitative interview to explore their views and experiences of the study procedures and for those randomized to the intervention, their views and experiences of the DA. Young people who had not indicated self-harm on the survey were also interviewed about their views of the study and potential utility of the DA for young people who self-harm. The sample was selected to include both males and females and a range of ages. All interviews were conducted during school hours in a private room on campus, and participants received a £10 Amazon voucher upon completion of the interview to thank them for their time.

Parents or carers of children attending the school (irrespective of whether their child had participated in the study) and teachers and pastoral staff were approached for a telephone interview to obtain their views on the intervention and recruitment into the feasibility trial. Consent for interview was obtained via email. Telephone interviews were conducted with parents or carers in a private room on the university site. All interviews were audio-recorded (with participant's permission) and transcribed verbatim; details were anonymized to preserve participant identity.

Ethics and Governance Approvals

This feasibility trial was approved by King's College London College Research Ethics Committee; ref PNM/14/15-114, and the trial was registered with the International Standard Randomized Controlled Trial registry (ISRCTN11230559).

Intervention Arm

The DA (called "My Self-Help Tool") is based on the principles of MCDA and designed for young people to be used by themselves, to find out about different help-seeking options for self-harm (such as family, general practitioner, or telephone helpline). In addition to the sources of support, users were asked to identify help-seeking attributes that were of importance to them, ranging from confidentiality to other concerns (such as not wanting to be seen as attention seeking). They were then required to indicate the degree of importance they attached to each identified attribute according to the help-seeking options they had chosen, for example, weighting how important maintenance of confidentiality was to them. Once they had made their selections, a personalized rating and ranking of the help-seeking options was presented to them based on the information they had submitted (see Multimedia Appendix 1) [10,12].

Control Arm

Participants in the control arm received general information on feelings and emotions from the ChildLine website. This information was displayed as a static (noninteractive) page in our questionnaire rather than a link that young people could use to connect to the ChildLine website. This comparison group was chosen to control for attention and time spent reviewing information. Those in the control arm were exposed to relevant static Web content but which did not involve decisional support.

Safety Protocols

All participants who disclosed self-harm during the study (irrespective if it was in the past 12 months or more than 12 months ago) were referred to the school counselor to ensure they remained safe and were given appropriate support, as explained before enrollment in the study information sheet. Parents were also informed of this referral in accordance with school policy.

Measures

Baseline Assessments: All Participants

The screening questionnaire comprised sociodemographics (gender, age, ethnicity, and living situation) and information about possible support networks (eg, siblings, boyfriend or girlfriend, or social worker), the Short Mood and Feelings Questionnaire (13-item self-rated measure of depressive symptoms with scores of 10 or greater indicating the likely presence of major depression) [13], and two questions on self-harming behavior: (1) "Have you ever deliberately tried to harm yourself (such as cut yourself or taken an overdose)?" and (2) "When was the last time you tried to harm yourself?" [14].

Decision Aid Group and Control Intervention

1. Stage of decision making scale: This scale measures the individual's readiness to engage in decision making [15]. It consists of one item with six response options anchored at 1 (haven't started to think about the choices) and 6 (have already made a decision and am unlikely to change my mind).
2. General Help-Seeking Questionnaire (GHSQ, intentions): This assesses future help-seeking intentions and recent and past help-seeking experiences [16]. It uses a 7-point Likert scale ranging from 1 (extremely unlikely) to 7 (extremely likely) for each help source option. Higher scores indicated higher intentions.
3. Questionnaire on anticipated discrimination: This 14-item questionnaire measures the extent to which people anticipate personally experiencing discrimination in key life domains as a result of mental health problems [17]. It uses a 4-point Likert scale ranging from 0=strongly disagree to 3=strongly agree. We used five items from this measure that are relevant to our study population (adolescents).
4. Decisional Conflict Scale (DCS): The decisional conflict scales measure personal perceptions of (1) Uncertainty in choosing between options, (2) Modifiable factors contributing to uncertainty, and (3) Effective decision making. The 16-item version of the scale was used [18]; each item is rated on a 5-point Likert scale ranging from 0=strongly agree to 4=strongly disagree. A total score and 5 subscores (uncertainty subscore, informed subscore, vales clarity subscore, support subscore, and effective decision subscore) are generated. Scores exceeding 37.5 are associated with decisional delay or feeling unsure about implementation. We asked questions pertaining to the support and uncertainty subscales only.

5. Questions on the DA (only completed by those allocated to the DA group): Participants were asked to answer questions about (1) whether they would follow the "recommended" option, (2) whether the use of the DA has changed any of their perceptions or feelings about their help-seeking options, (3) whether there is anything we could do to improve the DA, and (4) whether or not they would recommend the DA to other young people who have self-harmed.

The support and uncertainty subscales from the DCS and the Stage of Decision Making scale were repeated immediately after completing the DA. All measures were repeated at 4 weeks, with the only change being to the GHSQ, which asked about actual help-seeking behavior in the past 4 weeks.

Once this assessment was completed, all participants (and a small sample of nontrial participants) were invited to participate in a qualitative interview, which sought to explore factors relating to participation in the study and for intervention participants, views, and experiences of the DA (eg, how, if at all, the DA prompted help-seeking behavior).

Sample Size

We undertook a power calculation to give us a target number to aim toward. For continuous outcomes relating to decision making and empowerment, a sample size of 60 (30 randomized to the DA and 30 randomized to the control condition) would detect a standardized effect size of 0.75, with 80% power [19]. To obtain a sample of 60 young people reporting self-harm to be randomized, we needed to recruit and screen 600 pupils based on a 10% prevalence rate [2].

Randomization and Blinding

Following consent and baseline assessment, participants who were randomized into the intervention and control groups (ie, those who had self-harmed in the past year) were placed into one of eight trial strata (all boys were grouped into a single stratum, and girls were grouped into seven age strata). We stratified randomization by gender because self-harm typically occurs more frequently in female compared with male adolescents [20]. Each stratum was allocated using a random permuted block algorithm, with a block size of four. Appropriate locks were in place to ensure that randomization tokens could not be used multiple times or skipped over. Research staff were blinded to allocation of the intervention or control arms at post intervention and follow-up.

Statistical Analysis Plan

In keeping with recommendations for small-scale feasibility trials, the analysis focused on feasibility of scaling up to a full-scale RCT [21]. This consisted of the following:

1. To determine feasibility of recruitment to the study, parental and student invitation and consent rates were documented, and the number of young people meeting inclusion or exclusion criteria were examined. Details of those who declined to be randomized and an option for their reason for refusing were recorded.
2. Treatment acceptability was assessed by the proportion of participants who refused to use the DA. Retention up until 4-week follow-up was examined.
3. Feasibility of the research protocol was assessed by the proportion of participants failing to adhere to the full research protocol, the burden of which will be similar to that which could be expected in a full study. The target collection of complete data was 90% of all participants recruited.
4. Exploratory findings were conducted on outcome measures, and we used a CI approach to assist the justification for proceeding to a future trial. A linear regression with the treatment group contrast was used to assess the difference between groups, adjusted for baseline differences. A linear regression with a single binary explanatory variable is equivalent to a *t* test. It was chosen instead of a *t* test because it is not possible to perform a *t* test with more than one explanatory variable, so we would not have been able to adjust for baseline using a *t* test. Effect sizes for partial eta squared are larger values than eta-squared, ranging from 0.01 (small), 0.09 (medium), and 0.25 (large). All analyses were performed with Statistical Package for the Social Sciences (SPSS) versions 22.0 and 24.0 (IBM Corp) for Windows.

Qualitative Analysis

Thematic analysis [22] was used for this study. After initial familiarization with data from the first five transcripts, KP and RF generated a preliminary coding framework. Primary analysis was undertaken by one author (KP) using Nvivo10 (QSR International) [23]. KP coded all the interviews using the agreed framework with themes and subthemes identified, along with deviant and atypical cases. Discussions were held to ensure themes were adequately reflected in the raw data [11].

Results

Quantitative Findings

Feasibility of Recruitment and Consent Rates

Recruitment is shown in Figure 1. A total of 208 parents or guardians gave consent (17.87%, 208/1164). Attempts to contact the 208 young people resulted in 170 (81.7%) participants recruited over 10 months (October 2015-July 2016). No young people were excluded on the grounds of lack of capacity to consent.

Feasibility of Randomization Procedures, Response Rates, and Follow-Up Rates

Of the 170 young people who were screened using the Web-based questionnaire, 23 (13.5%) reported self-harming behavior in the past year (and 5 reported self-harm occurring over a year ago). None of the 23 eligible participants declined to be randomized (intervention n=10, control group n=13). Final follow-up was completed in August 2016. No baseline, postintervention, or 4-week follow-up data were missing.

Baseline Characteristics and Previous Help-Seeking for Self-Harm

Demographic data for the sample are displayed in Table 1.

Figure 1. Flowchart of the trial design. DA: decision aid.

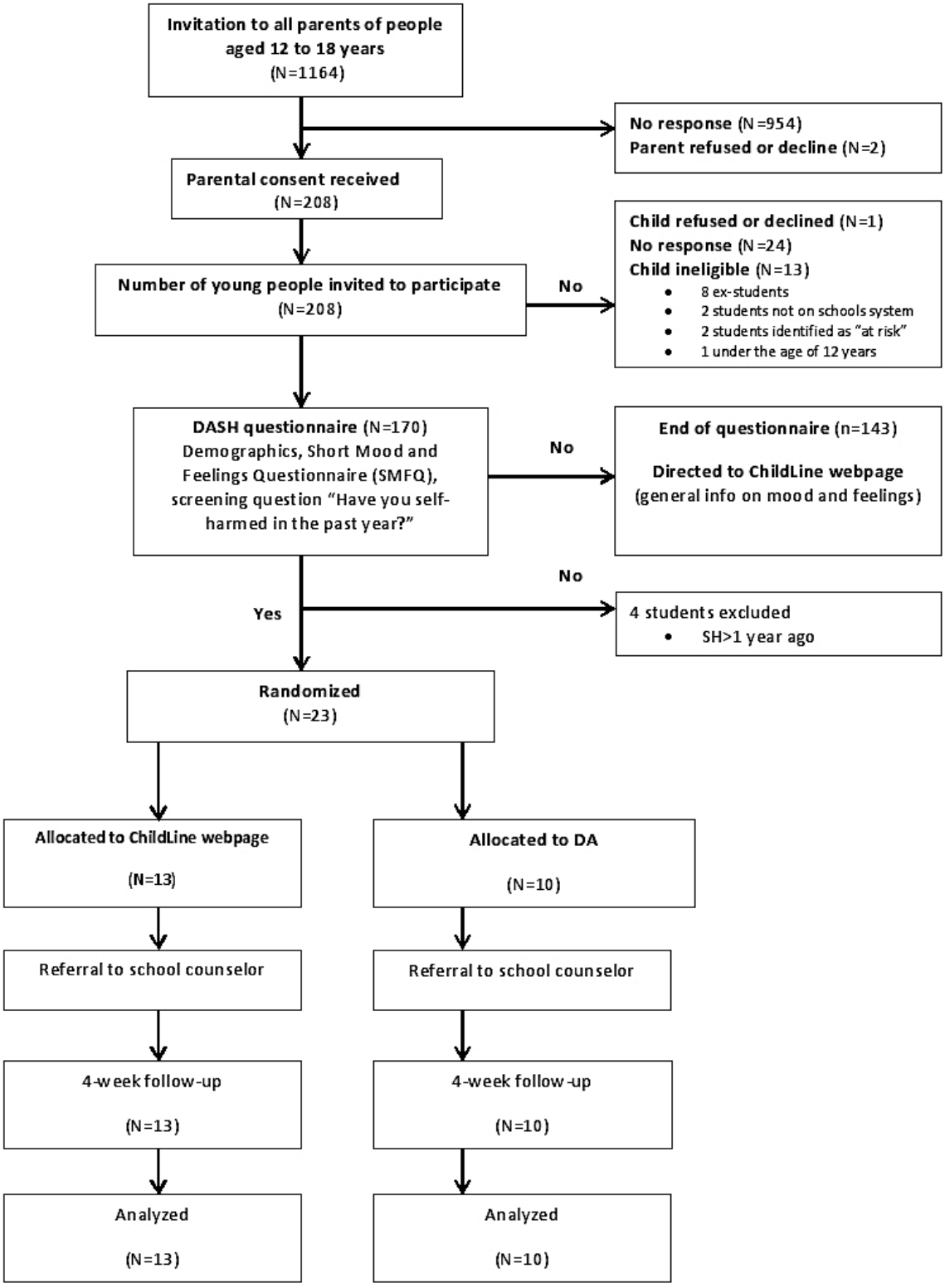


Table 1. Descriptive statistics for study sample.

Demographics	Decision aid (N=10)	Control (N=13)	Not randomized (N=147)
Gender, n (%)			
Female	6 (60)	8 (62)	77 (52.3)
Male	4 (40)	5 (38)	70 (47.6)
Ethnicity, n (%)			
White	10 (100)	11 (84)	110 (74.8)
Mixed or multiple	0 (0)	1 (8)	14 (9.5)
Asian or Asian British	0 (0)	0 (0)	5 (3.4)
Black or African or Caribbean or black British	0 (0)	0 (0)	14 (9.5)
Other	0 (0)	1 (8)	4 (2.7)
Age (years)			
12-15	8 (80)	12 (92)	138 (93.8)
16-18	2 (20)	1 (8)	32 (21.8)
Short Mood and Feelings Questionnaire total score, mean (SD)			
0-10	4 (40)	6 (46)	133 (90.5)
11-26 (depressive symptoms)	6 (60)	7 (54)	14 (9.5)

Table 2. Linear regression of outcome measures.

Outcome measures	Decision aid	Control	Regression		
	Mean (SD)	Mean (SD)	Group difference (95% CI)[a]	*t*, *P* values	Effect size (η^2)[b]
Stage of decision making					
Preintervention	3.7 (2.0)	3.1 (2.1)			
Postintervention	4.0 (1.6)	4.0 (1.7)	−0.4 (−1.4 to 0.8)	−0.68, .51	0.02
4-week follow-up	3.5 (3.5)	4.8 (1.6)	−1.4 (−3.0 to 0.3)	−0.17, .10	0.13
DCS[c] uncertainty subscale					
Preintervention	31.7 (32.8)	35.9 (33.9)			
Postintervention	31.7 (33.7)	37.2 (35.5)	−1.3 (−11.1 to 8.4)	−0.29, .78	0.00
4-week follow-up	40.0 (42.5)	30.8 (27.9)	11.1 (−14.3 to 37.7)	0.94, .36	0.04
DCS support subscale					
Preintervention	15.0 (18.3)	19.2 (23.4)			
Postintervention	15.0 (24.2)	11.5 (19.7)	6.8 (−5.4 to 19.0)	1.17, .26	0.06
4-week follow-up	21.7 (26.1)	15.4 (18.6)	5.7 (−14.1 to 25.6)	0.60, .55	0.02
Questionnaire on anticipated discrimination					
Preintervention	4.5 (2.7)	5.4 (2.2)			
4-week follow-up	6.1 (3.6)	4.4 (2.1)	0.4 (−0.8 to 0.9)	1.76, .10	0.13
GHSQ[d] (intentional help-seeking)					
Preintervention	36.4 (8.4)	45.8 (8.9)	9.1 (−16.7 to −1.4)	2.47, .02	0.23
GHSQ (actual help-seeking)					
4-week follow-up	1.6 (1.8)	2.2 (1.9)	0.6 (−2.3 to 1.0)	0.80, .44	0.03

[a]Adjusted for baseline scores.

[b]Partial eta squared.

[c]DCS: Decisional Conflict Scale.

[d]GHSQ: General Help-Seeking Questionnaire.

Of the 23 who had self-harmed in the past year, 6 (26%) had never disclosed their self-harm, and of the 17 that had previously disclosed, 9 (53%) had found the support helpful. Friends and family were the most common sources of disclosure (n=11).

Descriptive data on outcome measures are presented in Table 2. There was no difference is completion rates and minimal difference in the administration time of the measures. CIs around the coefficient estimates were very wide indicating, as anticipated, that the study was underpowered to detect significant differences.

Acceptability of the Intervention

All 10 young people (100%, 10/10) randomized to the intervention stated (1) they would follow the DA advice, (2) it had changed their attitude regarding help-seeking behavior, and (3) they would recommend the DA to others that are self-harming. No adverse events were reported as a result of using the DA.

Qualitative Findings

Participant Characteristics

A total of 14 young people were interviewed, comprising 9 trial participants (8 DA, 1 control) and 5 not reporting self-harming behavior (Table 3). Interviews lasted between 8 to 45 min. Three members of school staff (the school counselor, deputy head teacher and safeguarding officer, and a teacher) and 5 parents or carers were interviewed (all of whom had consented to their child's participation), with interviews lasting between 8 to 15 min.

The major themes were (1) Reason for participation, (2) Views and experiences of the intervention, and (3) Feasibility of delivering the intervention and conducting an RCT in a school setting.

Reasons for Participation

Study participation was discussed in the context of facilitators and barriers, namely, encouragement from others, a financial incentive, and stigma. Support from peers, the school counselor, and parents or carers were reported to be key factors in the decision to participate, as was the financial reward.

Anonymity, confidentiality, trust, and judgment were discussed independently and in relation to each other and appeared to play a key role in the young person's decision to participate in this research and disclose self-harming behavior. For example, confidentiality was referred to as both a facilitator and barrier to study participation and disclosure of self-harm; some students were not concerned about confidentiality and saw participation as an opportunity to get support; others felt that the possibility of other adults and young people discovering participation prevented involvement and disclosure, as illustrated in the following quote:

> *Fear of all the...fear of parents finding out and fear of the school knowing, just walking around the school knowing that all of headship team know you've done something, just...and you, kind of, give...it's the stigma around it, really.* [Student 11, nonself-harm]

Many young people interviewed had chosen not to discuss self-harm before study participation, with several reasons reported including lack of time, embarrassment, and not feeling ready for disclosure and possible professional support and intervention. Timing in relation to the young person being ready to seek support was a key factor for their decision on whether or not to take part in the study, as illustrated in the following quote:

> *...it (self-harming) just started escalating and then...I think the survey came at the right time for me because otherwise something, it could have gone anywhere.* [Student 5, self-harm]

Both those who had indicated and those who had not indicated self-harm reported that belonging to a larger group of participants also facilitated the decision to participate, and this was also discussed in the context of helping others who may have been going through the same thing as them, as illustrated in the following quote:

> *I know people that do self-harm, and I think it might be helpful for them, because they might get the support that they need through it.* [Student 14, nonself-harm]

Wider coverage of the study around the school and in the community to raise awareness of the research but also the prevalence of self-harm and mental health issues in young people was recommended to encourage participation and disclosure.

Views and Experiences of the Intervention

Young people reported a preference for a computer-based intervention and found the DA to be "*quick*" and "*easy to use.*" It was largely described as clear and comprehensive, although some students did report that it could be better tailored for younger students in terms of phrasing of language and interactivity. There were several other recommendations on how the intervention could be improved.

These included changing some aspects of the interface and language of the questions to make it clearer, broadening the scope of the DA so it was relevant to other mental health problems such as depression and anxiety, making the DA more widely available (to the general public), providing more information about the help-seeking options (eg, "what does a psychologist do?"), and embedding the tool within a general mental well-being context (eg, providing psychoeducation about mental health issues to young people and how to manage distress) so it could potentially reduce the stigma and isolation around self-harm and mental illness.

Table 3. Participant demographics and characteristics for qualitative interviews.

Student ID	Gender, female (F) or male (M)	Age range (years)	Self-harm (SH)[a] or nonself-harm (non-SH)[b]
1	M	12-15	SH
2	F	12-15	SH
3	F	12-15	SH
4	F	12-15	SH
5	F	12-15	SH
6	M	12-15	SH
7	M	12-15	SH
8	M	16-18	SH
9	F	12-15	SH
10	F	12-15	Non-SH
11	M	16-18	Non-SH
12	F	12-15	Non-SH
13	M	12-15	Non-SH
14	M	12-15	Non-SH

[a]Randomized.

[b]Not randomized.

For those who had self-harmed, the intervention (or participating in the study) provided the space to think about their behavior and the opportunity to open a dialogue about it, and for those who hadn't, it raised awareness of self-harming behavior and potential sources of support, as illustrated in the following quotes:

> *It kind of made me, that's kind of when I stopped feeling suicidal really as much as I did, but I haven't stopped completely* [Student 9, self-harm]

> *Well it definitely made me think, like, about the situations and self-harm a lot more. Like, I think if I never came to the study, I don't think that would ever have crossed my mind, or anything* [Student 6, self-harm]

For those who had reported self-harm and been randomized to the DA, this was also in the context of identifying different sources of support previously unknown to them, reducing the potential shame and judgment associated with disclosing behavior and seeking professional support. Participation also acted as a signpost to other potentially useful sources such as telephone helplines and online sources for some young people.

Postintervention outcomes were discussed in the context of the participant's survey responses and whether the DA recommendation was what they were expecting and if they felt they were able to follow the advice of the DA. Although some young people were expecting the outcome, others reported being surprised by the recommended option, as illustrated in the following quotes:

> *Yes. It was useful because I think the GP came quite high up, which is...No, because I didn't really know about, that you could get, like, help from the GP. So I thought that was quite interesting. I, you know, if anything happens I can just pop down the road to the GP practice* [Student 7, self-harm]

> *Because like, I wouldn't really talk to my mum for example, and then when it came up on that I was like, really?* [Student 2, self-harm]

Reports were mixed on whether participants chose to follow the advice of the DA (this was particularly the case if a professional help-seeking option was recommended), which is contradictory to what they indicated in the free-text of the survey, post intervention (where they had all indicated they would follow the advice of the DA), as illustrated in the following quote:

> *I talked to my very close friends. I didn't get to see my GP, but I talked to my mum and my dad about it.* [Student 1, self-harm]

Some young people described experiencing some cognitive-affective and post intervention behavioral change as a result of completing the DA, including increased awareness of different sources of support previously unknown to them, empowerment, self-reflection, reducing the potential shame and judgment associated with disclosing behavior, and help-seeking. However, others did not feel it had changed anything specific, as illustrated in the following quote:

> *What have I done? I've watched like, videos on YouTube of how to like, calm yourself down. So like crushing ice and cuddling a soft toy and things* [Student 2, self-harm]

Seeking professional support was largely discussed in reference to meeting the school counselor as a part of the safety protocol, which helped some young people identify alternative coping strategies in response to distress, as illustrated in the following quote:

> *And it's been really interesting all this, and I've learnt about how to get help for self-harm, what to do. It's also tied me into the school counsellor which is really helpful for me. I think that was more beneficial because I could have easily just slipped back and things have gone worse again, but it's good that you guys are keeping tabs on me* [Student 7, self-harm]

Feasibility of Delivering the Intervention and Conducting a Randomized Controlled Trial in a School Setting

The majority of participants reported that recruitment, completing the survey, and follow-up were straightforward and short processes and enjoyed participating in topical research.

The study, which required a room with a computer and Internet connection to complete the questionnaire and intervention, was not found to be too burdensome on resources. Furthermore, the school counselor, to whom all the randomized students were referred, did not feel that the study placed a significant burden on their workload. A member of staff reported that the schools participation in the study showed its commitment to addressing issues around mental health, as illustrated in the following quote:

> *I think that then that's highlighted issues that, kind of, maybe needed to be talked about more to do with self-harm, anxiety, mental health in general, so I think that's been really a positive part of it, and promoting...yes, promoting, kind of, awareness of...* [School staff member]

Parents also thought that the school setting was an appropriate place to deliver the intervention, as illustrated in the following quote:

> *I mean, I think, yes, all young people on the whole are in school and not many go to seek help and you kind of have to make it easy for people to, you know, get support where they are and where they're spending time and where there is, you know, some kind of safe environment around them* [Parent or carer]

Despite these comments, the response from parents or carers giving consent for us to invite their children to this study was low. Interviewed parents or carers thought that this may be because some parents believed the topic of self-harm was not relevant to their children; staff speculated that this may have been because of anxiety around "contagion" of self-harm, as illustrated in the following quote:

> *I think it was mainly just around the anxiety and then the idea that the, sort of, contagion effect that, oh,*

> *yes, if I say yes to this, then it's going to actually make it happen or make my child feel this, this, or make them self-harm or maybe if they're a part of it, then them and their friends, it'll, sort of, spread, but I think mainly around anxiety* [School staff member]

Areas for improvement (and so it might facilitate better engagement from parents) were similar to the recommendations given by the young people participating in these interviews. An additional suggestion was providing resources to parents or carers on increasing resilience and identifying or managing self-harming behavior in their children.

Discussion

Principal Findings

Undertaking self-harm research in a school setting is challenging. Although we recruited 81.7% (170/208) of young people into the study whose parents had given consent (13.5% of whom had self-harmed in the past year), fewer than 1 in 5 parents consented to us contacting their child. We were able to follow up all participants 4 weeks post intervention with no dropouts or missing data. The impact on school resources (eg, the school counselor's workload) was minimal, and the school reported that the study promoted the awareness of mental health issues and services available to students.

The sample size was too small and CI's too wide to make assumptions about the required sample size for a larger RCT. Findings were inconsistent between the survey and interviews on whether or not young people would follow the help-seeking recommendations from the DA, particularly if a professional option was recommended. This suggests the possibility of acquiescence bias.

Overall, those that were randomized to the DA found the intervention acceptable and would recommend it to other people that were self-harming. There were no differences in the measures, and all would be potentially appropriate for use in a larger future trial.

Strengths and Limitations

In addition to underrecruitment and small sample size, this study had several other limitations. Our safeguarding procedures may have reduced participation in the study and indeed enforced a help-seeking option (ie, referral to a school counselor). This was included in the protocol to maintain the safety of all trial participants who were considered to be a particularly vulnerable group on account of their age and the occurrence of their self-harm. However, the inclusion of this procedure may have dissuaded young people from answering the self-harm screening question honestly if they did not want the school or their parents to find out about their behavior. As all trial participants were referred to the school counselor, any impact of the DA may have been obscured.

We did not control for the effects of simply interacting with the Internet. Participants in the intervention group interacted with live content on a Web page, whereas those in the control condition interacted with static content. Research suggests that interaction with technologies can affect group decision making [24]. Further investigation is necessary to explore whether this is also the case at an individual level. The 4-week follow-up was short and did not allow sufficient time to assess change in decision making or help-seeking behavior. We collected limited information on self-harm behavior, such as frequency, type, and severity, and we were unable to obtain any qualitative information from nonconsenting parents.

There were a number of strengths in this feasibility trial. First, rates of self-harm were around those expected at 13.5% [2], suggesting that any negative impact of the safeguarding protocol was minimal within the sample recruited. Second, by indirectly including the school counselor as part of the intervention, we created a safe, pragmatic approach to the implementation of the DA in a school setting. E-mental health interventions have been shown to be effective tools; however, they often suffer from poor engagement from service users [25]. It has been suggested that including a face-to-face element can improve adherence and outcomes [26,27]. Third, qualitative interviews with students (both randomized and nonrandomized), parents or carers, and staff provided a deeper understanding of their views and experience of the DA and the process or implementation of conducting an RCT in a school setting. This helps us plan further developmental work to the DA and changes in future study design.

Implications for Future Research

Although it is best practice to obtain parental consent ("active consent") before the involvement of young people's participation in a study, previous research shows that this lowers response rates by 40% to 67% compared with passive consent (eg, opt out) and results in decreased participation in school surveys by at-risk groups [28]. This raises several important ethical issues: (1) is the topic of self-harm one for which mature and competent young people should be able to give consent without prior consent from their parents? (2) should research in the area of self-harm be automatically categorized as above the threshold of minimal-risk research? and (3) is the importance of the topic sufficiently high and the research so hampered by the current ethical safeguards that more harm is caused by the safeguards (as they effectively make it impossible to create an evidence base for this public health problem) than they benefit?

The mature-minor principle ("Gillick competency") acknowledged by the United Kingdom and the United States recognizes children's rights to consent to their own medical treatment without parental consent, if they have been deemed competent, based on their level of maturity rather than their age [29]. This extends to a research context whereby the Council for International Organizations of Medical Sciences refers to the waiving of parental consent in studies exploring adolescent's beliefs and sexual behaviors or recreational drug use if it puts young people at risk of questioning or intimidation by their parents [30,31]. However, there is the need to balance the right to autonomy and access to participating in research with the risk of harm. In the case of self-harm research, this is usually considered above the threshold of minimal-risk; however, there is a lack of evidence supporting possible adverse effects of intervention studies on suicidal behavior [32,33]. Previous research suggests school-based interventions targeting suicidal

behavior do not pose a risk of harm and may promote mental health awareness and reduce suicidal behaviors [34,35].

The complex issues around youth health research ethics are ongoing [31,36] and evident in the limitations of our feasibility trial. Research ethics committees may need to show greater flexibility in their interpretation of the guidelines around the necessity of parental consent for young people participating in self-harm research. Without this, we fear that research in the area will continue to be hampered by low response rates.

Going forward, further development of the DA may benefit from considering models of decision making within adolescent populations. Models that theoretically underpin the design of DAs have been confined to clinical decisions and settings and are largely based on adults; there is some evidence to suggest differences in decision-making processes between adolescents and adults [37]. The utility of the DA could be enhanced by including self-harm ideation. Adolescents who have thoughts of self-harm but have not engaged in self-harming behavior may be unaware of the benefits of seeking help, and the DA could potentially provide them with useful information on available support. Finally, if we are able to show proof of concept for a DA regarding help-seeking for self-harm, we can explore its applicability for other mental disorders.

Acknowledgments

The DASH study was funded by a grant from Guy's and St Thomas' charity (PI: Moran; project code: MAJ120701).

The authors would like to express their gratitude to Lorenzo Gordon and Mark Clements from Maldaba Ltd who provided the Annalisa and Elicia software used for the decision aid, randomization, support and advice regarding the development of the decision aid, and study methodology. PM was also supported by the National Institute for Health Research Biomedical Research Centre at University Hospitals Bristol National Health Service Foundation Trust and the University of Bristol. MS was supported by the NIHR Nottingham Biomedical Research Centre.

The authors would like to thank Sue Minto and David Weatherall, members of ChildLine for their contributions to the project management group and methodological advice.

Particular thanks goes to Emily Sargent, Simon Williams, and the students and staff that helped with the development and piloting of the decision aid.

The authors would like to specially thank John Hodsoll from King's College London and Rebecca Jones from University College London for their advice and guidance regarding the statistics.

The authors would like to acknowledge and thank Professor Mike Crawford, Dr Becky Mars, and the other members of the trial steering committee for their advice and support.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Demonstration of decision-aid "My Self-Help Tool".

[MP4 File (MP4 Video), 37MB - mental_v5i1e10_app1.mp4]

Multimedia Appendix 2

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 65KB - mental_v5i1e10_app2.pdf]

References

1. Moran P, Coffey C, Romaniuk H, Olsson C, Borschmann R, Carlin JB, et al. The natural history of self-harm from adolescence to young adulthood: a population-based cohort study. Lancet 2012 Jan 21;379(9812):236-243 [FREE Full text] [doi: 10.1016/S0140-6736(11)61141-0] [Medline: 22100201]
2. Ougrin D, Tranah T, Leigh E, Taylor L, Asarnow JR. Practitioner review: self-harm in adolescents. J Child Psychol Psychiatry 2012 Apr;53(4):337-350. [doi: 10.1111/j.1469-7610.2012.02525.x] [Medline: 22329807]
3. McManus SB. 2016. Mental health and wellbeing in England: Adult Psychiatric Morbidity Survey 2014 URL: https://digital.nhs.uk/catalogue/PUB21748 [accessed 2018-01-22] [WebCite Cache ID 6weo5GNVB]
4. Rowe S, French RS, Henderson C, Ougrin D, Slade M, Moran P. Help-seeking behaviour and adolescent self-harm: a systematic review. Aust N Z J Psychiatry 2014 Dec;48(12):1083-1095. [doi: 10.1177/0004867414555718] [Medline: 25335872]

5. Drug and Therapeutics Bulletin. An introduction to patient decision aids. Br Med J 2013 Jul 23;347:f4147. [doi: 10.1136/bmj.f4147] [Medline: 23881944]
6. The Ottawa Hospital. Patient Decision Aids URL: https://decisionaid.ohri.ca/ [accessed 2018-01-18] [WebCite Cache ID 6wZ7NVkJ4]
7. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2014 Jan 28(1):CD001431. [doi: 10.1002/14651858.CD001431.pub4] [Medline: 24470076]
8. Brinkman W, Hartl MJ, Poling LM, Shi G, Zender M, Sucharew H, et al. Shared decision-making to improve attention-deficit hyperactivity disorder care. Patient Educ Couns 2013 Oct;93(1):95-101 [FREE Full text] [doi: 10.1016/j.pec.2013.04.009] [Medline: 23669153]
9. Simmons M, Elmes A, McKenzie JE, Trevena L, Hetrick SE. Right choice, right time: evaluation of an online decision aid for youth depression. Health Expect 2017 Aug;20(4):714-723 [FREE Full text] [doi: 10.1111/hex.12510] [Medline: 27748004]
10. Dolan J. Multi-criteria clinical decision support: a primer on the use of multiple criteria decision making methods to promote evidence-based, patient-centered healthcare. Patient 2010;3(4):229-248 [FREE Full text] [doi: 10.2165/11539470-000000000-00000] [Medline: 21394218]
11. Rowe S, French RS, Henderson C, Ougrin D, Slade M, Moran P. Decisional support for young people who self-harm: protocol for a feasibility trial. BMJ Open 2016 Sep 28;6(9):e012161 [FREE Full text] [doi: 10.1136/bmjopen-2016-012161] [Medline: 27683517]
12. French R, Cowan FM, Wellings K, Dowie J. The development of a multi-criteria decision analysis aid to help with contraceptive choices: My Contraception Tool. J Fam Plann Reprod Health Care 2014 Apr;40(2):96-101. [doi: 10.1136/jfprhc-2013-100699] [Medline: 24265469]
13. Angold A. Development of a short questionnaire for use in epidemiological studies of depression in children and adolescents. Int J Methods Psychiatr Res 1995;5(4):237-249 [FREE Full text]
14. Ougrin D, Boege I. Brief report: the Self Harm Questionnaire: a new tool designed to improve identification of self harm in adolescents. J Adolesc 2013 Feb;36(1):221-225. [doi: 10.1016/j.adolescence.2012.09.006] [Medline: 23046733]
15. O'Connor A. 2000. User Manual - Stage of Decision Making URL: https://decisionaid.ohri.ca/docs/develop/user_manuals/um_stage_decision_making.pdf [accessed 2018-01-18] [WebCite Cache ID 6wZA9ZyHa]
16. Wilson C, Deane FP, Ciarrochi JV, Rickwood D. Measuring help seeking intentions: Properties of the General Help Seeking Questionnaire. CJC 2005;39(1):15-28 [FREE Full text]
17. Goodwin RD, Mocarski M, Marusic A, Beautrais A. Thoughts of self-harm and help-seeking behavior among youth in the community. Suicide Life Threat Behav 2013 Jun;43(3):305-312. [doi: 10.1111/sltb.12017] [Medline: 23379515]
18. O'Connor A. decisionaid.ohri.ca. User Manual - Decisional Conflict Scale URL: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_decisional_conflict.pdf [accessed 2018-01-18] [WebCite Cache ID 6wZAgPLAB]
19. Baetens I, Claes L, Muehlenkamp J, Grietens H, Onghena P. Non-suicidal and suicidal self-injurious behavior among Flemish adolescents: a web-survey. Arch Suicide Res 2011;15(1):56-67. [doi: 10.1080/13811118.2011.540467] [Medline: 21294000]
20. O'Connor RC, Rasmussen S, Miles J, Hawton K. Self-harm in adolescents: self-report survey in schools in Scotland. Br J Psychiatry 2009 Jan;194(1):68-72 [FREE Full text] [doi: 10.1192/bjp.bp.107.047704] [Medline: 19118330]
21. Lancaster G, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract 2004 May;10(2):307-312. [doi: 10.1111/j.2002.384.doc.x] [Medline: 15189396]
22. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101 [FREE Full text] [doi: 10.1191/1478088706qp063oa]
23. QSR International. 2002. URL: http://www.qsrinternational.com/nvivo/nvivo-products [accessed 2018-01-18] [WebCite Cache ID 6wZBJFpTx]
24. Baltes B, Dickson M, Sherman M, Bauer C, LaGanke J. Computer-mediated communication and group decision making: a meta-analysis. Organ Behav Hum Decis Process 2002 Jan;87(1):156-179. [doi: 10.1006/obhd.2001.2961]
25. Dean J, Potts HW, Barker C. Direction to an internet support group compared with online expressive writing for people with depression and anxiety: a randomized trial. JMIR Mental Health 2016 May 17;3(2):e12. [doi: 10.2196/mental.5133] [Medline: 27189142]
26. Helgadóttir FD, Menzies RG, Onslow M, Packman A, O'Brian S. Online CBT I: bridging the gap between eliza and modern online CBT treatment packages. Behav change 2012 Feb 22;26(04):245-253. [doi: 10.1375/bech.26.4.245]
27. Musiat P, Tarrier N. Collateral outcomes in e-mental health: a systematic review of the evidence for added benefits of computerized cognitive behavior therapy interventions for mental health. Psychol Med 2014 Nov;44(15):3137-3150. [doi: 10.1017/S0033291714000245] [Medline: 25065947]
28. Esbensen F, Melde C, Taylor TJ, Peterson D. Active parental consent in school-based research: how much is enough and how do we get it? Eval Rev 2008 Aug;32(4):335-362. [doi: 10.1177/0193841X08315175] [Medline: 18441216]

29. Santelli JS, Smith RA, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, Society for Adolescent Medicine. Guidelines for adolescent health research. A position paper of the Society for Adolescent Medicine. J Adolesc Health 2003 Nov;33(5):396-409. [Medline: 14596961]
30. CIOMS. 2002. International Ethical Guidelines for Biomedical Research Involving Human Subjects: Geneva URL: https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf [accessed 2018-01-18] [WebCite Cache ID 6wZCYLWW3]
31. Hiriscau E, Stingelin-Giles N, Wasserman D, Reiter-Theil S. Identifying ethical issues in mental health research with minors adolescents: results of a Delphi study. Int J Environ Res Public Health 2016 Dec 11;13(5) [FREE Full text] [doi: 10.3390/ijerph13050489] [Medline: 27187425]
32. Gould MS, Marrocco FA, Kleinman M, Thomas JG, Mostkoff K, Cote J, et al. Evaluating iatrogenic risk of youth suicide screening programs: a randomized controlled trial. J Am Med Assoc 2005 Apr 06;293(13):1635-1643. [doi: 10.1001/jama.293.13.1635] [Medline: 15811983]
33. Wasserman D, Hoven CW, Wasserman C, Wall M, Eisenberg R, Hadlaczky G, et al. School-based suicide prevention programmes: the SEYLE cluster-randomised, controlled trial. Lancet 2015 Apr;385(9977):1536-1544. [doi: 10.1016/S0140-6736(14)61213-7]
34. Rudd M, Mandrusiak M, Joiner TE, Berman AL, Van Orden KA, Hollar D. The emotional impact and ease of recall of warning signs for suicide: a controlled study. Suicide Life Threat Behav 2006 Jun;36(3):288-295. [doi: 10.1521/suli.2006.36.3.288] [Medline: 16805656]
35. Van Orden K, Joiner TE, Hollar D, Rudd MD, Mandrusiak M, Silverman MM. A test of the effectiveness of a list of suicide warning signs for the public. Suicide Life Threat Behav 2006 Jun;36(3):272-287. [doi: 10.1521/suli.2006.36.3.272] [Medline: 16805655]
36. Sanci L, Sawyer SM, Weller PJ, Bond LM, Patton GC. Youth health research ethics: time for a mature-minor clause? Med J Aust 2004 Apr 05;180(7):336-338. [Medline: 15059054]
37. Blakemore S, Robbins TW. Decision-making in the adolescent brain. Nat Neurosci 2012 Sep;15(9):1184-1191. [doi: 10.1038/nn.3177] [Medline: 22929913]

Abbreviations

DA: decision aid
DCS: Decisional Conflict Scale
GHSQ: General Help-Seeking Questionnaire
MCDA: multi-criteria decision analysis
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 16.06.17; peer-reviewed by E Karasouli, M Park; comments to author 25.08.17; revised version received 17.10.17; accepted 16.11.17; published 30.01.18.

Please cite as:
Rowe SL, Patel K, French RS, Henderson C, Ougrin D, Slade M, Moran P
Web-Based Decision Aid to Assist Help-Seeking Choices for Young People Who Self-Harm: Outcomes From a Randomized Controlled Feasibility Trial
JMIR Ment Health 2018;5(1):e10
URL: http://mental.jmir.org/2018/1/e10/
doi:10.2196/mental.8098
PMID:29382626

Original Paper

Acceptability, Use, and Safety of a Mobile Phone App (BlueIce) for Young People Who Self-Harm: Qualitative Study of Service Users' Experience

Rebecca Grist[1*], PhD; Joanna Porter[2*], BSc (Hons); Paul Stallard[1,2*], PhD

[1]Child and Adolescent Mental Health Group, Department for Health, University of Bath, Bath, United Kingdom

[2]Child and Family Mental Health, Temple House, Oxford Health National Health Service Foundation Trust, Keynsham, United Kingdom

[*]all authors contributed equally

Corresponding Author:
Rebecca Grist, PhD
Child and Adolescent Mental Health Group
Department for Health
University of Bath
Claverton Down
Bath, BA2 7AY
United Kingdom
Phone: 44 2253850 ext 86
Email: rg626@bath.ac.uk

Abstract

Background: Self-harm is common among adolescents and is associated with a number of negative psychosocial outcomes including a higher risk of suicide. Recent reviews highlight the lack of research into specific interventions for children and young people who self-harm. Developing innovative interventions that are coproduced with individuals with lived experience and that reduce self-harm are key challenges for self-harm prevention.

Objective: The aim of this study was to explore the acceptability, use, and safety of BlueIce, a mobile phone app for young people who self-harm and who are attending child and adolescent mental health services (CAMHS).

Methods: This study is part of a mixed methods phase 1 trial of BlueIce. Young people aged 12-17 years attending specialist CAMHS were recruited. Clinicians were invited to refer young people who were self-harming or who had a history of self-harm. On consent being obtained and baseline measures taken, participants used BlueIce as an adjunct to usual care for an initial familiarization period of 2 weeks. If after this time they wanted to continue, they used BlueIce for a further 10 weeks. Semistructured interviews were conducted at postfamiliarization (2 weeks after using BlueIce) and postuse (12 weeks after using BlueIce) to assess the acceptability, use, and safety of BlueIce. We undertook a qualitative analysis using a deductive approach, and then an inductive approach, to investigate common themes.

Results: Postfamiliarization interviews were conducted with 40 participants. Of these, 37 participants elected to use BlueIce, with postuse interviews being conducted with 33 participants. Following 6 key themes emerged from the data: (1) appraisal of BlueIce, (2) usability of BlueIce, (3) safety, (4) benefits of BlueIce, (5) agency and control, and (6) BlueIce less helpful. The participants reported that BlueIce was accessible, easy to use, and convenient. Many highlighted the mood diary and mood lifter sections as particularly helpful in offering a way to track their moods and offering new strategies to manage their thoughts to self-harm. No adverse effects were reported. For those who did not find BlueIce helpful, issues around motivation to stop self-harming impeded their ability to use the app.

Conclusions: BlueIce was judged to be a helpful and safe way of supporting adolescents to manage thoughts of self-harming. Adolescents reported numerous benefits of using BlueIce, and all would recommend the app to other young people who were struggling with self-harm. These preliminary findings are encouraging and provide initial support for the acceptability of BlueIce as a self-help intervention used in conjunction with the traditional face-to-face therapy.

(JMIR Ment Health 2018;5(1):e16) doi:10.2196/mental.8779

KEYWORDS

self-injurious behavior; mobile apps; adolescents; telemedicine; qualitative research; cognitive therapy; behavior therapy

Introduction

Background

Self-harm is a significant public health problem and is typically defined as an act of intentional self-injury or self-poisoning, irrespective of the type of motive or extent of suicidal intent [1]. Self-harm is common among adolescents and the prevalence is increasing. Community studies across different countries reliably report adolescents have a 13%-18% lifetime risk of self-harming [2-4]. In a UK-based community survey of adolescents aged 12-16 years, 1 in 4 reported self-harming thoughts and 1 in 6 had engaged in self-harming behavior over a 1-year period [5]. Repeated self-harming is common, with around half of adolescents who self-harm reporting doing so more than once [4-6]. Self-cutting appears to be the most common form of self-harm for adolescents in the community, whereas self-poisoning is the most common form seen in adolescents who present at hospital [4,7]. Only 1 in 8 adolescents who self-harm will present at hospital, the remainder of self-harm acts occur in private [4,7].

Self-harm is associated with a higher risk of mortality and suicide. Self-harm increases the likelihood that the person will eventually die by suicide [1]. Research indicates that of those who die by suicide, approximately 50% have a history of prior self-harm [8]. Although the risk of suicide in adolescents is low, it is the third leading cause of death for this age group worldwide [7,9]. Self-harm is also associated with a range of mental health problems such as depression, anxiety, substance misuse, eating disorders, and Attention Deficit Hyperactivity Disorder [1,7,10,11].

The National Institute of Health and Care Excellence (NICE) recommends offering 3 to 12 sessions of a psychological intervention that is specifically structured for people who self-harm, with the aim of reducing self-harm [1]. NICE also recommends the intervention contain either cognitive-behavioral, psychodynamic, or problem-solving elements [1]. Despite these recommendations, there is a paucity of research into specific interventions for children and adolescents who self-harm [11]. Evidence suggests that dialectical behavioral therapy (DBT) and cognitive behavioral therapy (CBT) warrant further research [11], and the key challenges for future research are the development and assessment of innovative interventions that are acceptable to young people, which reduce the risk of self-harm and enhance meaningful engagement with health services [7].

The last decade has seen a proliferation of mobile phone apps, and there are now more than 15,000 apps for health care with at least 29% designed for mental health [12]. The majority of adolescents now either own or have access to a mobile phone (96% of those aged 12-17 years) [13]. Mobile health (mHealth) therefore offers an accessible and potentially acceptable way to deliver and support mental health interventions for adolescents. A number of health organizations have developed policies for integrating mHealth and other digital technologies into health services, including child and adolescent mental health services (CAMHS) [14,15]. However, the quality and quantity of research evidence for the effectiveness of apps for mental health is scarce, particularly for adolescents [16].

It is imperative then that mobile phone apps for adolescents are subject to proper research evaluation [16] and ideally, codesigned with individuals with lived experience [11]. There is currently a paucity of research exploring the acceptability and safety of mobile apps for adolescents with mental health difficulties. A recent review of the research literature demonstrated that there are only a few feasibility studies exploring adolescent perspectives of mobile apps for mental health and only a minority of these included participants with lived experience of mental health difficulties [16]. To the knowledge of the authors, there are no mobile apps available for adolescents who self-harm that have been subject to published research evaluation.

Objective

When young people self-harm, they are usually on their own, but most have access to a mobile phone. We developed and coproduced a mobile phone app (BlueIce) with young people with lived experience of self-harm. A series of meetings with young people who had lived experience of self-harm ensured coproduction and design of BlueIce [17]. The original idea for BlueIce was discussed with these young people. Further meetings with young people focused on app content, design, and presentation. A beta version of BlueIce was produced. This beta version was reviewed by the young people and a group of child mental health professionals who provided further recommendations. These recommendations were implemented in the second beta version that was reviewed again and positively endorsed by the young people. Full details of BlueIce development are reported in the study protocol [17].

BlueIce provides a personalized toolbox of strategies that can be accessed at any time and is intended to be used any time between face-to-face sessions. These strategies are based on theoretical approaches including DBT, CBT, mindfulness, and behavioral activation. BlueIce includes a mood diary, a menu of personalized mood lifting activities, and automatic routing through safety checks to delay or prevent self-harm. Mood lifting activities are designed to improve mood and include a personalized music and photo library, physical activities, mood changing activities, audio recordings of relaxation and mindfulness exercises, identification and challenging of negative thoughts, and distress tolerance activities. The young person is routed to emergency numbers if after using the mood lifter, the person reports that the thoughts of self-harming have not reduced. BlueIce is intended to be used alongside the traditional face-to-face interventions that adolescents receive from CAMHS.

The aim of BlueIce is to help young people manage their emotions and to prevent nonsuicidal self-injury (NSSI). Measurable outcomes of BlueIce include changes in self-harm and psychological functioning including depression and anxiety.

Quantitative outcomes are reported elsewhere [18]. The aim of this study was to explore the acceptability, usability, and safety of BlueIce with young people aged 12-17 years who are self-harming and attending CAMHS. This study forms one part of a mixed methods phase 1 trial [17,18]. Here we report the qualitative data from participant interviews. We explored how young people used BlueIce, what they found positive and negative about the app, and whether they could use BlueIce when experiencing thoughts to self-harm.

Methods

Study Design

The study procedure consisted of an initial meeting (baseline), a familiarization period of 2 weeks and a second meeting (postfamiliarization), and then a further 10 weeks of app use and follow up meeting (postuse). We undertook semistructured interviews with young people at postfamiliarization and postuse. Interviews were conducted in person by the research team at locations convenient for the participant (generally either at home or at CAMHS). Interviews lasted around 40 min and were recorded and transcribed for analysis. Full study protocol is available [17]. The study was approved by the NHS South West—Exeter Research Ethics Committee (reference 16/SW/0018) and funded by the Health Foundation (2143 Oxford Health National Health Service [NHS] Foundation Trust).

Setting and Sample

We conducted the study within CAMHS provided by Oxford Health NHS Foundation Trust. The Trust provides mental health care for children and young people in Buckinghamshire, Oxfordshire, Swindon, Wiltshire, and Bath and North-East Somerset.

Young people were eligible to take part if they were aged between 12 and 17 years and either currently self-harming or had a history of self-harm and felt that they would harm themselves again. All participants were required to be receiving face-to-face care from CAMHS for the duration of the study. Exclusion criteria included active suicidal ideation or planning, a diagnosis of psychosis or a significant learning disability, a current safeguarding investigation or having been subject to abuse in the last 6 months, or an inability to understand English.

Recruitment and Consent

We initially provided study information to all clinical teams across Oxford Health NHS Trust via email. This was followed by meetings with clinical teams to demonstrate BlueIce and discuss any concerns or questions about the research. We conducted several other meetings with clinical teams following these initial meetings to maintain awareness of the project. All clinicians were given project information sheets and were asked to discuss the study with young people who they were working with and who met the inclusion criteria. If the young person indicated they would like to take part, the clinician passed their contact information and details of whether the young person had self-harmed in the last 4 weeks to the research team.

A member of the research team made contact and arranged to meet the young person and their carers (if they were younger than 16 years). At this initial meeting, the study was discussed and written consent was obtained from the young person. Parental consent was also obtained if the adolescent was younger than 16 years. At the initial meeting, the BlueIce app was downloaded onto the young person's phone. If the young person either did not have a phone or owned an iPhone, they were given an Android phone with BlueIce preloaded. The young person personalized the mood lifter section of BlueIce with the researcher. Participants were recruited between May and November 2016.

Role of Clinicians

Clinicians were responsible for identifying young people on their caseload who met the inclusion criteria and for providing them with project information. Consenting participants were provided with BlueIce, but they continued to attend face-to-face meetings with their clinician. As is usual practice, the clinician was responsible for reviewing risk and maintaining clinical responsibility for the young person in their care.

Clinicians had no role in setting up BlueIce with the participants and no role in providing technical assistance. There was no formal requirement for clinicians to discuss BlueIce with the young people in clinical sessions, and it was up to the young person if they wished to discuss the app with their clinician or not.

Data Collection

Semistructured interviews were conducted to capture participant's views broadly exploring the safety, acceptability, and usability of BlueIce. The postfamiliarization interviews incorporated the following aspects: (1) a general overview of how participants found using BlueIce, (2) what the participant liked and disliked about BlueIce, (3) what parts of BlueIce were particularly helpful and unhelpful, (4) any problems using BlueIce, (5) the degree to which participants thought BlueIce would help them prevent self-harm, and (6) the degree to which they thought BlueIce would make them feel like self-harming more. Interviews conducted at postuse included questions concerning the following: (1) if the participant had used BlueIce and reasons why or why not, (2) whether they used BlueIce when distressed, (3) if they used BlueIce to prevent self-harm and whether the app was helpful, (4) if they used BlueIce but it did not prevent an act of self-harm and why the app was not helpful, (5) what was helpful and unhelpful about BlueIce, (6) any problems or changes they would like to see, (7) the degree to which they found BlueIce to be easy or not easy and helpful or unhelpful, and (8) whether they would recommend BlueIce to other young people who self-harm.

Quantitative assessments were also completed at baseline, postfamiliarization, and postuse. These assessments included the Mood and Feelings Questionnaire (MFQ; assessing depression [19]), the Revised Child Anxiety and Depression Scale (RCADS; assessing anxiety [20]), and the Strengths and Difficulties Questionnaire (SDQ; assessing behaviors [21]). The results of which are available in the study by Stallard et al [18].

Analysis

Each interview was audio-recorded, subsequently transcribed verbatim, and manually coded. We took a thematic approach to search across the data and identify themes following the 6 phases of thematic analysis outlined by Braun and Clark [22]. This included the following: (1) familiarizing ourselves with the data; individual transcripts were read and reread and notes of interest were taken, (2) generating initial codes; a list of initial codes was devised first from a deductive approach based on our research questions (safety, acceptability, and usability of BlueIce) then from an inductive approach to ensure that the main emerging ideas in the data were captured, (3) searching for themes; collecting candidate themes, sub themes, and data extracts in relation to each theme, (4) reviewing themes; systematically reading the collated data extracts for each theme, checking for consistency, and checking that our themes accurately represent the dataset, (5) defining and naming themes, and (6) producing the report. Nvivo 10 (QSR International, Australia) was used to conduct the analysis. At each stage of the process, RG (researcher) and PS (principal investigator) met to discuss codes and themes and resolve any discrepancies, to improve reliability.

Results

Description of Participants

Over the duration of the trial, 37 different clinicians from 8 teams referred 54 young people. Of the 54 referrals, 4 did not meet the inclusion criteria, we were unable to contact 3 referrals, 2 dropped out of CAMHS before they could consent, and 1 declined to participate. The remaining 44 completed baseline assessments. Participants were predominantly girls 90% (40/44) with an average age of 15.98 years (standard deviation, SD=1.37) with 68% (30/44) having self-harmed at least once in the 4 weeks before starting the trial. At baseline, using recommended cut-offs, 95% (42/44) scored 29 or more on the MFQ, suggesting probable depression. Using age- and gender-adjusted cut-offs on the RCADS, 84% (37/44) screened positive for one or more anxiety disorders, and 84% (37/44) scored above cut-offs on the SDQ for a probable emotional disorder. On the RCADS, 94% (16/17) of parents rated their child above the cut-off for depression, and 88% (16/18) scored their child above the cut-off on the SDQ for significant emotional problems.

Postfamiliarization interviews were conducted with 90% (40/44) of participants. Of these, 92% (37/40) elected to use BlueIce, with post use interviews being conducted with 82% (33/40) of participants.

Summary of Themes

From these data, 6 key themes emerged: (1) appraisal of BlueIce, (2) usability of BlueIce, (3) safety (4) benefits of BlueIce, (5) agency and control, and (6) BlueIce less helpful. Table 1 details each theme including a definition and subthemes contained within.

Appraisal of BlueIce

Young people frequently reported that they found BlueIce to be helpful. The app was judged to provide a range of different techniques and strategies that offered a variety of options to manage self-harming urges. This accessibility and variety was valued by young people:

> *I've found it really helpful because I've tried using other apps and stuff but they only really cover like one aspect of what BlueIce offers…having app where there's everything that you need like a little tool kit I think that's really helpful* [Participant number 142]

An overwhelming majority of young people would recommend BlueIce to others who were self-harming. The 7 young people who reported that their self-harm did not reduce after using the app would still recommend BlueIce to others. They recognized that it could be beneficial for other people even though it did not directly benefit them.

Many young people also reported that BlueIce might benefit a wide range of people, not only those struggling with thoughts to self-harm:

> *My mum has quite a few mental illnesses and she had a look at the app and she actually really liked it as well so I don't know if it would be available to adults as well?* [Participant number 120]

BlueIce was designed to be discreet and not draw attention to or expose the young person's difficulties if someone else were to pick up their phone. This privacy was reported to be a significant benefit of the app:

> *It's perfectly discreet and like it doesn't have to be something that has to be hidden…it's just, I like the design of it, I think it's very well designed* [Participant number 111]

Young people also commented that they would like the ability to personalize BlueIce even more, and some noted the potential benefit of adding games into the app as another distraction technique:

> *Being able to personalise the colour, I thought that would be quite cool.* [Participant number 113]

Usability of BlueIce

Many young people who used BlueIce described the app as being easy to use, accessible, simple, and easy to navigate around. This ease of use was valued by participants as they did not want to add further stress to their situation:

> *It was really easy to get into and start using if you know what I mean, it was like once you knew how to use it, it was really easy.* [Participant number 126]

The young people who had BlueIce loaded on their own phone reported having the app on their device was convenient. This was because they had immediate access to the app and they could easily personalize the music and photo libraries from files already on their phone. Not being able to access BlueIce on their own device was a significant barrier to engagement for those participants who were provided an Android phone.

Table 1. Themes, theme definition, and subthemes derived from thematic analysis.

Theme	Definition	Subthemes
Appraisal of BlueIce	Indicators of BlueIce acceptability	• Helpful • Simple • Provides a range of activities and sections • Would recommend to others • Benefit to people with other mental health problems • More personalization • Add games
Usability of BlueIce	Ease and patterns of BlueIce usage	• Easy to use • Accessible • Convenient on own device • Barrier if not on own device • Situational barriers to use • Finding wording confusing • Frequency of app usage declining over the course of the study • Attrition due to therapeutic gain • High-frequency user
Safety and impact of BlueIce on self-harm	Indicators of BlueIce safety and purpose fulfillment	• Concerns about mood diary • Reassuring • BlueIce not making self-harm worse • BlueIce used when felt like self-harm • BlueIce stopped self-harm • BlueIce stopped more self-harm after initial episode • Reduction in self-harm
Benefits of BlueIce	Reported cognitive, behavioral, and affective benefits of using BlueIce	• Mood tracking and noticing patterns • Reminder things get better • Reminder you are able to cope • Identifying benefits on mood • Identifying triggers of negative moods • BlueIce as a catalyst for difficult conversations • New and personalized strategies • Reminder that they have strategies • Slow or reframe thinking • Distraction • Positive affective change
Agency and control	Perceived lack of ability to control self-harm urges and control emotion regulation	• Differing willingness to receive help • Urges to self-harm too overwhelming • Feeling too overwhelmed to use BlueIce • Urge to self-harm out of my control • Hopelessness about helpfulness of interventions
BlueIce less helpful	Experiences of participants for whom BlueIce did not reduce self-harm	• Not ready to stop self-harming • Motivation to use BlueIce • Personal crisis needing more CAMHS[a] contact • Ambivalence about helpfulness of BlueIce

[a]CAMHS: child and adolescent mental health services.

Situational barriers were also reported by young people, for example, being in a situation in which using BlueIce would have drawn attention to themselves or a situation in which they were unable to implement the strategies in the app (being at school, nighttime, parents being present):

> *It happened a few times because the worst place is at school. And I usually didn't bring the phone to school or didn't want to get it out halfway through lesson* [Participant number 162]

The type of therapy participants were receiving in their ongoing face-to-face treatment may have impacted their perception of

BlueIce. Specifically, if the participants had encountered CBT, mindfulness, or DBT techniques in their therapeutic work, this appeared to make that part of the mood lifter more understandable and used more. Of all the participants, 1 participant noted that their face-to-face work was important to understand why they were doing CBT and mindfulness techniques and why they were useful. The wording in the CBT section (*thinking traps*) was reported to be slightly confusing by 3 participants, as they had not encountered CBT in their therapeutic work. This was a barrier to engagement with these sections, but other sections were still utilized.

For many participants, engagement with BlueIce tended to be higher at the beginning, with use declining over the duration of the study. Most young people reported that this was because their thoughts of self-harm had reduced and they needed to use the app less. There were also a minority of young people who continued to be frequent users of BlueIce, either because they still struggled with thoughts of self-harm or they particularly liked using the mood diary to track their mood:

> *I have used BlueIce every day. I used the mood checker every day and found it quite easy to use.* [Participant number 144]

Safety

No adverse effects of using BlueIce were reported. This means that no clinician withdrew any young person from the study due to an escalation of risk or the emergence of suicidal planning or attempt. Furthermore, no participants had reported calling the emergency numbers provided on BlueIce.

The possibility that BlueIce might have unintentional consequences and increase unpleasant feelings was also explored. There were 2 young people who reported concerns that negative feelings might be triggered by reading about their own negative feelings or events or seeing many sad faces on the mood diary. However, both these young people also reported benefits from reflecting on their mood diary entries.

Young people frequently described having BlueIce as reassuring and that it made them feel safer that there was a tool they could use for instant support:

> *It does make you feel safer in a way because you've got that choice of if I do need help then it's right there…which I thought was really good* [Participant number 154]

Young people reported using BlueIce when they had thoughts of self-harming. For other young people, BlueIce was used to stop further self-harm after an initial episode:

> *I used to self-harm nearly every day without fail but since having the app I haven't self-harmed since really, like I've had two slip ups but that's it so it…it's definitely helped me a lot* [Participant number 115]

Benefits of BlueIce

Young people reported many positive responses to the mood diary and mood lifter sections, particularly changes in their cognitions and behaviors. The ability to notice patterns in mood was a frequently reported benefit of the mood diary. Mood tracking resulted in various benefits, including remembering that they could have happier times and that they are able to cope with bad times, seeing the advantage of implementing the techniques in the mood lifer section on their mood, and recording negative events in the day that may have contributed to a negative mood and identifying ways to change. Several participants also reported that BlueIce was a catalyst for starting conversations with others about their feelings, or that BlueIce was a place where thoughts and feelings that were too difficult to share with others could be externalized:

> *I really liked the diary 'cos…I dunno, 'cos especially when I'm feeling down I'm like 'OH I'm always so sad' or 'what is the point' but actually if I look back to the diary I can see that there were days when I was happy.* [Participant number 135]

Participants also reported numerous benefits of using the mood lifter section. In particular, this section gave young people new strategies for managing their thoughts to self-harm and prompted users to think about their own strategies that were personal to them and their interests. This section was frequently referred to as a reminder that they had strategies to manage their distress other than self-harming and that they had people, normally friends, who they could talk to for support. Young people also reported how the techniques in the mood lifter section provided a distraction for them, helped them relax, or helped them slow down and reframe their thinking in the moments they had thoughts to self-harm. Although each participant liked different aspects, participants tried all sections of the mood lifter:

> *It just kind of stopped like the whole rush of it, so it slowed everything down, made you think about what was actually going on* [Participant number 157]

Agency and Control

A number of participants noted that there were times when they are open to receiving support to stop self-harming and other times when they were less willing to accept help and to stop the act of self-harm. A common report was that on some occasions, their urges to self-harm were too intense to stop and too intense to use BlueIce. Feeling overwhelmed and overpowered by their thoughts to self-harm left young people feeling that their self-harming was out of their control and a sense of hopelessness about anything else they could do to help them at that point in time:

> *I might just sort of feel a bit wilful, sort of, somewhat want to stop myself from self-harming but sometimes I just want to self-harm and that's the end of it really* [Participant number 120]

> *I think a couple of times when the urges were just really high and I kind of knew in the back of my mind that nothing was going to help really* [Participant number 120]

BlueIce Less Helpful

A subgroup of 7 adolescents did not find BlueIce helpful in reducing their self-harm. These young people tended to report an ambivalence about the helpfulness of BlueIce and that they rarely used it. A common thread among these young people

was a sense that they were not ready to give up self-harming and they found it difficult to get motivated to use BlueIce:

> *I guess I was hesitant about trying it and I was also scared that it would work because…well…I don't know, that means I could get better, but I don't particularly want to get better* [Participant number 117]

Furthermore, at least 4 of the young people experienced personal crises during this study, which impacted their ability to use BlueIce. This generally involved an increased need for more face-to-face contact with CAMHS, which took precedence over using BlueIce:

> *I was more in contact with the crisis team and more involved with like CAMHs like more than once a week so I was kind of getting more things to do than just use the BlueIce app* [Participant number 137]

Discussion

Principal Findings and Comparison With Prior Work

The aim of this study was to explore the acceptability, use, and safety of BlueIce, a mobile phone app for young people who self-harm and attend CAMHS. Themes that transpired from our analysis suggested that BlueIce promoted positive changes for a number of adolescents, including helping to slow down or reframe their thinking, distraction from thoughts of self-harming, and identifying triggers of negative moods. Overall, BlueIce was deemed to be helpful, easy to use, and safe.

Acceptability

The majority of adolescents reported that BlueIce was helpful for them: in particular, having a range of techniques available in one app, techniques that kept them distracted and their hands busy, having an outlet for their emotions, and quick access to emergency numbers were deemed most helpful. All participants would recommend BlueIce to others, with a number of adolescents spontaneously suggesting that BlueIce would be helpful to other mental health populations, besides young people who self-harm. These results are encouraging as perceived helpfulness of a mental health intervention is considered a key indicator of acceptability [23] and one of the most important criterion for choosing to use a mental health intervention [24].

BlueIce was designed to be private, discrete, and confidential to use. BlueIce is password protected, a level of privacy valued by young people. The app was therefore discrete on their phones; for example, if one of their friends used their phone, it would not be obvious that a mental health app was installed. Previous research has suggested that concerns around privacy and discretion are important factors to consider in a mental health app design [16,25,26]. This is deemed especially important for adolescents because of a perceived stigma around accessing mental health services [27]. Our study highlights that these factors are also important for young people experiencing mental health problems and who are self-harming. It is advisable, therefore, that mental health apps be developed with privacy and discretion in mind.

Previous research has indicated that young people want the ability to personalize mental health apps [25]. BlueIce includes a level of personalization, such as the ability to add activities personalized to the interests of the adolescent and the ability to add pictures and music from their personal device. These elements of personalization were valued, although many adolescents would like to personalize the app even further by adding different colors to the app. Similarly, many participants stated that adding a game to BlueIce would be beneficial [28] as another distraction technique. There is a potential mismatch here between the adolescents' expectations and what could feasibly be produced within the resources available. We did, however, implement changes to BlueIce based on the feedback received. These changes included adding more options to the mood checker such as *OK* instead of *so-so* and *other*, which allows users to put in their own words about how they are feeling. Colors were added to each option on the mood wheel ranging from red (really sad) to green (really happy). As participants tended to report that they would prefer to text their contacts from BlueIce rather than call them, this option was also added.

Usability

BlueIce was consistently judged to be simple and easy to use. Adolescents reported that the app was accessible, easy to navigate, and was not burdensome. Adolescents also reported that they used BlueIce for its intended purpose: to manage their thoughts of self-harming. Ease of use is particularly important for facilitating engagement with e-mental health interventions [29], and adolescents consider ease of use as an important design requirement of mental health apps [25]. Our study adds emphasis to previous design recommendations that mental health apps for adolescents should be easy to use and require as little training as possible [30].

Participants reported the mood diary and mood lifter sections as parts of the app they particularly liked and used. Tracking and recognizing patterns in moods and identifying triggers for negative emotions were deemed to be the major benefits of using the mood diary regularly. Young people who self-reported high and continued engagement with BlueIce noted the mood diary was a major motivator for this. Young people reported that self-monitoring also helped them to cope with periods of time when they felt less positive, because they could see that they were able to have happier days and the periods of negative emotions do pass. Self-monitoring also highlighted to adolescents that the mood lifting activities were having a positive impact on their mood, and therefore, they could identify the therapeutic benefits of using BlueIce. These findings suggest some participants were using self-monitoring to track and reflect on their emotions and develop a level of awareness about what may influence positive or negative moods. This development of emotional self-awareness has been demonstrated as a benefit of app-based self-monitoring in previous work with adolescents [31,32]. Our findings, therefore, correspond with previous research, which indicates that mood self-monitoring is reported to be one of the most liked and engaged with sections of mental health apps [31] and can potentially produce higher compliance with self-monitoring than the traditional paper-based methods [26,33].

Self-reported use of BlueIce tended to be higher at the start of the study, with usage commonly dropping over time. This usage pattern corresponds with those evident in previous work [34,35]. For example, in a feasibility study of an app for adolescent anxiety (SmartCAT; N=9, aged 9-14 years), high utilization was evident during week 1, but leveled off over time and halved by week 7 [34]. Similarly, in a feasibility trial of Mobiletype, a mood self-monitoring app for young people [35], participants (N = 47, aged 14-24 years) completed 91% (47/51) of the entries every day in week 1, dropping to 58% (17/29) in week 4. Participants in this study used BlueIce over a duration of 12 weeks—much longer than the lengths of previous studies [34,35]; therefore, an amount of attrition is to be expected.

Attrition from eHealth interventions is a common phenomenon [36], but the causes are not well understood. Of those who gave reasons for discontinuing to use BlueIce, some identified positive reasons, for example, that they had not needed to use it so much. This corresponds with a general improvement on mental health outcomes at postintervention [18] and number of reports from participants that they only tended to use BlueIce when they were feeling low.

Participants did also report certain barriers to engagement with BlueIce. Many participants reported that not having BlueIce on their own phone meant they forgot to use the app or felt uncomfortable using it in public. This has now been addressed and BlueIce is available on both iPhone and Android platforms. Participants also felt that there were situations in which it was difficult for them to use BlueIce, such as being in school or being around their family. In these instances, they could not use the strategies in the mood lifter section to regulate their emotions. These practical barriers are more difficult to overcome, as they cannot be mitigated by the app design. Discussing these barriers with CAMHS therapists and identifying solutions would be beneficial in these circumstances.

For the 7 young people who did not show any improvement in their self-harm during the study, a number of issues were highlighted. These included finding the app repetitive, not finding it helpful, experiencing annoyance when asked questions about how they were feeling, and 1 participant reported preferring to speak to someone face-to-face. Most of these participants reported not being ready to stop self-harming and therefore experienced a lack of motivation to use BlueIce. These young people tended to acknowledge that BlueIce would be helpful if they had the necessary motivation to use it, and some indicated they had little faith that any interventions could help them overcome their difficulties. The need to be committed to change and lack of motivation have been identified as barriers to mHealth engagement in both adults [37-39] and adolescents [40]. Mental health practitioners should, therefore, consider service user motivation and readiness to change when recommending mHealth apps as an adjunct to face-to-face care. Making mHealth apps intrinsically more engaging by design could be a way to increase longer-term engagement and motivation. One promising avenue is the use of serious gaming, gamification principles, telepresence, and persuasive technology [28]. How these principles may be incorporated into BlueIce is for further research to address.

Safety

mHealth researchers have highlighted that mhealth apps can pose risks to patient safety and that steps should be taken to mitigate these risks [41,42]. Unfortunately, reporting of risks, adverse events, and safety of mental health apps is sparse in the current literature [16]. Given the nature of self-harm and associated comorbid difficulties, it was deemed critical to explore with young people whether BlueIce worked as intended, caused any unintentional adverse effects, or whether any other safety concerns arose during the study. Young people who used BlueIce reported that they used the app as intended, to help them manage their thoughts of self-harming. Some participants reported that BlueIce helped them not to act on their thoughts to self-harm. Others reported instances where BlueIce did not prevent an initial act of self-harm, but prevented them from continuing to harm themselves in that instance. Participants tended to acknowledge that BlueIce was helpful but would not be able to prevent every instance of self-harm. Participants explained that in these instances, they felt their emotions were too overwhelming and some reported feeling like nothing would have helped them in that moment. BlueIce is intended to be used as an adjunct to face-to-face meetings. This allows the young person's progress to be regularly reviewed and additional interventions provided to increase motivation and to develop protective skills.

Although 2 participants did report initial concerns that seeing their mood diary full of negative days might not help them, they did reflect further that overall the benefits of self-monitoring would outweigh these concerns. No participants believed BlueIce would increase their thoughts of self-harming, and no adverse events were reported. Many of the participants stated they felt reassured to have the app when they needed it, and most participants wanted to keep BlueIce at the end of the study. Overall, our results provide preliminary support for the safety of BlueIce as an adjunct to face-to-face therapy.

Limitations

Although our results are encouraging, our study does have some limitations. First, we report a self-selected case series of young people who actively elected to try BlueIce. Our group may therefore have had more positive attitudes toward using an mHealth intervention. Second, due to the interviews being conducted by research assistants, there is a possibility that participants reporting may be subject to bias. It should be noted, however, that the research assistants were not involved in the initial development of BlueIce and went to great lengths to reassure participants that negative feedback would be helpful to make changes to the app. Third, 37 participants chose to use BlueIce after the 2-week familiarization period, with postuse interviews being conducted with 33. We could not gain contact with the 4 participants who dropped out the study, and therefore, we do not have their feedback on why they discontinued the study, be it because of the research process, their experiences of using BlueIce, or other factors. Similarly, several participants did not find BlueIce helpful in reducing their self-harm. We must be mindful that BlueIce is a mobile phone app and that there is a limit to which it can stop all acts of self-harm. Although many participants in this category reported feeling

that nothing (ie, no intervention) would have helped them in that moment, the limitations of digital support should be acknowledged.

We also acknowledge that some of the questions in the postuse interview maybe subject to recall bias. For example, asking participants what factors influenced them to use or not use BlueIce in a moment of distress when they were struggling with thoughts of self-harm. This may be overcome in a subsequent phase 2 trial by the use of ecological momentary assessment methods and sampling as close to real time as possible.

Finally, BlueIce was provided in addition to usual face-to-face intervention. As such, there may be possible synergic effects between the face-to-face intervention and the usability, acceptability, and safety of the app. A randomized trial comparing treatment as usual with and without BlueIce is required to explore this further and gain better insight into the acceptability, use, and safety of BlueIce, beyond this exploratory, uncontrolled study.

Conclusions

To the knowledge of the authors, this is the first reported qualitative study detailing the experience of adolescents using an app specifically developed with young people for young people who self-harm. Interviews with adolescents who had used BlueIce demonstrated that it was considered an acceptable, easy, and safe app to use that helped young people manage their thoughts of self-harm. Young people reported a number of advantages of using BlueIce, in particular being able to track their mood and access techniques to help distract them from their thoughts of self-harm. Given the high acceptability of BlueIce, this study demonstrates the value of meaningful involvement of adolescents with lived experience in the design, production, and implementation of mHealth interventions. This study provides initial support for the acceptability, usability, and safety of BlueIce as an mHealth intervention for preventing self-harm used in conjunction with the traditional face-to-face therapy. A subsequent phase 2 randomized controlled trial is now warranted to demonstrate the effectiveness of BlueIce in reducing adolescent self-harm.

Acknowledgments

This project is funded by NHS England and the Health Foundation (2143 Oxford Health NHS FT). The funder has no role in the study design or in the writing of this manuscript.

Conflicts of Interest

None declared.

References

1. National Institute for Health Care Excellence. NICE. London: National Institute for Health and Care Excellence; 2011 Nov 23. Self-harm in over 8s: long-term management URL: https://www.nice.org.uk/guidance/cg133 [accessed 2017-08-18] [WebCite Cache ID 6so0ErY4a]
2. Mars B, Heron J, Crane C, Hawton K, Lewis G, Macleod J, et al. Clinical and social outcomes of adolescent self harm: population based birth cohort study. Br Med J 2014 Oct 21;349:g5954 [FREE Full text] [Medline: 25335825]
3. Kidger J, Heron J, Lewis G, Evans J, Gunnell D. Adolescent self-harm and suicidal thoughts in the ALSPAC cohort: a self-report survey in England. BMC Psychiatry 2012 Jun 27;12:69 [FREE Full text] [doi: 10.1186/1471-244X-12-69] [Medline: 22737989]
4. Madge N, Hewitt A, Hawton K, de Wilde EJ, Corcoran P, Fekete S, et al. Deliberate self-harm within an international community sample of young people: comparative findings from the Child & Adolescent Self-harm in Europe (CASE) Study. J Child Psychol Psychiatry 2008 Jun;49(6):667-677. [doi: 10.1111/j.1469-7610.2008.01879.x] [Medline: 18341543]
5. Stallard P, Spears M, Montgomery AA, Phillips R, Sayal K. Self-harm in young adolescents (12-16 years): onset and short-term continuation in a community sample. BMC Psychiatry 2013 Dec 02;13:328 [FREE Full text] [doi: 10.1186/1471-244X-13-328] [Medline: 24294921]
6. Hawton K, Bergen H, Kapur N, Cooper J, Steeg S, Ness J, et al. Repetition of self-harm and suicide following self-harm in children and adolescents: findings from the Multicentre Study of Self-harm in England. J Child Psychol Psychiatry 2012 Dec;53(12):1212-1219. [doi: 10.1111/j.1469-7610.2012.02559.x] [Medline: 22537181]
7. Hawton K, Saunders KE, O'Connor RC. Self-harm and suicide in adolescents. Lancet 2012 Jun 23;379(9834):2373-2382. [doi: 10.1016/S0140-6736(12)60322-5] [Medline: 22726518]
8. Hawton K, Bergen H, Kapur N, Cooper J, Steeg S, Ness J, et al. Repetition of self-harm and suicide following self-harm in children and adolescents: findings from the Multicentre Study of Self-harm in England. J Child Psychol Psychiatry 2012 Dec;53(12):1212-1219. [doi: 10.1111/j.1469-7610.2012.02559.x] [Medline: 22537181]
9. Patton GC, Coffey C, Sawyer SM, Viner RM, Haller DM, Bose K, et al. Global patterns of mortality in young people: a systematic analysis of population health data. Lancet 2009 Sep 12;374(9693):881-892 [FREE Full text] [doi: 10.1016/S0140-6736(09)60741-8] [Medline: 19748397]
10. Hawton K, Saunders K, Topiwala A, Haw C. Psychiatric disorders in patients presenting to hospital following self-harm: a systematic review. J Affect Disord 2013 Dec;151(3):821-830. [doi: 10.1016/j.jad.2013.08.020] [Medline: 24091302]

11. Hawton K, Witt KG, Taylor ST, Arensman E, Gunnell D, Townsend E, et al. Interventions for self-harm in children and adolescents. Cochrane Database Syst Rev 2015 Dec 21(12):CD012013. [doi: 10.1002/14651858.CD012013] [Medline: 26688129]
12. Anthes E. Mental health: there's an app for that. Nature 2016 Apr 7;532(7597):20-23. [doi: 10.1038/532020a] [Medline: 27078548]
13. eMarketer. 2013. Smartphones are increasingly UK kids' mobile phone of choice limited-function mobile phones may face a tough sell URL: https://www.emarketer.com/Article/Smartphones-Increasingly-UK-Kids-Mobile-Phone-of-Choice/1009910 [WebCite Cache ID 6so1fPyhZ]
14. The National Institute for Health Research Horizon Scanning Research Intelligence Centre. io.nihr. Birmingham: The National Institute for Health Research; 2015. New and emerging mobile health interventions that promote behavioural change URL: http://www.io.nihr.ac.uk/ [accessed 2017-08-18] [WebCite Cache ID 6so1pYQR3]
15. East ML, Havard BC. Mental health mobile apps: from infusion to diffusion in the mental health social system. JMIR Ment Health 2015;2(1):e10 [FREE Full text] [doi: 10.2196/mental.3954] [Medline: 26543907]
16. Grist R, Porter J, Stallard P. Mental health mobile apps for preadolescents and adolescents: a systematic review. J Med Internet Res 2017 May 25;19(5):e176 [FREE Full text] [doi: 10.2196/jmir.7332] [Medline: 28546138]
17. Stallard P, Porter J, Grist R. Safety, acceptability, and use of a smartphone app, BlueIce, for young people who self-harm: protocol for an open phase I trial. JMIR Res Protoc 2016 Nov 16;5(4):e217 [FREE Full text] [doi: 10.2196/resprot.6525] [Medline: 27852560]
18. Stallard P, Porter J, Grist R. A smartphone app (BlueIce) for young people who self-harm: open phase 1 pre-post trial. JMIR Mhealth Uhealth 2018 Jan 30;6(1):e32 [FREE Full text] [doi: 10.2196/mhealth.8917] [Medline: 29382632]
19. Wood A, Kroll L, Moore A, Harrington R. Properties of the mood and feelings questionnaire in adolescent psychiatric outpatients: a research note. J Child Psychol Psychiatry 1995 Feb;36(2):327-334. [Medline: 7759594]
20. Chorpita BF, Moffitt CE, Gray J. Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample. Behav Res Ther 2005 Mar;43(3):309-322. [doi: 10.1016/j.brat.2004.02.004] [Medline: 15680928]
21. Goodman R. The Strengths and Difficulties Questionnaire: a research note. J Child Psychol Psychiatry 1997 Jul;38(5):581-586. [Medline: 9255702]
22. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
23. Apolinário-Hagen J, Kemper J, Stürmer C. Public acceptability of e-mental health treatment services for psychological problems: a scoping review. JMIR Ment Health 2017 Apr 03;4(2):e10 [FREE Full text] [doi: 10.2196/mental.6186] [Medline: 28373153]
24. Musiat P, Goldstone P, Tarrier N. Understanding the acceptability of e-mental health--attitudes and expectations towards computerised self-help treatments for mental health problems. BMC Psychiatry 2014;14:109 [FREE Full text] [doi: 10.1186/1471-244X-14-109] [Medline: 24725765]
25. Kenny R, Dooley B, Fitzgerald A. Developing mental health mobile apps: exploring adolescents' perspectives. Health Informatics J 2016;22(2):265-275. [doi: 10.1177/1460458214555041] [Medline: 25385165]
26. Matthews M, Doherty G. In the mood: Engaging teenagers in psychotherapy using mobile phones. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. New York: ACM; 2011 Presented at: ACM CHI Conference on Human Factors in Computing Systems; May 07 - 12, 2011; Vancouver, BC, Canada p. 2947-2956 URL: http://doi.org/10.1145/1978942.1979379 [doi: 10.1145/1978942.1979379]
27. Bulanda JJ, Bruhn C, Byro-Johnson T, Zentmyer M. Addressing mental health stigma among young adolescents: evaluation of a youth-led approach. Health Soc Work 2014 May;39(2):73-80. [Medline: 24946423]
28. Fleming TM, De Beurs D, Khazaal Y, Gaggioli A, Riva G, Botella C, et al. Maximizing the impact of e-therapy and serious gaming: time for a paradigm shift. Front Psychiatry 2016;7:65 [FREE Full text] [Medline: 27148094]
29. Povey J, Mills PP, Dingwall KM, Lowell A, Singer J, Rotumah D, et al. Acceptability of mental health apps for Aboriginal and Torres Strait islander Australians: a qualitative study. J Med Internet Res 2016 Mar 11;18(3):e65 [FREE Full text] [doi: 10.2196/jmir.5314] [Medline: 26969043]
30. Matthews M, Doherty G, Coyle D, Sharry J. Designing mobile applications to support mental health interventions. In: Lumsden J, editor. Handbook of research on user interface design and evaluation for mobile technology. Pennsylvania: IGI, Gloabal; 2008:635-656.
31. Kenny R, Dooley B, Fitzgerald A. Feasibility of “CopeSmart”: a telemental health app for adolescents. JMIR Ment Health 2015 Aug 10;2(3):e22 [FREE Full text] [doi: 10.2196/mental.4370] [Medline: 26552425]
32. Reid SC, Kauer SD, Dudgeon P, Sanci LA, Shrier LA, Patton GC. A mobile phone program to track young people's experiences of mood, stress and coping. Development and testing of the mobiletype program. Soc Psychiatry Psychiatr Epidemiol 2009 Jun;44(6):501-507. [doi: 10.1007/s00127-008-0455-5] [Medline: 19011723]
33. Matthews M, Doherty G, Sharry J, Fitzpatrick C. Mobile phone mood charting for adolescents. Brit J Guid Couns 2008 May;36(2):113-129. [doi: 10.1080/03069880801926400]

34. Pramana G, Parmanto B, Kendall PC, Silk JS. The SmartCAT: an m-health platform for ecological momentary intervention in child anxiety treatment. Telemed J E Health 2014 May;20(5):419-427 [FREE Full text] [doi: 10.1089/tmj.2013.0214] [Medline: 24579913]
35. Reid SC, Kauer SD, Khor AS, Hearps SJ, Sanci LA, Kennedy AD, et al. Using a mobile phone application in youth mental health - an evaluation study. Aust Fam Physician 2012 Sep;41(9):711-714. [Medline: 22962650]
36. Eysenbach G. The law of attrition. J Med Internet Res 2005;7(1):e11 [FREE Full text] [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]
37. Peng W, Kanthawala S, Yuan S, Hussain SA. A qualitative study of user perceptions of mobile health apps. BMC Public Health 2016 Nov 14;16(1):1158 [FREE Full text] [doi: 10.1186/s12889-016-3808-0] [Medline: 27842533]
38. Ly K, Janni E, Wrede R, Sedem M, Donker T, Carlbring P, et al. Experiences of a guided smartphone-based behavioral activation therapy for depression: a qualitative study. Internet Interv 2015 Mar;2(1):60-68 [FREE Full text] [doi: 10.1016/j.invent.2014.12.002]
39. Svensson A, Magnusson M, Larsson C. Overcoming barriers: adolescents' experiences using a mobile phone dietary assessment app. JMIR Mhealth Uhealth 2016 Jul 29;4(3):e92 [FREE Full text] [doi: 10.2196/mhealth.5700] [Medline: 27473462]
40. Lewis TL, Wyatt JC. mHealth and mobile medical apps: a framework to assess risk and promote safer use. J Med Internet Res 2014 Sep 15;16(9):e210 [FREE Full text] [doi: 10.2196/jmir.3133] [Medline: 25223398]
41. Naeem F, Gire N, Xiang S, Yang M, Syed Y, Shokraneh F, et al. Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: an update. World J Psychiatry 2016 Jun 22;6(2):187-191 [FREE Full text] [doi: 10.5498/wjp.v6.i2.187] [Medline: 27354959]
42. Whittaker R, Merry S, Stasiak K, McDowell H, Doherty I, Shepherd M, et al. MEMO--a mobile phone depression prevention intervention for adolescents: development process and postprogram findings on acceptability from a randomized controlled trial. J Med Internet Res 2012;14(1):e13 [FREE Full text] [doi: 10.2196/jmir.1857] [Medline: 22278284]

Abbreviations

CBT: cognitive behavioral therapy
CAMHS: child and adolescent mental health services
DBT: dialectical behavioral therapy
mHealth: mobile health
MFQ: Mood and Feelings Questionnaire
NICE: National Institute of Health and Care Excellence
NSSI: nonsuicidal self-injury
RCADS: Revised Child Anxiety and Depression Scale
SDQ: Strengths and Difficulties Questionnaire

Edited by J Torous; submitted 04.09.17; peer-reviewed by A John, K Krysinska; comments to author 29.10.17; revised version received 29.11.17; accepted 19.12.17; published 23.02.18.

Please cite as:
Grist R, Porter J, Stallard P
Acceptability, Use, and Safety of a Mobile Phone App (BlueIce) for Young People Who Self-Harm: Qualitative Study of Service Users' Experience
JMIR Ment Health 2018;5(1):e16
URL: http://mental.jmir.org/2018/1/e16/
doi:10.2196/mental.8779
PMID:29475823

Original Paper

Work Addiction Test Questionnaire to Assess Workaholism: Validation of French Version

Hortense Ravoux[1,2], Dr, MD; Bruno Pereira[3], PhD; Georges Brousse[4,5], MD, PhD; Samuel Dewavrin[6], MSc, ATPL; Thomas Cornet[6], MBA; Martial Mermillod[7,8], PhD; Laurie Mondillon[2], PhD; Guillaume Vallet[2], PhD; Farès Moustafa[9], MD, PhD; Frédéric Dutheil[1,2,10], MD, PhD

[1]Service Santé Travail Environnement, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France

[2]Équipe Stress physiologique et psychosocial, Laboratoire de Psychologie Sociale et Cognitive, Université Clermont Auvergne, Centre National de la Recherche Scientifique, Clermont-Ferrand, France

[3]Service de Biostatistique, Direction de la Recherche Clinique et de l'Innovation, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France

[4]Service Addictologie, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France

[5]Neuro-Psycho-pharmacologie des systèmes dopaminergiques sous-corticaux, Université Clermont Auvergne, Clermont-Ferrand, France

[6]WittyFit, Paris, France

[7]Laboratoire de Psychologie et NeuroCognition, Centre National de la Recherche Scientifique, Université Grenoble Alpes, Grenoble, France

[8]Institut Universitaire de France, Paris, France

[9]Service des Urgences, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France

[10]Faculty of Health, Australian Catholic University, Melbourne, Victoria, Australia

Corresponding Author:
Frédéric Dutheil, MD, PhD
Service Santé Travail Environnement
Centre Hospitalier Universitaire de Clermont-Ferrand
58 rue Montalembert
Clermont-Ferrand, F-63000
France
Phone: 33 6 88 22 48 48
Fax: 33 4 73 27 46 49
Email: fred_dutheil@yahoo.fr

Abstract

Background: Work addiction is a significant public health problem with a growing prevalence. The Work Addiction Risk Test (WART) is the gold standard questionnaire to detect workaholism.

Objective: The main objective of this study was to validate the French version of the WART.

Methods: Questionnaires were proposed to voluntary French workers using the WittyFit software. There were no exclusion criteria. The questionnaire was administered anonymously for initial validity testing and readministered one week later for test-retest reliability. We also assessed the workers' sociodemographic characteristics, as well as other measurements for external validity, such as stress, well-being, and coaddictions to tobacco, alcohol, and cannabis. Several psychometric properties of the French-WART were explored: acceptability, reliability (internal consistency [Cronbach alpha coefficient] and reproducibility [Lin concordance coefficient]), construct validity (correlation coefficients and principal component analysis), and external validity (correlation coefficients).

Results: Among the 1580 workers using WittyFit, 187 (11.83%) agreed to complete the WART questionnaire. Of those, 128 completed the test-retest survey (68.4%). Acceptability found that all respondents had fully completed the questionnaire, with few floor or ceiling effects. Reliability was very good with a Cronbach alpha coefficient at .90 (internal consistency) and Lin concordance coefficient at .90 (95% CI .87-.94] with a difference on the retest of .04 (SD 4.9) (95% CI −9.6 to 9.7) (reproducibility). We identified three main dimensions (construct validity). Relationships between WART and stress and well-being confirmed its external validity.

Conclusions: The French version of the WART is a valid and reliable instrument to assess work addiction with satisfactory psychometric properties. Used in occupational medicine, this tool would allow the diagnosis of work addiction and can be easily implemented in current practice.

(JMIR Ment Health 2018;5(1):e12) doi:10.2196/mental.8215

KEYWORDS

behavior, addictive; work; validation studies as topic; questionnaires; social welfare; health; public health

Introduction

Addiction to work, or workaholism, is defined as "a compulsion or an uncontrollable need to work incessantly" [1-3]. This pathology is in line with the general criteria of addiction, that is, preoccupation with an addictive object or behavior, mood modification, interpersonal conflict, withdrawal syndrome, tolerance, relapses, or continuation of this behavior despite the knowledge of its negative effects [2-5]. There is a real typology based on the major characteristics of individuals (the compulsive-dependent, the perfectionists, the achievement-oriented, the bulimic, the relentless, etc) [2,6,7]. It is important to differentiate workers suffering from workaholism from those who are engaged at work [4,8,9]. Workaholics are propelled by an obsessive inner drive they cannot resist, whereas engaged workers are intrinsically motivated [8,10]. Addiction to work results from the individual's predisposition, sociocultural experiences, and behavioral reinforcements [1,2,9,11]. Addiction to work is a growing public health concern [1,11,12] with a prevalence ranging from 7.6% [13] to 22.2% [14] in European countries. Workaholics dedicate more time and energy to work than seems necessary [2,7,8]. This behavioral addiction would negatively affect the individual's health and could lead to relationship problems (family conflicts, marital problems, impact on their children, and poor social relationship) [10,11,15], neuropsychic troubles (depression, burnout, sleep disorders, and general dissatisfaction) [2,4,8-10,15-17], consequences to professional life in the long term (lower productivity levels, absences, and strain at work) [1-3,11,17], and poorer physical health [11].

As we are being confronted with this growing health problem, it appears absolutely essential to possess validated tools. The Work Addiction Risk Test (WART) is a reference questionnaire for work addiction [2]. This test was developed by Robinson et al in 1999 [2,18-20] based on the experiences of clinicians treating workaholics [2]. We chose this tool because of its wide use (approximately 150 studies) and usability [2]. The English version of the WART has satisfactory psychometric properties [6,20]. *Reliability* is represented by *internal consistency* with a Cronbach alpha coefficient ranging from .85 [21] to .88 [18], and *reproducibility* with a test-retest correlation coefficient of .83 [20,22], and a Spearman-Brown split-half reliability coefficient of 0.85 [20]. *Construct validity* is built around five dimensions: compulsive tendencies, control, impaired communication and self-absorption, inability to delegate, and self-worth [20]. For *external validity*, work addiction was linked to a high level of stress [3,14,15,18,23] and a poor level of well-being [1-4]. In addition to work addiction, the same worker may also suffer from several addictions, such as consuming tobacco, cannabis, or alcohol [1,24]. To our knowledge, no studies have reported acceptability of the English version of WART.

The main objective of this investigation was the validation of the French version of the WART to allow its use in current practice. We aimed to evaluate its acceptability, reliability, construct, validity, and external validity. Stress, well-being, and coaddictions to tobacco, alcohol, and cannabis were used for evaluating external validity.

Methods

Recruitment

Questionnaires were proposed to voluntary French workers using the WittyFit software [25]. WittyFit is a Web platform that aims to improve the well-being at work, with a public-private partnership with the University Hospital of Clermont-Ferrand. Workers using WittyFit answer-validated questionnaires on behavioral data for baseline health profiling. The concept of WittyFit is to provide individualized feedback based on evidence-based medicine, with an aim to support behavioral change using a formal evaluation of changes in knowledge, practices, and health outcomes over time. The database is implemented from a human resource–generated number, which is then automatically converted into another number in the WittyFit database. Data provided by employers (such as from the professional roles or the occupational sector) are automatically associated with the human resource–generated number. All data are anonymous, and the name of the employee is never entered into the database. The study was approved by the National Commission for Data Protection and Liberties and by the South-East VI Ethics Committee (ClinicalTrials.gov NCT number NCT02596737). There were no exclusion criteria. The WittyFit users were informed of a forthcoming questionnaire validation study through this platform explaining the purpose of the study and the need to complete the questionnaire twice (test and retest, 1 week later).

The Work Addiction Risk Test Questionnaire

The WART is a self-administered test with 25 statements for which the answers are scored *1-never true* to *4-always true* [20,26]. Respondents read the statements and mark their answers to describe their work habits [19,27]. The total score is the sum of the responses to the items—25 to 100—and the higher the score, the more one is considered addicted to work [18,21]. Scores from 25 to 56 were defined as "at low-risk of work addiction"; 57 to 66 as "at medium-risk of work addiction", and from 67 to 100 as "at high-risk of work addiction" [12,18]. The WART consists of five dimensions, including compulsive tendencies (9 items: 3, 5, 6, 7, 8, 15, 18, 19, 20); control (7

items: 2, 4, 11, 12, 16, 17, 22); impaired communication and self-absorption (5 items: 13, 21, 23, 24, 25); inability to delegate (1 item: 1); and self-worth (2 items: 9 and 10) [1,15,20]. The first two dimensions are the key elements to differentiate workaholics [1].

Translation of the Work Addiction Risk Test

In accordance with the literature [28], the following steps were performed for the validation of the French version of the WART: (1) translations of the WART into French performed by 2 independent native French translators; (2) back translation of the French version of the WART into English by 2 native English speakers, who had no knowledge of the original English version; (3) synthesis and comparison of all translations by a committee of experts, multidisciplinary and bilingual, to develop the final version of the WART; (4) validation study of the French version. The questionnaire was administered for the initial validity testing and readministered 1 week later for test-retest reliability. Workers received an individual alert through the WittyFit software to complete the surveys. The French version of the WART is presented in Multimedia Appendix 1.

External Validity: Other Measurements

Well-being and perceived stress at work and at home were evaluated using visual analog scales (VAS) by moving a cursor on a horizontal, noncalibrated line, ranging from very low (0) on the left to very high (100) on the right [29-31]. Furthermore, tobacco, alcohol, and cannabis consumption were evaluated using 3 specific VAS—the number of cigarettes smoked per day from 0 to 30, the number of glasses of alcohol consumed per day from 0 to 8, and the number of cannabis consumption per month from 0 to 30.

Statistical Analysis

The number of subjects required were determined in advance by following recommendations [32] and in accordance with our recruitment abilities. In this context, a complement of at least 120 participants appeared to be relevant for the test and 60 for the retest.

Statistical analysis was carried out using the Stata software version 13 (StataCorp). Qualitative data were described in size and associated frequencies, and the data were compared between groups—those who only completed the questionnaire once (*test*) and those who completed the survey twice (*test and retest*)—with the chi-square test or with the Fisher exact test. Quantitative data, expressed by the mean (SD) or the median (interquartile ranges) regarding the statistical distribution (the Shapiro-Wilk test), were compared between groups with the Student *t* test (or an analysis of variance [ANOVA]) or Mann-Whitney *U* test or the Kruskal-Wallis test, if the *t* test's conditions were not respected (normality and homoscedasticity considered by the Bartlett test) for the quantitative variables. When appropriate ($P<.05$), a post hoc test for multiple comparison was deemed, namely, the Tukey-Kramer postANOVA test and Dunn test after the Kruskal-Wallis test. The comparisons between the groups for category parameters were achieved with the chi-square test or with the Fisher exact test. The difference was defined as statistically significant when the level of significance (P) was less than .05 (alpha risk=5%).

The psychometric properties of the WART were explored. We assessed the acceptability based on the calculation of missing data for each item and the dimension of the WART—data quality was deemed acceptable if less than 5% of data were missing. The accepted maximum for floor and ceiling effects was 15% [32]. The reliability of the French version was evaluated according to two criteria: (1) internal consistency based on the calculation of the Cronbach alpha coefficient (desirable values higher than .70-0.80) [32-39] and (2) reproducibility. The correlation coefficient (Pearson or Spearman, as per the statistic distribution) and Lin concordance coefficient were computed to assess test-retest reliability [40]. Values above .7 were considered satisfactory. An analysis using a mixed model (random effect subject time) and Bland and Altman's graphic illustrations completed the analysis. The construct validity of the French version of the WART was explored by reviewing interitem and interdimensional correlations and using multidimensional factorial analysis (principal component analysis). The analysis of the interdimensional correlations assessed the redundancy between dimensions with expected positive correlations but which were not too high (.60-.80) [32-39]. The multidimensional analysis allowed the assessment of the gathered items with regard to different dimensions. The external validity was assessed by studying correlations between the WART and other psychological measures, such as perceived stress, well-being, or other putative addiction.

Results

Participants

Among the 1580 workers using WittyFit, 11.83% (187/1580) agreed to answer the WART questionnaire. Among them, 86.1% (161/187) completed the sociodemographic characteristics and the VAS. The test-retest survey was completed by 68.4% (128/187) workers. Workers' characteristics did not differ between those who only completed the questionnaire once (*test*) and those who completed the survey twice (*test and retest*), except in tobacco consumption, with more smoker participants responding only in the test than the participants who responded both at the test and retest (32 vs 16% of smokers, $P=.01$) (Table 1).

Results From the Work Addiction Risk Test Questionnaire

Of the 187 individuals who completed the WART questionnaire, 45.5% (85/187) were at low risk of work addiction, 32.6% (61/187) at medium risk, and 20.8 (41/197) at high risk. Women had a higher risk of work addiction than men did (27% vs 15% of workers at high risk of work addiction, $P=.02$). According to the WART, individuals exhibiting a high risk of work addiction worked for an average of 7 more hours per week than those at a low risk—46.9 (13.6) hours versus 39.4 (10.9) hours, $P=.005$.

Table 1. Difference between people at the test and retest in terms of sociodemographic characteristics.

Variable	Source			*P* value[a]
	Test (n=187)	Test only (n=59)	Test and retest (n=189)	
Sex, Women, n (%)	95 (50.8)	30 (52.6)	58 (55.8)	.70
Age (years), mean(SD)	41.6 (11.7)	42.0 (12.2)	41.8 (11.7)	.92
Family situation, n (%)				
Single	36 (20.5)	17 (29.8)	17 (16.4)	.15
De facto	48 (27.3)	12 (21.1)	32 (30.8)	
Married	91 (51.7)	28 (49.1)	54 (51.9)	
Widow(ed)	1 (0.6)	0 (0.0)	1 (1.0)	
Education level, n (%)				
General Certificate of Secondary Education	2 (1.1)	1 (1.8)	1 (1.0)	.88
General Certificate of Education–Advanced Level	8 (4.6)	4 (7.0)	4 (3.9)	
Higher national diploma	14 (8.0)	4 (7.0)	9 (8.7)	
Bachelor's degree	22 (12.5)	7 (12.3)	13 (12.5)	
Master's degree	130 (73.9)	41 (71.9)	77 (74.0)	
Occupational group, n (%)				
Merchants-business	6 (3.4)	1 (1.8)	5 (4.8)	.62
Employees	31 (17.6)	13 (22.8)	15 (14.4)	
Intermediate profession	12 (6.8)	3 (5.3)	7 (6.7)	
Inactive employment	10 (5.7)	4 (7.0)	6 (5.8)	
Manager-intellectual profession	117 (66.5)	36 (63.2)	71 (68.3)	
Hours worked per week, mean (SD)	41.6 (12.1)	42.5 (12.3)	40.8 (12.4)	.41
Seniority in the company (years), mean (SD)	10.8 (10.5)	10.9 (10.2)	11.1 (11.2)	.83
body mass index, $kg.m^{-2}$, mean (SD)	24.2 (4.4)	25.1 (5.0)	23.7 (4.0)	.06
metabolic equivalent of task, mean (SD)	50.9 (55.5)	53.3 (53.1)	47.6 (51.4)	.44
Tobacco smoker, n (%)	39 (20.9)	19 (32.2)	20 (15.6)	.01
Alcohol users,n (%)	30 (16.0)	9 (15.3)	21 (16.4)	.84
Cannabis consumer,n (%)	14 (7.5)	5 (8.5)	9 (7.0)	.77
WART[b]				
Score, mean (SD)	57.8 (11.2)	56.2 (11.6)	58.6 (11.0)	.14
% of participants with a score <56	45.5	50.8	43.0	.51

[a]*P* value between *test only* and *test and retest*.

[b]WART: Work Addiction Risk Test.

Acceptability

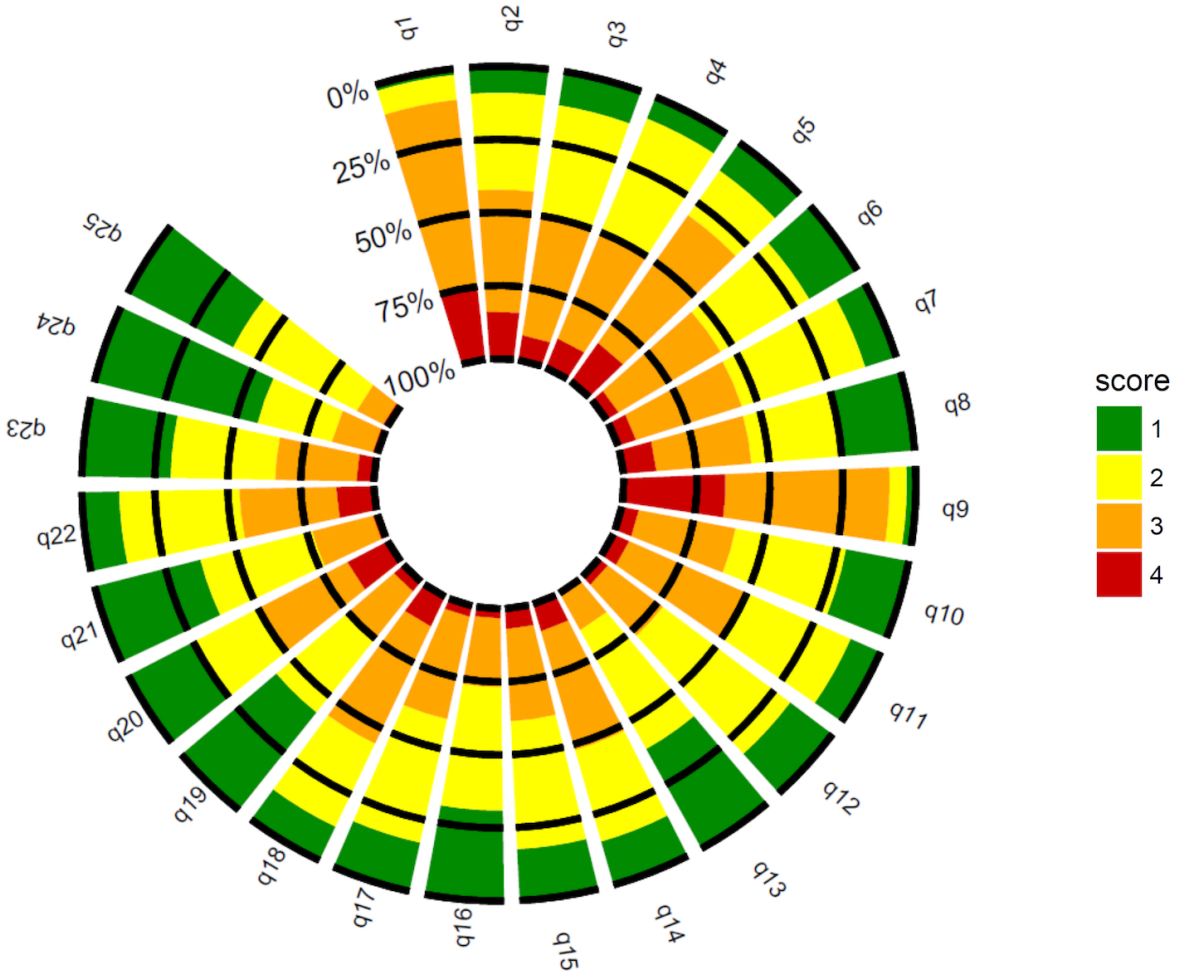
The results for data quality and acceptability of the French version of the WART are displayed in Figure 1 (see Multimedia Appendix 2). Data quality was commonly considered satisfactory if 95% of the scale was fully completed [41,42] (at least 24 of the 25 items). All of the 187 individuals who completed the WART questionnaire did so fully. In fact, no one partially replied to the questionnaire. Therefore, there were no missing data.

Internal Validity

Internal Consistency

The entire WART had a Cronbach alpha of .90. The Cronbach alpha values for the various dimensions of the WART were .85 for compulsive tendencies, .82 for control, and .57 for impaired communication and self-absorption.

Figure 1. Data quality and acceptability of the French version of the Work Addiction Risk Test (WART) (n=187).



Correlation

Item-total correlation coefficients for the scale as a whole ranged from .02 to .59. Interitem correlations ranged from .23 (Questions 3 and 20) to .54 (Questions 7 and 8) for compulsive tendencies; .19 (Questions 16 and 22) to .50 (Questions 2 and 17) for control; and .08 (Questions 13 and 24) to .37 (Questions 21 and 23) for impaired communication and self-absorption. The assessment of the correlations between the questionnaire in its entirety and each dimension was statistically significant (P<.05) and showed that the correlation coefficient between WART and compulsive tendencies was .89; control was .84; impaired communication and self-absorption was .74; inability to delegate was .52; and self-worth was .31.

Principal Component Analysis

By applying the Kaiser's criteria, in other words, the associated eigenvalues above 1 associated with a plot of the eigenvalues, we have determined four main components. Components 1 and 2 together explained the maximal variance. As presented in Figure 2, the first dimension of the French WART was associated with Component 1 and was composed of items 2, 9, 10, 11, 12, 13, 14, 16, 17, 22, and 25; the second dimension was associated with Component 2 and was composed of items 3, 4, 5, 6, 7, 8, 18, 19, and 21; and the third dimension was associated with Component 1 and was composed of items 15, 20, and 23.

Reproducibility

The Lin concordance coefficient was .90 (95% CI 0.87-0.94) for the entire WART with a difference between the test and the retest of 0.04 (SD 4.92) (95% CI −9.61 to 9.69). The Bland and Altman plot is shown in Figure 3. For each dimension, Lin concordance coefficients were as follows: .86 (95% CI 0.82-0.91) for compulsive tendencies, .86 (95% CI 0.82-0.91) for control, .76 (95% CI 0.68-0.83) for impaired communication and self-absorption, .73 (95% CI 0.65-0.81) for self-worth, and .66 (95% CI 0.56-0.75) for the inability to delegate (Table 2). Exhaustive results for the Lin concordance coefficient and Cohen kappa for each item are shown in Figure 4 (see Multimedia Appendix 3).

External Validity

External validity was evaluated by calculating a correlation coefficient between the WART and the others questionnaires (Table 3). The WART was well correlated to the VAS Stress at Work (coefficient correlation .43) and Stress at Home (.41) and inversely to VAS Well-being (−.40) (P<.05). The VAS Well-being had a reverse correlation with all dimensions of the WART (P<.05). The WART was poorly correlated with tobacco, alcohol, or cannabis consumption.

Figure 2. Principal component analysis: circle of correlation or the three dimensions of the French Work Addiction Risk Test (WART).

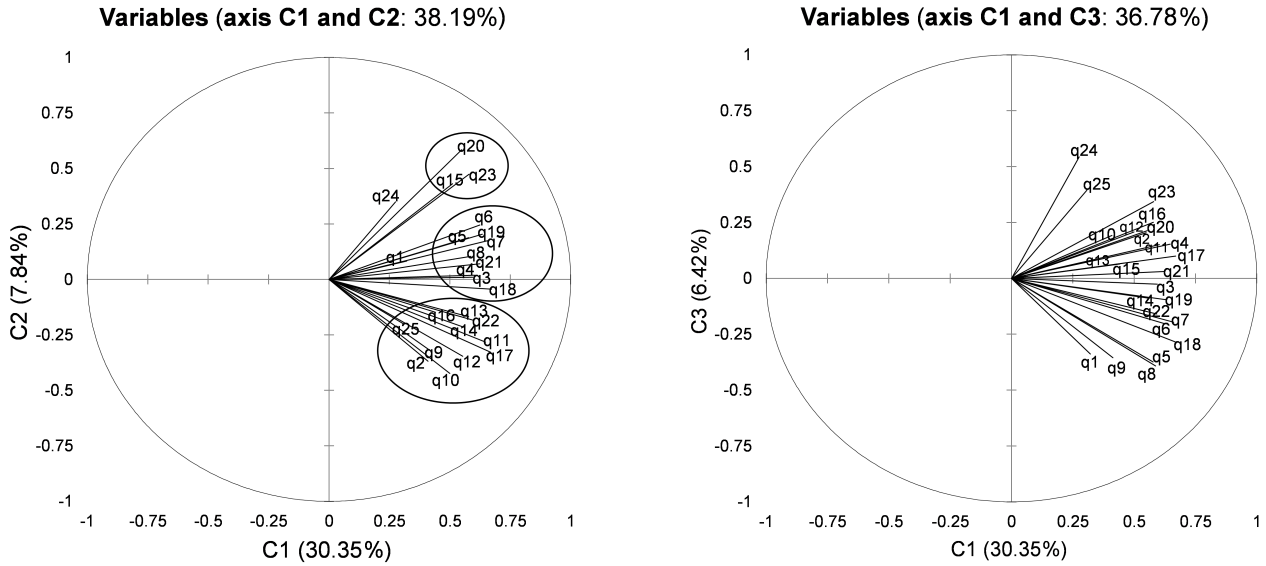


Figure 3. Bland and Altman plot or representation of agreement between both series of measures for the French Work Addiction Risk Test (WART).

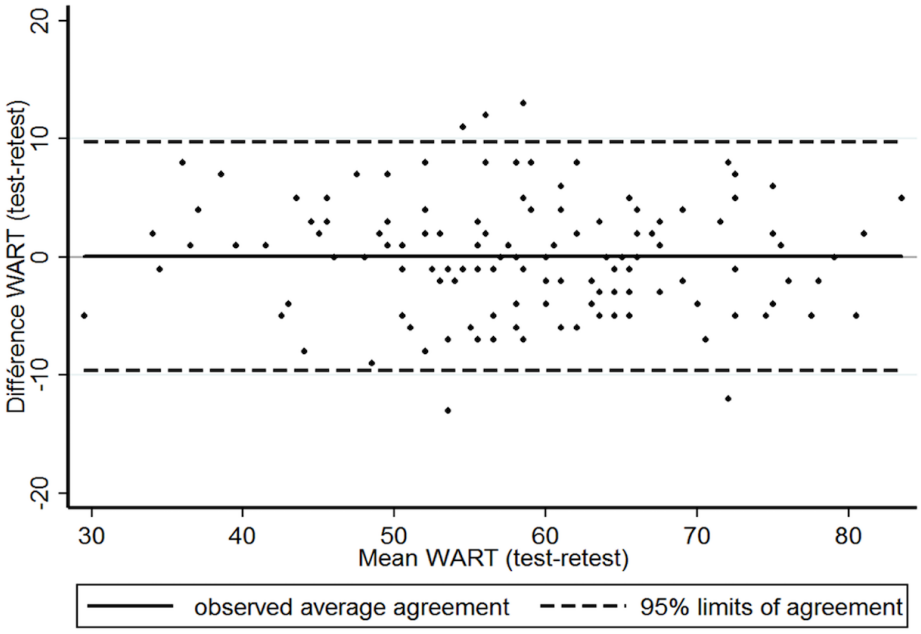


Table 2. Test-retest reproducibility for each dimension with measurement of the Lin concordance coefficient.

Dimensions	Lin concordance coefficient (95% CI)	Difference (SD), 95% CI
Compulsive tendencies	.86 (0.82-0.91)	0.09 (2.71), −5.24 to 5.41
Control	.86 (0.82-0.91)	0.02 (2.05), −4.00 to 4.03
Impaired communication and self-absorption	.76 (0.68-0.83)	0.05 (1.69), −3.27 to −3.36
Self-worth	.73 (0.65-0.81)	−0.12 (0.91), −1.91 to 1.68
Inability to delegate	.66 (0.56-0.75)	0.11 (0.49), −0.85 to 1.06

Figure 4. Lin concordance coefficient and Cohen kappa for each item of the Work Addiction Risk Test (WART).

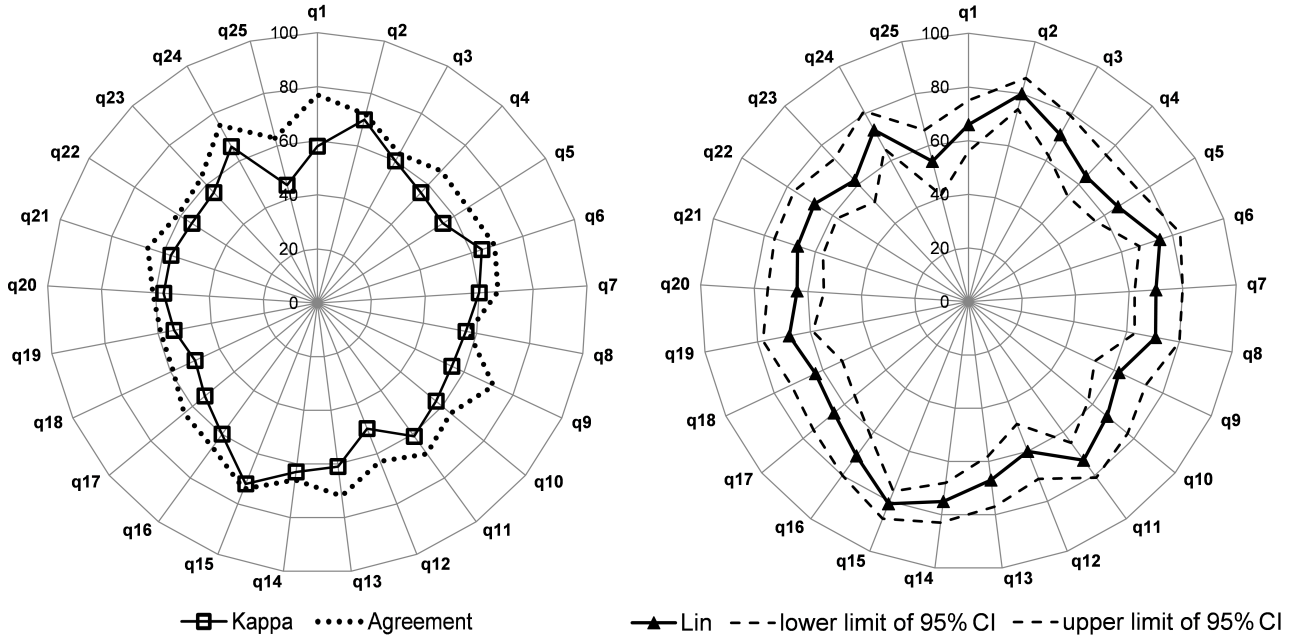


Table 3. External validity of the French Work Addiction Risk Test (WART), measure of correlation between WART and its dimension, and others questionnaires.

Variable	Dimensions of WART					
	WART total	Compulsive tendencies	Control	Impaired communication and self-absorption	Self-worth	Inability to delegate
Tobacco, number of cigarettes smoked per day from 0 to 30	−.10	−.10	.02	−.11	−.13	−.06
Alcohol, number of glass of alcohol per day from 0 to 8	−.12	.07	.11	.16[a]	.08	.02
Cannabis, consumption per month from 0 to 30	−.07	−.10	.02	−.05	.02	.07
Stress at work, VAS[b] from 0 to 100	.43[a]	.41[a]	.34[a]	.32[a]	.10	.00
Stress at home, VAS from 0 to 100	.41[a]	.36[a]	.35[a]	.32[a]	.07	.08
Well-being, VAS from 0 to 100	−.40[a]	−.33[a]	−.38[a]	−.26[a]	−.17[a]	−.11[a]

[a]$P<.05$.

[b]VAS: visual analog scale.

Discussion

This study allowed the validation of the WART questionnaire in French and focused on its acceptability, internal validity and reproducibility, construct validity, and external validity.

Prevalence of Work Addiction and Relationships With Workers' Characteristics

We found that 22% of the workers were at a high risk of suffering from work addiction, with predominance in women. Previous literature using WART demonstrated similar prevalence in similar populations, such as 13% of hospital doctors [12] and 22% for academic employees [14]. However, the prevalence of work addiction can be lower in other populations, such as in Italian teenagers (8%) [13], or with the use of other questionnaires (8%) [5,43]. Although some studies did not find gender differences in the prevalence of work addiction using the WART [12-14] or other questionnaires [5,43], the most recent studies report that women are at a higher risk of workaholism [23,44], which is in line with our results (27% vs 15%). This may suggest an evolution of women's emancipation in our society, with more involvement at work [45,46]. We demonstrated that individuals with work addiction worked 7 hours more per week than those at low risk (46.9 vs 39.4 hours). The engagement in work, in terms of hours spent, is a characteristic of workaholism [6,16], with individuals devoting a majority of their time to work and working beyond what is required [6,16]. Our sensitivity analysis found no differences between the workers' characteristics at the test and the retest, except for smoking. Among the workers responding only at the test, there were more smokers as compared with the workers responding to both the test and the retest (32% vs 16%).

The smokers could have been less motivated to respond twice, with literature suggesting a link between smoking and low levels of conscientiousness [47], impulsivity [48], lack of attention [49], impaired working memory [50], or less access to Internet [51].

Acceptability of the French Version of the Work Addiction Risk Test

A floor or ceiling effect occurs when more than 15% of participants have the lowest or highest possible score [32,52]. A floor or ceiling effect may signify that extreme items are missing in the lower or upper end of the scale and, thus, may limit content validity. Therefore, participants with the extreme scores cannot be distinguished from each other, and reliability, as well as responsiveness is reduced because change cannot be measured in these participants [32,52]. In the French validation of the WART questionnaire, the majority of the items presented a threshold lower than 15%, as recommended in the literature [32,52]. We observed a ceiling effect for only 5 items: 1 (25% of respondents), 2 (16%), 5 (16%), 9 (35%), and 20 (16%). For example, with a possible score ranging from 1 to 4 on a 4-point Likert scale, the mean score for item 1 was 3.1 (SD 0.6) with a median of 3; 2% of responders had the lowest possible value (1) and 25% had the highest value (4). The Unfortunately, there are no studies examining the acceptability of the WART that can be used to compare our results with. So, we cannot conclude whether these results are a characteristic of our responders, a consequence of our translation, or a characteristic already present in the original English version. However, the acceptability of the French version of the WART is correct with few floor or ceiling effects. Moreover, some other well-recognized and validated questionnaires did not report acceptability in their original studies [53-57], or others reported poorer acceptability [42,58-60].

Internal Consistency and Reproducibility

The WART's *internal consistency* appeared satisfactory with a Cronbach alpha value, which is higher than its value in the validation of the English version (.85 [21], 0.88 [18]). The English version of the WART consists of five dimensions. We highlighted the items for compulsive tendencies (Cronbach alpha=.85), and the items for control (Cronbach alpha=.82) were closely interlinked, in line with the literature [20].

We found a high level of correlation between the overall WART score and the total score for 3 dimensions—(1) compulsive tendencies (coefficient correlation .89), (2) control (.84), and (3) impaired communication and self-absorption (.74). These three dimensions would have the greatest impact in differentiating individuals with work addiction among the population, which is in line with the literature [20]. The *reproducibility* study appeared satisfactory for the whole questionnaire, its dimensions, and the stand-alone items. Actually, the Lin concordance coefficient was .90 for the entire WART with a difference between the test and retest of 0.04 (SD 4.92), reflecting a very good reliability over time. This result was in line with the literature on the English version, which reported a Lin concordance coefficient for the test-retest of .83 at a 2-week interval [20-22,26]. Moreover, despite the fact that the literature on the English version of the WART did not report the Lin concordance coefficient for each dimension, we retrieved a Lin concordance coefficient higher than .80 for two dimensions (compulsive tendencies and control) in our French version.

Construct Validity

Despite the fact that the French version of the WART has strong psychometric properties, results of the factorial analysis did not confirm the five dimensions of the latest study [20] but instead confirmed three dimensions. Moreover, correlations between items of each dimension remained weak, as well as a poor Cronbach alpha for items of impaired communication and self-absorption. This could be explained when examining this latest construct of the five dimensions, which was based on a low level of the correlation coefficient (.30) [20] when we used a cutoff set at .6 to .8 as described in the statistical section. Moreover, the original English version of the WART had five other different dimensions that were not drawn from a statistical approach but from the five symptoms used by clinicians for the diagnosis of workaholism: "overdoing" (Items 3, 5, 6, 7, and 15), "self-worth" (Items 8, 9, 10, 19, and 20), "control-perfectionism" (Items 1, 2, 4, 11, 12, 16, 17, 18, 21, 22, and 25), "intimacy" (Items 23 and 24), and "mental preoccupation-future reference" (Items 13 and 14) [18,21]. Those five dimensions were also not demonstrated in our analysis. However, construct differences between two language versions of the same questionnaire are common, as seen for Karasek [61,62], Hospital Anxiety and Depression Scale [60], or other questionnaires [59,63,64]. Although unlikely, translation may have changed the weight of some items. As the psychometric properties of the WART were mainly assessed on university students, our sample of French workers may emphasize some cultural specificities and work habits [65]. Cultural specificities would be investigated in subsequent work.

External Validity

We demonstrated the relationships between the WART and VAS for "stress at work" or "stress at home" in accordance with the literature [14,15,23], and we confirmed the external validity of the French version of the WART questionnaire. The greater the risk of work addiction, the higher the stress [18]. Conversely, the well-being level was negatively correlated with the WART scores, as previously reported [2]. We did not find any significant relationships between the French-WART and tobacco, alcohol, or cannabis addictions, but to our knowledge, no studies have previously demonstrated such links.

Limitations

The response rate may seem low compared with other studies also using a questionnaire in the French population [66-71]. However, we included a substantial sample size of workers, allowing to carry out the statistical analyses with the number of subjects required, determined a priori. Moreover, a number of respondents followed recommendations for the validation of the questionnaires [32-39]. Our sample size retrieved a sufficient prevalence of workers with a high risk of work addiction to allow a robust analysis. Despite the literature reports that a high dropout rate is inherent to this type of study with several questionnaires on the Internet [72], the number of participants who responded to both the test and retest was higher than commonly reported in the literature [60,61]. Our study may have included too many questionnaires in addition to the French version of the WART, which could have negatively affected participation [72]. Despite the observed difference of the

construct, our study emphasized the excellent psychometric properties of the French version of the WART in terms of internal consistency, reproducibility, and external validity. Furthermore, there are other validated questionnaires with an internal construct differing from their original version [60-64]. We used some nonvalidated VAS. We did not control the size and type of screens used by the workers to complete the questionnaires, which may have affected our results, especially for VAS. To our knowledge, no studies have previously evaluated the influence of perception side on scores at VAS; and a study comparing answers to VAS of stress and well-being throughout different supports (paper, large computer screen, tablet, and a smartphone) is needed.

Conclusions

The French version of the WART is a valid and reliable instrument to assess work addiction, with satisfactory psychometric properties. Used in occupational medicine, this tool would allow the diagnosis of work addiction and can be easily implemented in current practice.

Acknowledgments

The study is funded by WittyFit. We express our sincere gratitude to all the voluntary workers using WittyFit, who participated in this study.

Authors' Contributions

FD participated as the main investigator. HR and FD contributed to the conception of the protocol. SD, TC, and FD created the specific software for this study. HR, BP, and FD contributed to data analysis. HR and FD drafted the manuscript. All authors revised the manuscript and added substantial input. All authors read and approved the final manuscript. HR, BP, and FD take responsibility for the integrity of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The French version of the WART.

[PDF File (Adobe PDF File), 35KB - mental_v5i1e12_app1.pdf]

Multimedia Appendix 2

Data quality and acceptability of the French version of the WART.

[PDF File (Adobe PDF File), 27KB - mental_v5i1e12_app2.pdf]

Multimedia Appendix 3

Data of Lin concordance coefficient and Cohen kappa for each item of the WART.

[PDF File (Adobe PDF File), 29KB - mental_v5i1e12_app3.pdf]

References

1. Quinones C, Griffiths MD. Addiction to work: a critical review of the workaholism construct and recommendations for assessment. J Psychosoc Nurs Ment Health Serv 2015 Oct;53(10):48-59. [doi: 10.3928/02793695-20150923-04] [Medline: 26489104]
2. Andreassen CS. Workaholism: An overview and current status of the research. J Behav Addict 2014 Mar;3(1):1-11 [FREE Full text] [doi: 10.1556/JBA.2.2013.017] [Medline: 25215209]
3. Sussman S. Workaholism: a review. J Addict Res Ther 2012 Jan 10;Suppl 6(1):pii: 4120 [FREE Full text] [doi: 10.4172/2155-6105.S6-001] [Medline: 24273685]
4. Shimazu A, Schaufeli WB, Kamiyama K, Kawakami N. Workaholism vs. work engagement: the two different predictors of future well-being and performance. Int J Behav Med 2015 Feb;22(1):18-23. [doi: 10.1007/s12529-014-9410-x] [Medline: 24696043]
5. Andreassen CS, Griffiths MD, Hetland J, Kravina L, Jensen F, Pallesen S. The prevalence of workaholism: a survey study in a nationally representative sample of Norwegian employees. PLoS One 2014;9(8):e102446 [FREE Full text] [doi: 10.1371/journal.pone.0102446] [Medline: 25118877]
6. Buelens M, Poelmans SA. Enriching the Spence and Robbins' typology of workaholism. J Organ Change Manag 2004 Oct;17(5):440-458. [doi: 10.1108/09534810410554470]

7. Scott KS, Moor KS, Miceli MP. An exploration of the meaning and consequences of workaholism. Hum Relat 1997;50(3):287-314. [doi: 10.1023/A:1016986307298]
8. Schaufeli WB, Shimazu A, Taris TW. Being driven to work excessively hard: the evaluation of a two-factor measure of workaholism in the Netherlands and Japan. Cross Cult Res 2009 May 19;43(4):320-348. [doi: 10.1177/1069397109337239]
9. Van Beek I, Taris TW, Schaufeli WB. Workaholic and work engaged employees: dead ringers or worlds apart? J Occup Health Psychol 2011 Oct;16(4):468-482. [doi: 10.1037/a0024392] [Medline: 21787085]
10. Schaufeli WB, Bakker AB, van der Heijden FM, Prins JT. Workaholism, burnout and well-being among junior doctors: the mediating role of role conflict. Work Stress 2009 Apr;23(2):155-172. [doi: 10.1080/02678370902834021]
11. Ng TW, Sorensen KL, Feldman DC. Dimensions, antecedents, and consequences of workaholism: a conceptual integration and extension. J. Organ Behav 2006 Jan;28(1):111-136. [doi: 10.1002/job.424]
12. Rezvani A, Bouju G, Keriven-Dessomme B, Moret L, Grall-Bronnec M. Workaholism: are physicians at risk? Occup Med (Lond) 2014 Sep;64(6):410-416. [doi: 10.1093/occmed/kqu081] [Medline: 25022279]
13. Villella C, Martinotti G, Di Nicola M, Cassano M, La Torre G, Gliubizzi MD. Behavioural addictions in adolescents and young adults: results from a prevalence study. J Gambl Stud 2011 Jun;27(2):203-214. [doi: 10.1007/s10899-010-9206-0] [Medline: 20559694]
14. Bartczak M, Oginska-Bulik N. Workaholism and mental health among Polish academic workers. Int J Occup Saf Ergon 2012;18(1):3-13. [doi: 10.1080/10803548.2012.11076910] [Medline: 22429525]
15. Matuska KM. Workaholism, life balance, and well‐being: a comparative analysis. J Occup Sci 2010 Jun;17(2):104-111. [doi: 10.1080/14427591.2010.9686681]
16. Spence JT, Robbins AS. Workaholism: definition, measurement, and preliminary results. J Pers Assess 1992 Feb;58(1):160-178. [doi: 10.1207/s15327752jpa5801_15] [Medline: 16370875]
17. Kubota K, Shimazu A, Kawakami N, Takahashi M, Nakata A, Schaufeli WB. Association between workaholism and sleep problems among hospital nurses. Ind Health 2010;48(6):864-871. [Medline: 20616459]
18. Robinson BE. The Work Addiction Risk Test: development of a tentative measure of workaholism. Percept Mot Skills 1999 Feb;88(1):199-210. [doi: 10.2466/pms.1999.88.1.199] [Medline: 10214644]
19. Robinson BE, Post P. Validity of the work addiction risk test. Percept Mot Skills 1994 Feb;78(1):337-338. [doi: 10.2466/pms.1994.78.1.337] [Medline: 8177682]
20. Flowers CP, Robinson B. A structural and discriminant analysis of the work addiction risk test. Educ Psychol Meas 2002 Jun;62(3):517-526. [doi: 10.1177/00164402062003008]
21. Robinson BE, Post P. Risk of addiction to work and family functioning. Psychol Rep 1997 Aug;81(1):91-95. [doi: 10.2466/pr0.1997.81.1.91] [Medline: 9293197]
22. Robinson BE, Post P, Khakee JF. Test-retest reliability of the work addiction risk test. Percept Mot Skills 1992 Jun;74(3 Pt 1):926. [doi: 10.2466/pms.1992.74.3.926] [Medline: 1608730]
23. Andreassen CS, Griffiths MD, Sinha R, Hetland J, Pallesen S. The relationships between workaholism and symptoms of psychiatric disorders: a large-scale cross-sectional study. PLoS One 2016;11(5):e0152978 [FREE Full text] [doi: 10.1371/journal.pone.0152978] [Medline: 27192149]
24. Haylett SA, Stephenson GM, Lefever RM. Covariation in addictive behaviours: a study of addictive orientations using the Shorter PROMIS Questionnaire. Addict Behav 2004 Jan;29(1):61-71. [Medline: 14667421]
25. Dutheil F, Duclos M, Naughton G, Dewavrin S, Cornet T, Huguet P, et al. WittyFit-Live Your Work Differently: study protocol for a workplace-delivered health promotion. JMIR Res Protoc 2017 Apr 13;6(4):e58 [FREE Full text] [doi: 10.2196/resprot.6267] [Medline: 28408363]
26. Robinson BE. Concurrent validity of the work addiction risk test as a measure of workaholism. Psychol Rep 1996 Dec;79(3 Pt 2):1313-1314. [doi: 10.2466/pr0.1996.79.3f.1313] [Medline: 9009786]
27. Robinson BE, Phillips B. Measuring workaholism: content validity of the work addiction risk test. Psychol Rep 1995 Oct;77(2):657-658. [doi: 10.2466/pr0.1995.77.2.657] [Medline: 8559897]
28. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol 1993 Dec;46(12):1417-1432. [Medline: 8263569]
29. Dutheil F, Trousselard M, Perrier C, Lac G, Chamoux A, Duclos M, et al. Urinary interleukin-8 is a biomarker of stress in emergency physicians, especially with advancing age--the JOBSTRESS* randomized trial. PLoS One 2013;8(8):e71658 [FREE Full text] [doi: 10.1371/journal.pone.0071658] [Medline: 23977105]
30. Dutheil F, Boudet G, Perrier C, Lac G, Ouchchane L, Chamoux A, et al. JOBSTRESS study: comparison of heart rate variability in emergency physicians working a 24-hour shift or a 14-hour night shift--a randomized trial. Int J Cardiol 2012 Jul 12;158(2):322-325. [doi: 10.1016/j.ijcard.2012.04.141] [Medline: 22608270]
31. Dutheil F, Pereira B, Moustafa F, Naughton G, Lesage FX, Lambert C. At-risk and intervention thresholds of occupational stress using a visual analogue scale. PLoS One 2017;12(6):e0178948 [FREE Full text] [doi: 10.1371/journal.pone.0178948] [Medline: 28586383]
32. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 2007 Jan;60(1):34-42. [doi: 10.1016/j.jclinepi.2006.03.012] [Medline: 17161752]

33. Terwee CB, Mokkink LB, Knol DL, Ostelo RW, Bouter LM, de Vet HC. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. Qual Life Res 2012 May;21(4):651-657 [FREE Full text] [doi: 10.1007/s11136-011-9960-1] [Medline: 21732199]
34. Terwee CB, Prinsen CA, Ricci Garotti MG, Suman A, de Vet HC, Mokkink LB. The quality of systematic reviews of health-related outcome measurement instruments. Qual Life Res 2016 Apr;25(4):767-779 [FREE Full text] [doi: 10.1007/s11136-015-1122-4] [Medline: 26346986]
35. Mokkink LB, Terwee CB, Gibbons E, Stratford PW, Alonso J, Patrick DL, et al. Inter-rater agreement and reliability of the COSMIN (COnsensus-based Standards for the selection of health status Measurement Instruments) checklist. BMC Med Res Methodol 2010 Sep 22;10:82 [FREE Full text] [doi: 10.1186/1471-2288-10-82] [Medline: 20860789]
36. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. BMC Med Res Methodol 2010 Mar 18;10:22 [FREE Full text] [doi: 10.1186/1471-2288-10-22] [Medline: 20298572]
37. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, et al. Protocol of the COSMIN study: COnsensus-based Standards for the selection of health Measurement INstruments. BMC Med Res Methodol 2006 Jan 24;6:2 [FREE Full text] [doi: 10.1186/1471-2288-6-2] [Medline: 16433905]
38. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res 2010 May;19(4):539-549 [FREE Full text] [doi: 10.1007/s11136-010-9606-8] [Medline: 20169472]
39. Mokkink LB, Terwee CB, Stratford PW, Alonso J, Patrick DL, Riphagen I, et al. Evaluation of the methodological quality of systematic reviews of health status measurement instruments. Qual Life Res 2009 Apr;18(3):313-333. [doi: 10.1007/s11136-009-9451-9] [Medline: 19238586]
40. Knell G, Gabriel KP, Businelle MS, Shuval K, Wetter DW, Kendzor DE. Ecological momentary assessment of physical activity: validation study. J Med Internet Res 2017 Jul 18;19(7):e253 [FREE Full text] [doi: 10.2196/jmir.7602] [Medline: 28720556]
41. Pourtier-Piotte C, Pereira B, Soubrier M, Thomas E, Gerbaud L, Coudeyre E. French validation of the Foot Function Index (FFI). Ann Phys Rehabil Med 2015 Oct;58(5):276-282 [FREE Full text] [doi: 10.1016/j.rehab.2015.07.003] [Medline: 26343763]
42. Rieu I, Martinez-Martin P, Pereira B, De Chazeron I, Verhagen Metman L, Jahanshahi M, et al. International validation of a behavioral scale in Parkinson's disease without dementia. Mov Disord 2015 Apr 15;30(5):705-713. [doi: 10.1002/mds.26223] [Medline: 25809278]
43. Taris TW, Van Beek I, Schaufeli WB. Demographic and occupational correlates of workaholism. Psychol Rep 2012 Apr;110(2):547-554. [doi: 10.2466/03.09.17.PR0.110.2.547-554] [Medline: 22662409]
44. Beiler-May A, Williamson RL, Clark MA, Carter NT. Gender bias in the measurement of workaholism. J Pers Assess 2017;99(1):104-110. [doi: 10.1080/00223891.2016.1198795] [Medline: 27409147]
45. Palumbo AJ, De Roos AJ, Cannuscio C, Robinson L, Mossey J, Weitlauf J, et al. Work characteristics associated with physical functioning in women. Int J Environ Res Public Health 2017 Apr 15;14(4):pii: E424 [FREE Full text] [doi: 10.3390/ijerph14040424] [Medline: 28420131]
46. Peckham TK, Baker MG, Camp JE, Kaufman JD, Seixas NS. Creating a future for Occupational health. Ann Work Expo Health 2017 Jan 01;61(1):3-15. [doi: 10.1093/annweh/wxw011] [Medline: 28395315]
47. Yáñez AM, Leiva A, Estela A, Čukić I. The associations of personality traits and parental education with smoking behaviour among adolescents. PLoS One 2017 Mar;12(3):e0174211 [FREE Full text] [doi: 10.1371/journal.pone.0174211] [Medline: 28333969]
48. Dakwar E, Popii M, Coccaro EF. Lifetime history of cigarette smoking associated with aggression and impulsivity in both healthy and personality disordered volunteers. J Pers Disord 2011 Oct;25(5):645-655 [FREE Full text] [doi: 10.1521/pedi.2011.25.5.645] [Medline: 22023301]
49. Treur JL, Willemsen G, Bartels M, Geels LM, van Beek JH, Huppertz C, et al. Smoking during adolescence as a risk factor for attention problems. Biol Psychiatry 2015 Nov 01;78(9):656-663. [doi: 10.1016/j.biopsych.2014.06.019] [Medline: 25092631]
50. Jacobsen LK, Krystal JH, Mencl WE, Westerveld M, Frost SJ, Pugh KR. Effects of smoking and smoking abstinence on cognition in adolescent tobacco smokers. Biol Psychiatry 2005 Jan 01;57(1):56-66. [doi: 10.1016/j.biopsych.2004.10.022] [Medline: 15607301]
51. Cunningham JA. Access and interest: two important issues in considering the feasibility of web-assisted tobacco interventions. J Med Internet Res 2008 Nov 03;10(5):e37 [FREE Full text] [doi: 10.2196/jmir.1000] [Medline: 18984558]
52. Wamper KE, Sierevelt IN, Poolman RW, Bhandari M, Haverkamp D. The Harris hip score: do ceiling effects limit its usefulness in orthopedics? Acta Orthop 2010 Dec;81(6):703-707 [FREE Full text] [doi: 10.3109/17453674.2010.537808] [Medline: 21110703]
53. Fagerström KO. Measuring degree of physical dependence to tobacco smoking with reference to individualization of treatment. Addict Behav 1978;3(3-4):235-241. [Medline: 735910]

54. Karasek R, Brisson C, Kawakami N, Houtman I, Bongers P, Amick B. The job content questionnaire (JCQ): an instrument for internationally comparative assessments of psychosocial job characteristics. J Occup Health Psychol 1998 Oct;3(4):322-355. [Medline: 9805280]
55. Saunders JB, Aasland OG, Babor TF, De la Fuente JR, Grant M. Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption--II. Addiction 1993 Jun;88(6):791-804. [Medline: 8329970]
56. Snaith RP. The hospital anxiety and depression scale. Health Qual Life Outcomes 2003 Aug 01;1:29 [FREE Full text] [doi: 10.1186/1477-7525-1-29] [Medline: 12914662]
57. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983 Jun;67(6):361-370. [doi: 10.1111/j.1600-0447.1983.tb09716.x]
58. Supino PG, Borer JS, Franciosa JA, Preibisz JJ, Hochreiter C, Isom OW, et al. Acceptability and psychometric properties of the Minnesota living with heart failure questionnaire among patients undergoing heart valve surgery: validation and comparison with SF-36. J Card Fail 2009 Apr;15(3):267-277. [doi: 10.1016/j.cardfail.2008.10.003] [Medline: 19327629]
59. Micoulaud-Franchi JA, Sauteraud A, Olive J, Sagaspe P, Bioulac S, Philip P. Validation of the French version of the acceptability e-scale (AES) for mental e-health systems. Psychiatry Res 2016 Mar 30;237:196-200. [doi: 10.1016/j.psychres.2016.01.043] [Medline: 26809367]
60. Reda AA. Reliability and validity of the Ethiopian version of the hospital anxiety and depression scale (HADS) in HIV infected patients. PLoS One 2011 Jan 25;6(1):e16049 [FREE Full text] [doi: 10.1371/journal.pone.0016049] [Medline: 21283565]
61. Hoang TG, Corbière M, Negrini A, Pham MK, Reinharz D, Hoang TG, et al. Validation of the Karasek-job content questionnaire to measure job strain in Vietnam. Psychol Rep 2013 Oct;113(2):363-379. [doi: 10.2466/01.03.PR0.113x20z3] [Medline: 24597435]
62. Pelfrene E, Vlerick P, Mak RP, De Smet P, Kornitzer M, De Backer G. Scale reliability and validity of the Karasek 'job demand-control-support' model in the Belstress study. Work Stress 2001 Oct;15(4):297-313. [doi: 10.1080/02678370110086399]
63. Chamayou JL, Tsenova V, Gonthier C, Blatier C, Yahyaoui A. [French validation of the frustration discomfort scale]. Encephale 2016 Aug;42(4):325-332. [doi: 10.1016/j.encep.2015.08.005] [Medline: 26410729]
64. Dachez J, Ndobo A, Ameline A. French validation of the multidimensional attitude scale toward persons with disabilities (MAS): the case of attitudes toward autism and their moderating factors. J Autism Dev Disord 2015 Aug;45(8):2508-2518. [doi: 10.1007/s10803-015-2417-6] [Medline: 25788215]
65. Maio G. The cultural specifity of research ethics--or why ethical debate in France is different. J Med Ethics 2002 Jun;28(3):147-150 [FREE Full text] [Medline: 12042397]
66. Dutheil F, Delaire P, Boudet G, Rouffiac K, Djeriri K, Souweine B, et al. [Cost/effectiveness comparison of the vaccine campaign and reduction of sick leave, after vaccination against influenza among the Clermont-Ferrand University Hospital staff]. Med Mal Infect 2008;38(11):567-573. [doi: 10.1016/j.medmal.2008.09.019] [Medline: 19008061]
67. Dutheil F, Kelly C, Biat I, Provost D, Baud O, Laurichesse H, et al. [Relation between the level of knowledge and the rate of vaccination against the flu virus among the staff of the Clermont-Ferrand University hospital]. Med Mal Infect 2008 Nov;38(11):586-594. [doi: 10.1016/j.medmal.2008.09.017] [Medline: 18976872]
68. Kelly C, Dutheil F, Haniez P, Boudet G, Rouffiac K, Traore O, et al. [Analysis of motivations for antiflu vaccination of the Clermont-Ferrand University Hospital staff]. Med Mal Infect 2008 Nov;38(11):574-585. [doi: 10.1016/j.medmal.2008.09.018] [Medline: 18954950]
69. Lanhers C, Pereira B, Garde G, Maublant C, Dutheil F, Coudeyre E. Evaluation of 'I-Preventive': a digital preventive tool for musculoskeletal disorders in computer workers-a pilot cluster randomised trial. Br Med J Open 2016 Sep 22;6(9):e011304 [FREE Full text] [doi: 10.1136/bmjopen-2016-011304] [Medline: 27660316]
70. Lopez V, Chamoux A, Tempier M, Thiel H, Ughetto S, Trousselard M, et al. The long-term effects of occupational exposure to vinyl chloride monomer on microcirculation: a cross-sectional study 15 years after retirement. Br Med J Open 2013 Jun 20;3(6):pii: e002785 [FREE Full text] [doi: 10.1136/bmjopen-2013-002785] [Medline: 23794583]
71. Tekath M, Dutheil F, Bellini R, Roche A, Pereira B, Naughton G, et al. Comparison of the ultra-low-dose Veo algorithm with the gold standard filtered back projection for detecting pulmonary asbestos-related conditions: a clinical observational study. Br Med J Open 2014 May 30;4(5):e004980 [FREE Full text] [doi: 10.1136/bmjopen-2014-004980] [Medline: 24879827]
72. Edwards P, Roberts I, Sandercock P, Frost C. Follow-up by mail in clinical trials: does questionnaire length matter? Control Clin Trials 2004 Feb;25(1):31-52. [doi: 10.1016/j.cct.2003.08.013] [Medline: 14980747]

Abbreviations

ANOVA: analysis of variance
VAS: visual analog scale
WART: Work Addiction Risk Test

Edited by G Eysenbach; submitted 30.06.17; peer-reviewed by L Fontana, P Jimenez; comments to author 07.09.17; revised version received 25.10.17; accepted 30.11.17; published 13.02.18.

Please cite as:
Ravoux H, Pereira B, Brousse G, Dewavrin S, Cornet T, Mermillod M, Mondillon L, Vallet G, Moustafa F, Dutheil F
Work Addiction Test Questionnaire to Assess Workaholism: Validation of French Version
JMIR Ment Health 2018;5(1):e12
URL: http://mental.jmir.org/2018/1/e12/
doi:10.2196/mental.8215
PMID:29439945

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org